WORLD TRADE ORGANIZATION

Dispute Settlement Reports

1998
Volume III

Pages 697-1176

THE WTO DISPUTE SETTLEMENT REPORTS

The *Dispute Settlement Reports* of the World Trade Organization (the "WTO") include panel and Appellate Body reports, as well as arbitration awards, in disputes concerning the rights and obligations of WTO Members under the provisions of the *Marrakesh Agreement Establishing the World Trade Organization*. The *Dispute Settlement Reports* are available in English, French and Spanish.

This volume may be cited as DSR 1998:III

TABLE OF CONTENTS

Page

EUROPEAN COMMUNITIES - MESURES CONCERNING MEAT AND MEAT PRODUCTS (HORMONES)

(COMPLAINT BY THE UNITED STATES)

Report of the Panel
WT/DS26/R/USA

Adopted by the Dispute Settlement Body on 13 February 1998
as modified by the Appellate Body Report

TABLE OF CONTENTS

Page

Page

Page

I. INTRODUCTION

1.1 On 26 January 1996, the United States requested consultations with the European Communities, pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), Article 11 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), Article 14 of the Agreement on Technical Barriers to Trade ("TBT Agreement"), Article 19 of the Agreement on Agriculture and Article XXII of the General Agreement on Tariffs and Trade 1994 ("GATT"), regarding the Council Directive Prohibiting the Use in Livestock Farming of Certain Substances Having a Hormonal Action and related measures (WT/DS26/1).

1.2 On 2 February 1997, pursuant to Article 4.11 of the DSU, Australia (WT/DS26/3) and New Zealand (WT/DS26/2), followed on 8 February by Canada (WT/DS26/4), requested to be joined in these consultations. The European Communities accepted these requests on 19 March 1996 (WT/DS26/5).

1.3 On 27 March 1996, the United States, Australia, Canada and New Zealand held joint consultations with the European Communities but failed to reach a mutually satisfactory solution.

1.4 On 25 April 1996, pursuant to Article 11 of the SPS Agreement, Article 14 of the TBT Agreement, Article 19 of the Agreement on Agriculture, Article XXIII:2 of the GATT, and Article 6 of the DSU, the United States requested the Dispute Settlement Body ("DSB") to establish a panel with standard terms of reference (WT/DS/26/6). The United States claimed that the EC measures:

> "... adversely affect imports of meat and meat products and appear to be inconsistent with the obligations of the European Communities under the General Agreement on Tariffs and Trade 1994, the Agreement on the Application of Sanitary and Phytosanitary Measures, the Agreement on Technical Barriers to Trade, and the Agreement on Agriculture. The provisions of these agreements with which these measures appear to be inconsistent include, but are not limited to, the following:
>
> (1) General Agreement on Tariffs and Trade 1994, Article III or Article XI;
>
> (2) Agreement on the Application of Sanitary and Phytosanitary Measures, Articles 2, 3 and 5;
>
> (3) Agreement on Technical Barriers to Trade, Article 2; and
>
> (4) Agreement on Agriculture, Article 4.
>
> These measures also appear to nullify or impair the benefits accruing to the United States directly or indirectly under the cited agreements".

1.5 On 20 May 1996, the DSB established a Panel in accordance with the request made by the United States. The agreed standard terms of reference of the Panel were (WT/DS26/7):

> "To examine, in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS26/6, the matter referred to the DSB by the United States in that document and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements".

1.6 Australia, Canada, New Zealand and Norway reserved their rights to participate in the Panel proceedings as third parties.

1.7 On 2 July 1996, the Panel was constituted with the following composition:

Chairman:	Mr. Thomas Cottier
Panellists:	Mr. Jun Yokota
	Mr. Peter Palecka

1.8 The Panel met with the parties on 10 October 1996 and 11 November 1996. It met with third parties on 10 October 1996. The Panel con-

sulted scientific and technical experts on 17-18 February 1997 in a meeting held jointly with the panel proceeding brought by Canada on the same EC measures.[1]

1.9 On 28 November 1996, the Chairman of the Panel informed the DSB that the Panel would not be able to issue its report within six months. The reasons for that delay are stated in document WT/DS/26/8.

1.10 The Panel issued its interim report to the parties on 7 May 1997. Following a request made by the European Communities pursuant to Article 15.2 of the DSU, the Panel held a further meeting with the parties on 4 June 1997. The Panel issued its final report to the parties to the dispute on 30 June 1997.

II. FACTUAL ASPECTS

1. The Measures at Issue

2.1 This dispute concerns EC measures, in particular Council Directive 81/602/EEC ("Directive 81/602/EEC"), Council Directive 88/146/EEC ("Directive 88/146/EEC") and Council Directive 88/299/EEC ("Directive 88/299/EEC").[2]

2.2 Directive 81/602/EEC prohibits the administering to farm animals of substances having a *thyrostatic action* or substances having an *oestrogenic, androgenic or gestagenic* action; the placing on the market or slaughtering of farm animals to which these substances have been administered; the placing on the market of meat from such animals; the processing of meat from such animals and the placing on the market of meat products prepared from or with such meat. The Directive provides two exceptions to the prohibition: one exception is provided for substances with an oestrogenic, androgenic or gestagenic action when they are used for therapeutic or zootechnical purposes and administered by a veterinarian or under a veterinarian's responsibility. The other exception was for oestradiol-17β, progesterone, testosterone, trenbolone acetate (or TBA) and zeranol - when they were used for growth promotion purposes and their use was governed according to the individual regulatory schemes maintained by EC member States. This exception was made pending an examination of the effects of these hormones on the health of consumers and the adoption of an EC rule. EC member States are obliged to apply their regulatory schemes to imports from third countries in a manner not more favourable than that applied to intra-EC trade.

2.3 Directive 88/146/EEC extends the prohibition imposed by Directive 81/602/EEC to the administration to farm animals of trenbolone acetate and ze-

---

1 WT/DS48/6.

2 Other measures relevant to the dispute are contained in Directives 72/462/EEC, 81/602/EEC, 81/851/EEC, 81/852/EEC, 85/358/EEC, referenced in Directive 88/146/EEC; the decisions, control programme and derogations referred to in Article 6(2), Article 6(7) and Article 7, respectively, of Directive 88/146/EEC; and any amendments or modifications, including Directives 96/22/EC and 96/23/EC.

ranol for any purpose, and oestradiol-17β, testosterone and progesterone for fattening purposes. However, the Directive maintains the permission to administer these three natural hormones to animals for therapeutic and zootechnical purposes under prescribed conditions; in particular, therapeutic treatment is defined to mean the administering to an individual animal of any of the substances which are authorized to treat a fertility problem diagnosed on examination by a veterinarian. The products which are used for therapeutic treatment may be administered only by a veterinarian, in the form of an injection (to the exclusion of implantation) to farm animals which have been clearly identified. Such treatment must be registered by the veterinarian and these animals may not be slaughtered before expiry of the period fixed. In the case of animals at the end of their reproductive career, the treatments are prohibited from being administered during the fattening period following the end of their breeding life. Article 4 of directive 88/146/EEC explicitly requires that undertakings in the EC member States producing the prohibited hormones, those companies authorized to market these hormones for whatever purposes and undertakings producing pharmaceutical and veterinary products based on those substances, must keep a detailed register recording (in chronological order) the quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary products. The importation from third countries of animals and meat from animals to which have been administered substances with thyrostatic, oestrogenic, androgenic or gestagenic action is prohibited.[3] However, under certain conditions, Article 7 of Directive 88/146/EEC allows trade in those animals and meat from those animals treated for therapeutic or zootechnical purposes, including imports from third countries.[4]

2.4 Directive 88/299/EEC lays down the conditions for applying the derogations, provided for in Article 7 of Directive 88/146/EEC, from the prohibition on trade in certain categories of animals and their meat. The first derogation of the

[3] Article 6(7) of Directive 88/146/EEC requires the establishment of a control programme as regards imports from third countries to ensure that imports do not receive more favourable treatment than EC products. This control programme also provides for rules on the frequency of controls on imports from each third country and on guarantees offered by the inspection regulation of third countries. Such checks on imports are now carried out in accordance with Directives 91/496/EEC and 90/675/EEC.

[4] Article 7 of Directive 88/146/EEC allows derogations in respect to trade in animals intended for reproduction and reproductive animals at the end of their career (and in respect of meat from these various animals, taking into account the guarantees given), which in the course of their existence have been treated under the provisions of Article 4 of Directive 81/602/EEC. This article authorizes the administration to farm animals of substances with oestrogenic, androgenic or gestagenic action approved in accordance with the Directives on veterinary medical products (other than substances referred to in Article 3 of Directive 81/602/EEC) for therapeutic use, synchronization of oestrus, termination of unwanted gestation, the improvement of fertility and the preparation of donors and recipients for the implantation of embryos. The administering of these substances shall be effected by a veterinarian, however, EC member States may allow the synchronization of oestrus and the preparation of donors and recipients for the implantation of embryos to be done not by a veterinarian but under his direct responsibility.

Directive requires EC member States to authorize trade in animals intended for reproduction and reproductive animals at the end of their career (and of meat of such animals) which, during their reproductive career, have undergone one of two categories of treatments: The first category is therapeutic treatment with one of the following substances: oestradiol-17β, testosterone and progesterone; and those derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application which appear in a list of approved products. The second category is the administration of substances having an oestrogenic, androgenic or gestagenic action for synchronization of oestrus, termination of unwanted gestation, the improvement of fertility and the preparation of donors and recipients for the implantation of embryos, provided that the products in which they are contained appear on a list of approved products and with the respect of strict conditions of use concerning, in particular, the respect of the withdrawal period, the monitoring of those conditions of use and of the means of identification of the animals. In addition, Articles 3 and 4 of this Directive provide that trade between the EC member States of the European Communities in animals intended for reproduction and reproductive animals and meat from such animals is allowed only if all the conditions laid down in the Directive are respected, in particular as regards the waiting period and the requirement that animals have not received any of the above treatments with any of the above substances during the fattening period following the end of their breeding life. The EC stamp may be affixed to the meat only if the waiting time ended before the animals are slaughtered. The second derogation in Directive 88/299/EEC allows imports from third countries of treated animals and meat of such animals under guarantees equivalent to those for domestic animals and meat.

2.5 Directive 96/22/EC will replace Directives 81/602/EEC, 88/146/EEC and 88/299/EEC as from 1 July 1997. It will maintain the prohibition on the use of these hormones for growth promotion purposes; extend the prohibition on the use of beta-agonists; restrict the use of the hormones at issue for therapeutic or zootechnical purposes, reinforcing in particular the role of the veterinarian; and reinforce the provisions on control and testing. Penalties and sanctions in case of violations are to be increased where checks detect the presence of prohibited substances or products or residues of substances administered illegally. Such substances or products will be confiscated and any treated animals or meat placed under official supervision until penalties have been applied.

2. The Substances at Issue (Hormones)

2.6 Hormones (chemicals) produced by the bodies of humans and animals are called endogenous or natural hormones. (Phyto-hormones are produced by some plants.) Compounds chemically synthesized to mimic the effect of natural hormones are called synthetic or xenobiotic hormones. Natural hormones are secreted into the blood stream by specialized cells and travel throughout the body. Hormones act by binding protein receptors present in hormone-responsive tissues. The receptor undergoes a conformational change, binds to specific DNA

sequences and regulates specific genes within a cell. Synthetic hormones may differ from endogenous (natural) hormones in their rate of metabolism and excretion.

2.7 Hormones function in four broad areas: reproduction; growth and development; maintenance of the internal environment; and production, utilization and storage of energy. One hormone can have multiple actions. For example, the male hormone testosterone controls many processes from the development of the fetus to libido in the adult. One function may be controlled by multiple hormones: the menstrual cycle involves oestradiol, progesterone, follicle-stimulating hormone and luteinizing hormone.

2.8 Of the six hormones involved in this dispute, three are naturally occurring hormones produced by humans and animals: oestradiol-17β, progesterone and testosterone (hereafter also referred to as natural hormones). Oestradiol-17β is a sex steroidal hormone with oestrogenic action (i.e., responsible for female characteristics); testosterone is a sex steroidal hormone with androgenic action (i.e., responsible for male characteristics); progesterone is a sex steroidal hormone with gestagenic action (i.e., responsible for maintaining pregnancy). These three hormones are produced throughout the lifetime of each individual and are required for normal physiological functioning and maturation. Hormone levels vary with the tissue, with the species of animal and with the sex and individual. Hormone levels vary most dramatically with puberty, pregnancy and castration.

2.9 The other three hormones involved in this dispute are artificially produced hormones: trenbolone, zeranol and melengestrol acetate (MGA) (hereafter also referred to as synthetic hormones). These hormones mimic the biological activity of the natural hormones. Trenbolone mimics the action of testosterone; zeranol mimics the action of oestradiol-17β; and MGA mimics progesterone.

2.10 In the United States, the three natural hormones may be used for medical treatment (therapeutic). Oestradiol-17β is also permitted for zootechnical purposes. In the United States the six hormones are also approved for growth promotion purposes. Three of the hormones used for growth promotion purposes, trenbolone, zeranol, and MGA, have no zootechnical or therapeutic uses. For growth promotion purposes, five of these hormones (except MGA) are formulated as pellets (with approved and fixed amounts of compound) designed to be implanted in the ear of the animal. The ear is discarded at slaughter. MGA is administered as a feed additive.

3. The Codex Alimentarius Standards

2.11 The SPS Agreement makes reference, in a number of provisions, to "the relevant international standards, guidelines and recommendations". Annex A:3(a) of the SPS Agreement states that the international standards, guidelines and recommendations relevant for food safety are those established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide

residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.

2.12 The Codex Alimentarius Commission (hereafter the "Codex Commission") is a joint FAO/WHO advisory body established to implement the Joint FAO/WHO Food Standards Programme. The purpose of this programme is to protect the health of consumers and to ensure fair practices in food trade through the elaboration of food standards. These standards, together with notifications received from governments with respect to their acceptance or otherwise of the standards, constitute the Codex Alimentarius. The Codex Alimentarius (hereafter "the Codex") is thus a collection of internationally adopted food standards presented in a uniform manner.

2.13 Membership of the Codex Commission is open to all member Nations and Associate members of FAO and/or WHO and is composed of government representatives of these members. Most of its members, including the United States and the EC member States, are WTO Members. The European Communities has an observer status in the Codex Commission. The Codex Commission has established a number of subsidiary bodies, including the Codex Committee on Residues of Veterinary Drugs in Food ("CCRVDF").

2.14 The technical and scientific analysis of veterinary drugs, food additives and some other substances in foods and beverages is not undertaken by the Codex Commission itself but independently by the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"). The JECFA is composed of independent scientists who serve in their individual capacities as experts, not as representatives of their governments or organizations. The goal of the JECFA evaluation of veterinary drugs is:

> "to establish safe levels of intake by setting Acceptable Daily Intakes (ADI) and to develop maximum residue limits when veterinary drugs are used in accordance with good veterinary practice".[5]

(a) The Elaboration of Codex Standards

2.15 The elaboration of Codex standards involves an 8-step process:

Step 1: The Codex Commission decides to elaborate a standard and identifies which subsidiary body or other body should undertake the work, taking into account the "Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies". Decisions to elaborate standards may also be taken by subsidiary bodies of the Codex Commission subject to subsequent approval by the Codex Commission or its Executive Committee.

[5] Codex Alimentarius, Vol.3, Residues of Veterinary Drugs in Foods, p.vi.

Step 2: The Codex Commission secretariat arranges for the preparation of a "proposed draft standard". In the case of veterinary drugs, JECFA is in charge of preparing recommendations for maximum residue levels.

Step 3: The secretariat distributes the "proposed draft standard" to the members of the Commission for comments.

Step 4: The comments received are sent by the secretariat to the CCRVDF which considers the comments and prepares, if appropriate, a proposed draft standard.

Step 5: The proposed draft standard is submitted through the secretariat to the Codex Commission or to the Executive Committee with a view to its adoption as a "draft standard".

Step 6: The "draft standard" is sent by the secretariat to all members and interested international organizations for comments on all aspects, including possible implications of the "draft standard" for their economic interests.

Step 7: The comments received are sent by the secretariat to the CCVDRF, which considers such comments and may amend the "draft standard".

Step 8: The "draft standard" is submitted through the secretariat to the Codex Commission together with any written proposals received from members and interested international organizations for amendments at Step 8 with a view to its adoption as a "Codex standard". Adoption of standards is normally done on the basis of a consensus decision, however, if requested, a vote may be taken. In this case, a decision by the majority of Codex members is required. An accelerated elaboration procedure may be used when there is an urgent need for a standard.

2.16 The Codex Commission keeps under review and may revise Codex standards, generally following procedures similar to those used for the elaboration of standards. Codex standards are published and sent to governments for acceptance and to international organizations to which competence in the matter has been transferred by their EC member States. Acceptance of the standards is voluntary and Codex members are not required to indicate formal acceptance of Codex standards, guidelines or recommendations. The implementation of Codex standards at the national level is the responsibility of members.

(b) Codex Standards for Five Hormones at Issue

2.17 Codex standards for veterinary drugs are normally stated in terms of an Acceptable Daily Intake ("ADI") and a Maximum Residue Limit ("MRL"). An ADI is "an estimate by JECFA of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable

health risk (standard man = 60 kg)".[6] An ADI is derived from the experimental No Observable Effect Level ("NOEL") in the most appropriate animal species, by applying an appropriate safety factor. To account for sensitivity variabilities between humans and animals, and dietary variabilities among humans, a safety factor is typically applied. When data from long-term animal toxicity studies are available, a safety factor of 100 is generally applied. Larger safety factors, up to 1000, may be used in certain cases.

2.18 A Codex MRL is one of the tools for ensuring that intake does not exceed the ADI and that "Good Practice in the use of Veterinary Drugs" ("GPVD") is observed. It is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in µg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Commission to be legally permitted or recognized as acceptable in or on a food. Test animals are first treated with the drug in accordance with proposed GPVD and, on the basis of this usage, tentative MRLs are set for various tissues. These MRLs are then compared with the ADI, considering dietary food intake. If the MRL established on the basis of proposed GPVD would cause the ADI to be exceeded, the MRL will be lowered to a level which ensures that the ADI is not exceeded, and the proposed GPVD will also be made stricter. If, on the other hand, the proposed MRL would not cause the ADI to be exceeded (as is most frequently the case), the MRL will be proposed for adoption. Thus, MRLs are frequently set at levels below (even far below) the theoretical safe levels determined from an ADI. An MRL may also be reduced to be consistent with the GPVD as approved by national authorities or increased (to a level still below the safe level) to be detectable using practical methods.

2.19 "Good Practice in the Use of Veterinary Drugs" (GPVD), is defined as:

> "the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions."[7]

According to the Codex expert advising the Panel, the terms "good veterinary practice" and "good veterinary and husbandry practice", when used in JECFA reports, are synonyms for GPVD.

2.20 For the hormones at issue, JECFA considered five of the six substances (all except MGA) and made recommendations on four of them (excluding trenbolone) during its 32nd Session in 1987. For trenbolone, further data was sought and a JECFA recommendation made in 1989. The CCRVDF considered the JECFA recommendations at its meetings in 1987 and recommended draft standards for the three endogenous hormones and zeranol. These draft standards were approved by the Codex Commission at Step 5 in 1989. Standards for these four hormones were considered at Step 8 by the Codex Commission in June 1991, but, following a vote on the matter, were not adopted. A draft standard for tren-

[6] Codex Alimentarius, Vol.3, Residues of Veterinary Drugs in Foods, p.65.
[7] *Ibid.*

bolone at Step 5 was adopted on 1991. In June 1995, the Codex Commission adopted standards, at Step 8, for the five hormones, on the basis of a vote. These standards apply exclusively with respect to cattle, and meat and meat products of bovine origin, when these hormones are used for growth promotion purposes.

2.21 With respect to the three natural hormones in dispute, oestradiol-17β, progesterone and testosterone, similar Codex standards apply. For these three hormones it was considered "*unnecessary*" to establish an ADI or MRL.[8] Specifically, the Codex states that:

> "Establishing an ADI and an [MRL] for a hormone that is produced endogenously at variable levels in human beings was considered unnecessary by the Committee. Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health."[9]

2.22 The 32nd JECFA Report of 1988 ("1988 JECFA Report"), on which the Codex standards are based, concluded that residues arising from the use of testosterone and oestradiol-17β as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health and that the amount of exogenous progesterone ingested in meat from treated animals would not be capable of exerting an hormonal effect, and therefore, any toxic effect, in human beings. Since, according to JECFA, the potential toxic effect of residues of these hormones is directly related to their hormonal effect, the report concluded that the additional residue levels in treated animals are not capable of exerting any toxic effect. On the basis of this safety assessment and in view of the difficulty of determining the levels of residues attributable to the use of these hormones for growth promoting purposes in cattle (residues of endogenous natural hormones in meat cannot be practically distinguished from those exogenously administered), JECFA concluded that it was "unnecessary" to establish an ADI or MRL for these hormones.

2.23 With respect to two of the synthetic hormones at issue, zeranol and trenbolone, the Codex standards are the following: an ADI of 0-0.5 and 0-0.02 μg/kg body weight, respectively, and for both hormones an MRL of 2 μg/kg in bovine muscle and 10 μg/kg in bovine liver.

2.24 The 1988 JECFA Report, on which the Codex standard for zeranol is based, noted that zeranol was a weak oestrogen which mimicked the action of oestradiol-17β. The Report concluded that the toxic (*in casu* tumorigenic) effect of zeranol is associated with its hormonal (i.e. oestrogenic) properties and that an ADI could thus be established on the basis of a no-hormonal-effect level. Adopting what it considered to be a conservative approach by using as a basis

---

[8] Codex Alimentarius, Vol. 3 - 1995, Section 1, pp.7, 12 and 14.
[9] *Ibid.*, Section 1, footnote, pp.7, 12 and 14.

studies on ovariectomized female cynomolgus monkeys (highly sensitive to oestrogenic substances) and using a safety factor of 100, JECFA set an ADI for human beings of 0-0.5 μg/kg of body weight. For a 70 kg person consuming 500 g of meat daily over an entire lifetime, the maximum permissible or safe level of zeranol residues in meat would then, according to JECFA, be 70 μg/kg of edible tissue. However, the Report noted that when zeranol is administered to cattle according to good animal husbandry practice, the maximum mean residue levels did not exceed 0.2 μg/kg in muscle, 10 μg/kg in liver, 2 μg/kg in kidney, and 0.3 μg/kg in fat at any time after implantation. These residue levels obtained on the basis of good animal husbandry practice are thus below the maximum permissible level of 70 μg/kg. However, in order to set a level which is detectable by routine residue analysis methods, the Codex MRL was increased to 2 μg/kg in muscle and set at 10 μg/kg in liver.

2.25 Trenbolone acetate is the chemical form or ester used for the administration of trenbolone. Trenbolone, or trenbolone acetate ("TBA"), an androgen which mimics the action of testosterone, is rapidly hydrolysed after administration to cattle. The major metabolite (i.e. compound into which TBA breaks down by chemical activity after entering the body) is α-trenbolone, occurring *inter alia* in liver, and β-trenbolone present in muscle. With respect to TBA, the 1988 JECFA Report concluded that its potential toxic effects only arise as a consequence of its hormonal activity. The report further concluded that, therefore, an ADI could be established on the basis of a no-hormonal-effect level. Adopting what it considered to be a conservative approach by using as a basis studies on castrated male rhesus macaque monkeys (which are highly sensitive to compounds with antigonadotropic activity) and pigs (which are a sensitive model for assessing hormonal effects of TBA) and using a safety factor of 100, JECFA later set an ADI for human beings of 0-0.02 μg/kg of body weight (34th JECFA Report of 1989). The maximum ADI for a 60 kg person would thus be 1.2 μg of TBA residues. JECFA then set MRL's for β-trenbolone in muscle and α-trenbolone in liver of 2 μg/kg and 10 μg/kg, respectively, based on average residue levels in heifers at 15-30 days after implantation of 300 mg TBA, noting that concentrations would be even lower at proposed GPVD. According to JECFA, the MRL's thus obtained on the basis of conservative estimates should not exceed the Codex ADI or safe level at any time after implantation of the drug, that is, irrespective of the withdrawal period used.

4. History of Events

2.26 European consumers' concern over the use of hormones for growth promotion purposes in livestock grew steadily throughout the 1970s as the result of the illegal use of dethylstilboestrol, commonly known as DES (see paragraph 4.123), in veal production in France and incidents, particularly in Italy, where adolescents had been reported to be suffering from hormonal irregularities and veal had come under suspicion as a possible cause. European consumer organizations called for a boycott of veal, and the market for veal was severely af-

fected. On 20 September 1980, the EC Council of (Agriculture) Ministers adopted a declaration in favour of a ban on the use of oestrogen and endorsed the principle of greater harmonisation of legislation on veterinary medicines and of greater control on animal rearing, both at the production and slaughtering stages.

2.27 On 31 October 1980, the EC Commission proposed legislation aimed at banning the use of all hormone products (COM (80) 614), except for therapeutic purposes. This proposal was expanded later by documents COM(80)920 and COM(80)922, presented on 6 January 1981. These allowed for the controlled use for therapeutic and zootechnical purposes of three natural hormone products, and introduced a number of control measures on the production and handling of such products, together with proposals on the testing of animals. On 13 February 1981, the European Parliament adopted the "Nielsen Report" approving the Commission proposals. The EC Economic and Social Committee endorsed the proposals in February 1981. However, three EC member States (Belgium, Ireland and the United Kingdom) sought to have the three natural hormones remain available both as therapeutic drugs and as growth promotion agents, and Ireland and the United Kingdom also argued for the retention of the synthetic hormones, trenbolone and zeranol. Moreover, third countries, including Argentina, Australia, Canada, New Zealand, South Africa and the United States, also raised questions concerning the impact of any ban on their exports to the European Communities.

2.28 The EC Council of Ministers adopted its first Directive on the issue (81/602/EEC) on 31 July 1981. In that Directive, and in regard to five of the hormones at issue (all but MGA), the Council directed the Commission to provide, not later than 1 July 1984, a report on the experience acquired and scientific developments, accompanied, if necessary, by proposals taking into account these developments. Accordingly, the Commission set up a Scientific Group on Anabolic Agents in Animal Production, chaired by Professor G.E. Lamming (the "Lamming Group"). The question addressed to the Lamming Group was:

> "Does the use for fattening purposes in animals of the following substances: oestradiol-17β, testosterone, progesterone, trenbolone and zeranol present any harmful effect to health".[10]

The Lamming Group issued an interim report on 22 September 1982 (the "Lamming Report"). The Lamming Report concluded as follows:

> "The Scientific Working Group is of the opinion that the use of oestradiol-17β, testosterone and progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application would not present any harmful

[10] Report of the (EC) Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the Basis of the Report of the Scientific Group on Anabolic Agents in Animal Production, pp.1 and 12.

> effects to the health of the consumer when used under the appropriate conditions as growth promoters in farm animals.
>
> "Evaluation of data on "trenbolone" and "zeranol" revealed that some data on the hormonal non-effect-level and the toxicology of these compounds and their metabolites are still missing.
>
> "The Scientific Working Group considers it necessary that additional information be provided before a final conclusion can be given on trenbolone and zeranol.
>
> "Proper programmes to control and monitor the use of anabolic agents are essential.
>
> "It is necessary to continue scientific investigations on the relevance of the present use of the "no-hormone-effect" level related to the harmful effects of anabolic agents".

2.29 The EC Scientific Veterinary Committee gave its reaction to the Lamming Report on 9 November 1982, followed by the EC Scientific Committee for Animal Nutrition on 17 November 1982 and by the EC Scientific Committee for Food on 4 February 1983. These Committees supported the conclusions and recommendations of the Lamming Report, but stressed the need to lay down provisions regarding the establishment of proper programmes to control and monitor the use of anabolic agents with regard, in particular, to instructions for use, surveillance programmes and analysis methods. In January 1984, the Commission asked a group of experts within the EC Scientific Committee on Anabolic Agents to review the information on trenbolone and zeranol. On 12 June 1984, the Commission published a proposal (COM(84)295 final) for a Council Directive amending Directive 81/602/EEC, which envisaged the controlled use of the three natural hormones for growth promotion purposes and proposed re-examining the ban on the two synthetic hormones after their scientific evaluation had been completed. However, the European Parliament, the EC Economic and Social Committee and the EC Council of Ministers rejected the Commission's proposal.

2.30 The EC Commission amended its proposal accordingly and on 31 December 1985 the EC Council adopted Directive 85/649/EEC. This Directive banned the use of all the substances concerned for growth promotion purposes and established more detailed provisions concerning authorized therapeutic uses. The Directive was challenged in the European Court of Justice, which annulled it on procedural grounds. The proposals were re-introduced by the EC Commission and re-adopted by the EC Council as Council Directive 88/146/EEC on 16 March 1988.

2.31 Following reports of significant use of illegal growth-promoting hormonal substances in a number of EC member States, on 26 September 1988 the European Parliament established a "Committee of Enquiry into the Problem of Quality in the Meat Sector". The Report of this Committee (the "Pimenta Report") endorsed the ban on the use of hormones and was adopted by the European Parliament on 29 March 1989 (see paragraphs 4.36-4.39). The essential findings of the Pimenta Report were that the prohibition of hormonal substances for non-

therapeutic (i.e. growth-promoting) purposes must be maintained and expanded because:

(i) this was the only way to restore consumer confidence in the meat sector;

(ii) 10 out of 12 national veterinary experts indicated that a total ban would facilitate implementation and control;

(iii) The scientific conclusions regarding the use of natural hormones rested upon strict conditions of use which it believed could not in reality be attained. The Committee was of the opinion that use of the natural/nature-identical hormones carries the risk of inexperienced application, incorrect dosage and unsupervised injection which could pose a risk to the animal and the consumer, and also noted doubts with regard to long-term cumulative and interactive potential carcinogenicity. In addition, the Committee believed that proven necessity and socio-economic desirability should be criteria of acceptability for the use of (bio)chemical growth promoters in animal-rearing;

(iv) The Committee did not accept the argument that prohibiting the use for growth promotion of some natural or nature-identical hormones would result in an increase in the use of other, more dangerous growth-promoting substances to the detriment of the consumer;

(v) The Committee believed that the Commission should promote the concept of *animal welfare* in agricultural production.

2.32 The European Parliament adopted another report on the issue of use of hormones for animal growth promotion, the "Collins Report" of 7 February 1989.[11] This report argued that:

> "Current licensing systems for the regulation of veterinary medicines (including at present, growth promoting products) require that a new product satisfy three criteria: safety, quality and efficacy. These criteria may well be satisfactory for therapeutic drugs. They are by no means sufficient for growth promoting products. For the latter it is proposed here that the Community's veterinary medicine licensing system be adapted to include a *"fourth hurdle", entailing an objective socio-economic and environmental impact assessment"*. In the Commission's July 1988 draft proposals for the reform of veterinary medicine licensing in the Community this idea

[11] European Parliament, Committee on the Environment, Public Health and Consumer Protection, Report on "The USA's Refusal to comply with Community legislation on slaughterhouses and hormones and the consequences of this refusal", EP 128 381/B, 7 February 1989, named after its reporter Mr. Collins, MEP.

> was accepted in principle. The final version of the proposals (December 1988) does not include this concept. It is clear, however, that the social, agricultural and environmental implications of the use of growth and yield promoting pharmaceuticals require a licensing system somewhat different from that which exists for these products when used for therapeutic purposes".

2.33 The EC Commission organized a scientific conference on this subject in Brussels from 29 November to 1 December 1996. With regard to the natural hormones, the 1995 EC Scientific Conference on Growth Promotion in Meat Production (the "1995 EC Scientific Conference") concluded that:

> "At present, there is no evidence for possible health risks to the consumer due to the use of natural sex hormones for growth promotion, since:
>
> > Residue levels of these substances measured in meat of treated animals fall within the physiological range observed in meat of comparable untreated animals.
> >
> > The daily production of sex hormones by humans is much higher than the amounts possibly consumed from meat, even in the most sensitive humans (prepubertal children and menopausal women).
> >
> > Due to an extensive first-pass metabolism, the bioavailability of ingested hormones is low, thus providing a further safety margin."[12]

With regard to the synthetic hormones, zeranol and trenbolone, the 1995 EC Scientific Conference concluded that:

> "At the doses needed for growth promotion, residue levels [of trenbolone and zeranol] are well below the levels regarded as safe (the MRLs). There are, at present, no indications of a possible human health risk from the low levels of covalently-bound residues of trenbolone."[13]

5. History of Events under the GATT

2.34 In March 1987, the United States raised the issue of the EC ban under the Tokyo Round Agreement on Technical Barriers to Trade ("TBT Agreement"). Bilateral consultations between the United States and the European Communities failed to resolve the dispute. Arguing that the EC Directive was not supported by scientific information, the United States requested the establishment of a techni-

[12] "Assessment of Health Risk - Working Group II", in *1995 EC Scientific Conference Proceedings*, pp. 20-21.
[13] *Ibid.*

cal experts group ("TEG") under Article 14.5 of the TBT Agreement to examine the question. This request was denied following the EC response that the use of growth promotants was a process and production method (PPM), and that parties to the TBT Agreement only had an obligation not to use PPMs to circumvent the Agreement. The European Communities favoured the establishment of a panel "to evaluate the rights and obligations of Parties deriving from Article 14.25 (of the TBT Agreement)".[14] The dispute went unresolved.

2.35 On 1 January 1989, the United States introduced retaliatory measures in the form of 100 per cent ad valorem duties on a list of products imported from the European Communities. The European Communities consequently asked for the establishment of a panel. This request was denied by the United States. In 1989, a joint US/EC Task Force agreed on certain measures which allowed imports into the European Communities of US meat certified to have not been produced with hormones. This resulted in the United States withdrawing some products from the retaliation list. The other EC products figuring in the list remained subject to the retaliatory action. On 19 June 1996, the European Communities requested the establishment of a panel to examine this matter. On 15 July 1996, after this Panel was composed, the United States terminated its retaliatory action in its entirety.

III. CLAIMS OF THE PARTIES

3.1 The **United States** claimed that the EC ban on the importation and sale of animals, and meat derived from animals, that had been administered any of the six hormones at issue for growth promotion purposes (oestradiol-17β, progesterone, testosterone, trenbolone, zeranol and melengestrol acetate (MGA)) was inconsistent with the SPS Agreement and the GATT.

3.2 Arguing that the EC measures were sanitary measures, the United States claimed, with regard to the SPS Agreement, that these measures: directly and indirectly affected international trade; were not based on an assessment of risk and were consequently inconsistent with Article 5.1 of the Agreement; were maintained without sufficient scientific evidence in contravention of Article 2.2; were not justified as a "provisional" measure under Article 5.7; breached Articles 2.2 and 5.6 in that they were not based on scientific principles; were not applied only to the extent necessary to protect human life or health and were more trade-restrictive than required to achieve the appropriate level of sanitary protection; arbitrarily or unjustifiably discriminated between Members where identical or similar conditions prevailed, in contravention of Article 2.3; constituted a disguised restriction on international trade, in breach of Article 2.3; contravened Article 3.1 because they were not based on the relevant international standards, guidelines or recommendations and that this departure from international stan-

[14] GATT document TBT/M/Spec/7, p.9, para. 34.

dards was not justified by Article 3.3; and were based on arbitrary or unjustifiable distinctions in the levels of protection in different situations, resulting in discrimination or a disguised restriction on international trade in contravention of Article 5.

3.3 The United States claimed that the EC measures discriminated against imports and were inconsistent with Article III of GATT. Arguing that US meat and animals were "like" EC meat and animals, the United States claimed that the EC measures were inconsistent with Article III:4 of GATT because they prohibited the importation and sale of certain imported meat and animals, while permitting the sale of like domestic products. The EC measures therefore treated US imports less favourably than domestic production. The United States further claimed that the European Communities had no legitimate policy purpose for discriminating against US meat and animals. The United States also claimed that the EC measures were inconsistent with Article I:1 of GATT because they failed to accord to imports from the United States the advantages, favours, privileges or immunities granted to like animals and meat originating in the territories of other countries. Finally, the United States argued that the EC measures could not be justified by resort to Article XX of GATT, in particular Article XX(b), because the European Communities had put forward no evidence to support its measures on health grounds, and the measures were "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade". The United States claimed that if the EC measures were not sanitary measures, they would be inconsistent with the TBT Agreement; in particular they were technical regulations within the meaning of the TBT Agreement, and would be inconsistent with Articles 2.1, 2.2, and 5.1.1 and 5.1.2.

3.4 The **European Communities** submitted that the analysis of the SPS and/or TBT Agreements should take place only if alleged violations of GATT Articles were found. Therefore, in their defense, the European Communities first invoked GATT. With regard to the alleged violation of Article III:4 of GATT, the European Communities argued that the animals to which the hormones at issue had been administered for growth promotion, and meat from those animals, were not "like" other animals and meat from those animals, respectively. Furthermore, the European Communities argued that even if they were found to be "like", imported products were not given "less favourable treatment" than domestic products. Therefore, the European Communities claimed that its measures did not infringe Article III:4 of GATT. The European Communities claimed that in case its measures were found to be contrary to Article III:4, they were justified by Article XX(b), which did not affect the power of a Member to adopt a policy in order to protect human and animal health.

3.5 With regard to the alleged violation of Article I of GATT, the European Communities claimed that such violation was not mentioned in the Panel's terms of reference, was not mentioned in the documents by which the United States requested consultations and was not discussed during the consultations that were held subsequently. The European Communities claimed that even if animals and

meat from animals to which the hormones at issue had been administered for growth promotion were found to be "like" (quod non), the measures at issue applied without distinction to all imports of meat irrespective of their country of origin and not only to imports originating in the United States. Accordingly, the European Communities argued that its measures did not violate Article I:1 of GATT.

3.6 The European Communities claimed that the measures at issue, in any event, did not violate any provision of the SPS Agreement because they satisfied all the conditions imposed by it. The measures were based on scientific principles as required by Article 2.2 of the SPS Agreement, and a risk assessment had been performed which established the scientific basis for regulatory action. The European Communities observed that the SPS Agreement recognized a Member's right to establish the level of protection which the Member determined to be appropriate. The European Communities claimed that the measures at issue aimed at achieving a level of protection which was higher than could be achieved if the recommendations of Codex Alimentarius for these hormones were followed. It also claimed that WTO dispute settlement panels were not competent to judge its *level* of sanitary protection nor the scientific evidence upon which it was based, but only whether its *measures* were in conformity with the provisions of the SPS Agreement. It further claimed that the US arguments in fact attacked the EC chosen level of protection, not its measures, because they suggested that residues of these hormones, above naturally present levels, did not pose any risk to health and, therefore, did not warrant the application of any measures to control them. The European Communities also claimed that its measures were based on the precautionary principle. Moreover, it claimed that the United States had failed to discharge its burden of proof because it had failed to show that the measures at issue were no more trade restrictive than required to achieve the EC appropriate level of sanitary protection. The European Communities claimed that its measures were applied in exactly the same way to all animals treated with these hormones and meat from such animals intended for consumption in the EC market, whatever its origin; there was consequently no discrimination nor disguised restriction on international trade. The European Communities did not submit arguments on TBT because it considered that the measures at issue fell with the SPS Agreement. The European Communities claimed that because the measures at issue did not violate any of the provisions of the SPS Agreement, they should be found also to be in conformity with the rules of GATT, in particular Article XX:b, in case a violation of one of its provisions were to be found.

IV. ARGUMENTS OF THE PARTIES

1. Relationship Between GATT 1994 and the SPS Agreement

4.1 The **European Communities** considered that the SPS Agreement would apply only if a violation of the Articles of GATT were to be established. The

European Communities argued that the General Interpretative Note to Annex 1A of the WTO Agreement provided that:

> "In the event of conflict between a provision of the General Agreement on Tariffs and Trade 1994 and a provision of another agreement in Annex 1A to the Agreement Establishing the World Trade Organisation ...., the provision of the other agreement shall prevail to the extent of the conflict" (emphasis added).

4.2 The European Communities argued that the SPS Agreement codified, as the last recital of its preamble stated, the desire of the Members "to elaborate rules for the application of the provisions of GATT which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)". Furthermore, it was well established GATT law and practice that GATT 1947 did not affect the power of its Members to set up a regulatory *policy* which they deemed necessary in order to protect human, animal or plant health. But the conformity of the *measures* it applied for that purpose could be reviewed under GATT.[15] It was, therefore, admitted that a violation of GATT by a *measure* should be established first, before recourse to possible justifications (e.g. under Article XX(b)) could be considered. In such an event, the Panel could review the *measure* but not the underlying policy objective on which it was alleged to be based. The European Communities noted that there were several new provisions in the SPS Agreement that established a series of rights and obligations for Members. However, the SPS Agreement reaffirmed the right of Members to adopt or enforce measures the Member deemed to be necessary to protect human, animal or plant health (recitals 1 and 6 of preamble). It could therefore be argued that most of the obligations created by the SPS Agreement were already applied under GATT 1947 through interpretations of Article XX(b) by panel reports and the CONTRACTING PARTIES.

4.3 The European Communities claimed that Article 2.4 of the SPS Agreement established that SPS measures which conformed to the Agreement were "presumed" to be in accordance with the obligations of the Members "under the provisions of GATT which relate to the use of sanitary or phytosanitary measures, *in particular* the provisions of Article XX(b)" (emphasis added). Despite the fact that the words "in particular" appeared in Article 2:4, it was hard to imagine *other* provisions of GATT "which relate to the use of sanitary or phytosanitary measures".

4.4 The European Communities noted that, in their "Statement of Administrative Action", the USTR had explained that:

> "The S&P negotiations initially began as an attempt to elaborate on the provisions of Article XX(b). The Agreement extends beyond an interpretation of existing GATT provisions, however, and includes

[15] See, e.g. the panel report on "Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes", adopted on 5 October 1990, DS10/R.

> new obligations - in particular, transparency requirements such as providing notice of, and an opportunity to comment on, proposed S&P measures."[16]

Therefore, if the SPS Agreement were to be defined as a *self-standing* agreement this was not because it interpreted provisions of GATT other that Article XX(b), but only because it laid down additional *procedural* requirements. The substantive role of the SPS Agreement, was to interpret Article XX(b) of GATT. In other words, recourse to the substantive provisions of the SPS Agreement could be made only under the same conditions under which recourse could be made to Article XX of GATT, that was only *after* a violation of another provision of GATT was first established. As far as the additional, procedural obligations laid down by the SPS Agreement were concerned, these could be examined by the Panel directly and independently of any need to establish first a violation of the provisions of GATT.

4.5 The **United States** claimed that the EC ban was subject to the SPS Agreement because the Agreement applied to "all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade"[17] and the EC measures were sanitary measures, as defined by the SPS Agreement, which directly and indirectly affected international trade. The SPS Agreement was specifically tailored to SPS measures and was the *lex specialis* in this instance. It made sense to look first to the agreement most specifically designed to address the types of measures and issues involved. The SPS Agreement applied to *all* SPS measures, and applied whether or not a Member was invoking a GATT exception for such measures. It imposed requirements additional to those in Article III and to the conditions for justifying the application of the exception in Article XX(b). For instance, Article 3.2 of the SPS Agreement provided that an SPS measure conforming to international standards, guidelines or recommendations was presumed to be consistent with the "relevant provisions" of not only GATT, but also the SPS Agreement itself. The Agreement stood independently from GATT. Thus, a complaining party did not need to first show that an SPS measure was inconsistent with GATT before it might invoke the provisions of the SPS Agreement.

4.6 The United States submitted that the negotiating record confirmed that the SPS Agreement was intended to go beyond GATT and to impose requirements additional to those in GATT. In the earliest phases of negotiations on SPS issues, the discussions had focused on further definition of Article XX(b). Up to the Dunkel Draft text (MTN.TNC/W/FA of 20 December 1991), the SPS text was phrased as a Decision of the CONTRACTING PARTIES interpreting the GATT, simply because participants had wished the proposed disciplines to apply to all GATT contracting parties and only a Decision (as opposed to an optional-

[16] US Statement of Administrative Action, p.87.
[17] Article 1.1 of the SPS Agreement.

membership Code) would accomplish that result.[18] However, in April 1992, when the possibility emerged of using the MTO Agreement (later renamed the WTO Agreement) to tie the Uruguay Round results together into a "single undertaking", negotiators had agreed to change the form of the text to a free-standing Agreement in Annex 1A of the MTO Agreement.[19] In contrast, the various Understandings on GATT Articles began as decisions interpreting the GATT and were finally incorporated into GATT. Had the negotiators intended that the SPS Agreement be nothing but a clarification of the GATT, in whole or in part, the United States argued, they would have given its provisions the same form as, for instance, the Understanding on the Interpretation of Article XVII of the GATT. The European Communities' suggestion that the SPS Agreement could be divided between provisions that applied to all SPS measures (and applied under all circumstances), and other provisions which only applied if an SPS measure violated the GATT, had no basis in the text of the SPS Agreement.

2. The SPS Agreement

4.7 The **United States** claimed that according to the definition of sanitary and phytosanitary measures in the SPS Agreement, whether a measure was a sanitary measure depended on its purpose[20]. The United States noted that the purported sanitary purpose of the EC measures was stated in the texts of the EC Council Directives themselves, and was apparent from the history of the EC measures and subsequent statements of the European Communities, including statements to Contracting Parties of the GATT 1947. In reviewing the proposal for Directive 81/602/EEC, the European Economic and Social Committee had recognized that

---

[18] "Given the desire of participants for the application of the proposed disciplines to all contracting parties, this draft has been presented in the form of a Decision of the CONTRACTING PARTIES on the Application of Sanitary and Phytosanitary Measures. However, this is without prejudice to the final form the agreement might take." MTN.GNG/NG5/WGSP/7, 20 November 1990, p.1.

[19] P.21 of document 707 dated 15 April 1992, "Review of Individual Texts in the Draft Final Act (Texts on Agriculture), Informal Note by the Secretariat" (Secretariat proposal to rectify the form to change it from a decision to an agreement), and p.19 of document 963 dated 10 June 1992, "Review of Individual Texts in the Draft Final Act, Informal Note by the Secretariat" (record of rectifications agreed in the Legal Drafting Group in April 1992, including this change in form). The paragraphing of the text was rearranged into article format during the legal drafting process for the Marrakesh Final Act in February 1994. Secretariat proposals for rectifications at p.71 of MTN/FA/Corr.2 dated 18 February 1994, and agreed rectifications in MTN/FA/Corr.5 dated 11 March 1994.

[20] Article 2.1 of the SPS Agreement. The United States argued that the European Communities was mistaken in its perception of the coverage of the SPS Agreement. The EC claim that sanitary and phytosanitary measures were defined based in part on the type of product to which the measure applied was incorrect. Nothing in the SPS Agreement limited its coverage by the type of product. The SPS Agreement applied to *any* sanitary or phytosanitary measure. For example, measures restricting the importation of construction equipment to ensure that it was not carrying soil with plant pests or diseases, or that it did not harbour plant pests, were phytosanitary measures, even though they applied to construction equipment. The same would be true for measures applicable to lawn furniture to ensure that it did not harbour cocoons of a plant pest, or measures applicable to tires to make sure they did not host mosquitoes carrying infectious diseases for humans.

"there is an urgent need to draw up EC provisions in order to protect human health".[21] Similarly, the debate of the European Parliament on the proposal for Directive 88/146/EEC underscored the claim that the EC measures were designed to protect human health from risks associated with the use of the hormones at issue.[22] The preamble to Directive 81/602/EEC stated in part: "Whereas, due to the residues that they leave in meat, certain substances with a thyrostatic, oestrogenic, androgenic or gestagenic action may be dangerous for consumers" and "Whereas, moreover, the harmless or harmful effects of the use of Oestradiol-17β, Progesterone, Testosterone, Trenbolone and Zeranol still have to be examined in detail." This concern for human health was carried forward with Directive 88/146/EEC.[23] In addition, during the discussion in the Tokyo Round Committee on Technical Barriers to Trade concerning the EC measures, the EC representative had stated that the European Communities "adopted the Directive as the best way of avoiding any health risks connected with the use of hormonal substances".[24] The United States argued that although the European Communities had stated that the purpose of its measures was a sanitary purpose, ostensibly to protect human life or health within the European Communities from risks arising from additives, contaminants, or toxins in food, the measures were not legitimate sanitary measures.

4.8 The **European Communities** agreed with the United States that the measures challenged were better defined as measures falling within the scope of the SPS Agreement rather than the TBT Agreement. The European Communities noted that an essential link of the SPS disciplines with the regulatory freedom of the parties was that the measures applied were of concern to the SPS Agreement (and the WTO system) only if they affected international trade. Moreover, the SPS Agreement defined the measures to which it applied on the basis of the *objective* of the measure *and* the *type* of product to which it was applied.

---

[21] Paragraph 1.2 of the opinion, *EC Official Journal* No C 138/29, 9 June 1981. This opinion is cited in the preamble to Directive 81/602/EEC.

[22] Debate published in the Annex to the *EC Official Journal* No 2-330 of 10 October 1985, beginning, p.232.

[23] Directive 88/146/EEC states that:

> "Whereas the administration to farm animals of certain substances having a hormonal action is at present regulated in different ways in the member States; whereas while their immediate effect on animals from the farmer's point of view is clear, assessments of their effect on human health vary and this is reflected in the regulations governing their use; whereas this divergence distorts the conditions of competition in products that are the subject of common market organizations and is a serious barrier to intra-EC trade."

[24] Paragraph 12, TBT/M/Spec/7 (Committee on Technical Barriers to Trade, Minutes of Meeting held on 23 July and 28 July 1987). See also paragraph 6 of TBT/M/Spec/7 ("The complaint of the United States should not deter his authorities from applying the measures that they had adopted to protect the health and safety of their population."), as well as paragraphs 9 and 24. See also paragraphs 11 through 13 of TBT/M/Spec/5.

4.9 The **United States** claimed that the EC measures on their face applied to imports of animals and meat, prohibiting imports of animals to which any of the hormones at issue had been administered for growth promotion purposes, and imports of meat from such animals. They clearly affected international trade and, when they were applied, they closed market access for significant quantities of imports from the United States [25] and other Members and continued to block imports of animals and meat.

4.10 The United States observed that US exports of beef and veal to the European Communities in the three years prior to the ban (1986-88) averaged in the hundreds of millions of dollars, and trade to the European Communities during the 1985-87 period was growing at about 30 per cent per year.[26] In 1989, when the ban went into effect, US exports plummeted to nearly zero. Moreover, as a result of various rounds of multilateral trade negotiations, the European Communities had bound its tariffs on all products affected by the measures at issue. In the Tokyo Round of Multilateral Trade Negotiations, concluded in 1979 prior to the adoption of the EC measures at issue here, the United States negotiated a quota for 10,000 tonnes of high-quality beef subject to a tariff of 20 per cent ad valorem and free of any variable levy. In the Uruguay Round, this 10,000-tonne quota was converted to a tariff-rate quota and the variable levy on beef imported in excess of 10,000 tonnes was "tariffied". The European Communities also had bound duties on offal products (e.g., hearts, livers, and kidneys). As a result of the EC beef import ban, US exports of these products to the European Communities had been substantially impaired.

4.11 The United States argued that the SPS Agreement was designed to ensure that no Member maintained protectionist barriers to trade in the guise of SPS measures and that Article 1.1 required that sanitary measures "be developed and applied in accordance with the provisions of this Agreement". The requirement that measures be "developed" in accordance with the SPS Agreement did not apply here since the EC measures were developed prior to the entry into force of the WTO. However, the European Communities were still required to "apply" these measures in accordance with the provisions of the SPS Agreement.

4.12 Moreover, in order to differentiate between legitimate SPS measures and other types of measures, the United States noted that the SPS Agreement provided a number of disciplines for sanitary measures. These included an obligation that each sanitary measure:

(i) be based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health[27];

---

[25] According to a table provided by the United States, an average 70 per cent of all US cattle were treated with one or more of these hormones.

[26] The United States estimated in 1988 that the EC measures cut off approximately $100 million in US exports.

[27] Article 5.1 of the SPS Agreement.

(ii) not be maintained without sufficient scientific evidence[28];

(iii) be based on scientific principles[29];

(iv) not be more trade-restrictive than required to achieve the appropriate level of sanitary protection, taking into account technical and economic feasibility[30];

(v) not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevailed[31];

(vi) not be applied in a manner that would constitute a disguised restriction on international trade[32]; and

(vii) be based on international standards, guidelines or recommendations, where they existed[33].

The United States claimed that the EC measures failed each of these requirements. The EC ban was not a legitimate sanitary measure because it severely restricted international trade, was not applied only to the extent necessary to protect human life or health, was not based on scientific principles, was maintained without sufficient scientific evidence, was not based on an assessment of the risks, and was more trade-restrictive than required to achieve the appropriate level of protection. It also constituted a disguised restriction on international trade.

4.13 The **European Communities** responded that, as envisaged in the EC legislation, imports might take place from third countries provided that guarantees were offered that no animal and no meat coming from an animal to which hormonal substances had been administered would be exported to the European Communities. The EC legislation in question did not impose a ban on *US* meat or on meat from *any* other origin. The US exported fresh meat not destined for human consumption and exported to the European Communities hormone-free meat products for human consumption on the basis of measures agreed by the joint US/EC Task Force. The US exports of meat to the EC market for the years 1989 to 1994 were as follows: 1988: 72,557 tonnes, 1989: 8,380 tonnes, 1990: 3,617 tonnes, 1991: 1,156 tonnes, 1992: 6,320 tonnes, 1993: 6,833 tonnes, 1994: 6,594 tonnes, 1995: 8,499 tonnes.[34]

4.14 The European Communities agreed that the SPS Agreement imposed the disciplines enumerated by the United States and considered that its measures satisfied all those disciplines. When the EC Commission had first proposed to the EC Council in 1980 to take measures in this area as well as in 1988, it had found itself facing certain factual, legal and scientific situations. From the factual point

---

28 Article 22 of the SPS Agreement.
29 *Ibid.*
30 *Ibid.*, Article 5.6.
31 *Ibid.*, Article 2.3.
32 *Ibid.*, Article 2.3.
33 *Ibid.*, Article 3.1.
34 The European Communities explained that the figures were based on Eurostat statistics.

of view, consumer concerns over the use of hormones for growth promotion in livestock were very high. Despite the traditionally cautious approach to the regulation of dangerous substances followed by the EC member States, consumer confidence in science and regulators (especially among well-informed consumer organisations and groups) was very low. This factual situation had not changed during the entire period that had preceded the adoption of Directive 96/22/EC. Consumer concerns were even higher today.

4.15 The European Communities noted that from the legal point of view, the use of hormones in animal growth promotion had long been prohibited in most EC member States; only some EC member States allowed the use of some of these substances under certain conditions.[35] With the progressive establishment of the common market, the divergence in the legislation of EC member States was inhibiting free trade within the European Communities in animals and meat from animals treated with some of these hormones, and distorting the conditions of competition among EC meat producers.

4.16 Furthermore, the European Communities observed that from the scientific point of view, the situation was very unclear in the early 1980s. The relevant international organizations - FAO, WHO, the Office international des épizootics (OIE) and the Codex Commission - had started to seriously examine the safety of these hormones in meat production only during the 1980s. The first substantive and comprehensive scientific report had been published by OIE in 1983. JECFA had discussed and issued a substantive and comprehensive scientific report on these hormones only in 1988. Furthermore, *none* of these scientific reports established beyond doubt that the use of these hormones in animal growth was safe for human health. For example, in the 1983 OIE Scientific Report it was stated:

> "Even though many unknown influences still exist with regard to the details of the mechanism of action, particularly with reference to how the message brought by the receptor is translated into action in the cell nucleus, we are nevertheless beginning to have some understanding of how anabolics work" (page 62).

With regard to the three so-called "natural" hormones, the European Communities noted that all of the above scientific reports suggested that they were "unlikely to pose a hazard to human health" if used "in accordance with good veterinary or animal husbandry practice".[36] As regards the other so-called "synthetic" hormones, reliable toxicological data were still missing in the 1988 JECFA Report (page 26). Their use for animal growth promotion had been *provisionally* recommended in accordance with good animal husbandry practice and residue

[35] The European Communities indicated that 4 or 5 EC member States allowed the use of some of these hormones for growth promotion until their prohibition at EC level. The information on level of use, if available at all, would only be known to those individual EC member States. One EC member State, the United Kingdom, had indicated that anecdotal evidence suggested that growth promoting hormones might have been used up to 40 per cent of the United Kingdom cattle prior to the ban.

[36] *1988 JECFA Report*, pp.19 *et seq.*

checking in order to ensure that the so-called Acceptable Residue Levels (ARLs) *provisionally* recommended were not exceeded. The European Communities argued that even today the state of scientific knowledge was not much different from what it was in 1981 and 1988 when the challenged measures had been adopted (as shown by the 1995 EC Scientific Conference).

4.17 The **United States** argued that although the purported major objective of the EC ban was to protect human health, the real purpose was to protect EC meat production from third-country competition. Noting that the European Communities cited as the purposes of these measures (i) protection of human health and (ii) a desire to alter the terms of competition for animals and meat in order to render these conditions "largely identical" within the EC market, the United States claimed that neither reason offered a valid justification under the WTO agreements. Furthermore, in developing the hormone ban, the European Communities were also motivated by the fact that the ban would help reduce surplus supplies of meat in the European Communities and lower the cost of the EC Common Agricultural Policy. The United States argued that this attempt to protect domestic production from more competitive imports was protectionism and was inconsistent with EC WTO obligations.

4.18 The United States noted in this regard that in April 1984, the European Communities had introduced milk quotas to reduce the oversupply of milk, which resulted in an increase in cattle slaughter. EC intervention stocks of beef, which were slightly less than 400,000 tonnes in November 1983, soared to over 800,000 tonnes by the end of 1985.

4.19 The **European Communities** rejected the US argument that the EC measures had been adopted in order to protect domestic production from foreign competition. The reference to the divergence in the legislation of the EC member States which distorted the conditions of competition and affected free circulation of products in intra-EC trade (1st and 2nd paragraphs of Directive 88/146/EEC), was made for the sole purpose of justifying the need to take action at the EC level. Because of its internal constitutional structure, the European Communities was obliged to take action in order to eliminate distortions in the conditions of competition and to increase free intra-EC trade.[37] The preamble of the Directive thus clearly explained that the underlying objective was to respond in an *harmonized way* to the effect of these hormones on human health. This objective, however, was not in itself independent or more important than the objective of safeguarding against risks to human and animal health resulting from the substances at issue.

4.20 The European Communities further argued that action at the EC level was explicitly permitted by Article XXIV:8(a) of GATT. It submitted that when the European Court of Justice examined the object and purpose of Directive

[37] The European Communities noted that this obligation resulted from Articles 100 and 100A, in conjunction, in this case, with Articles 30 and 36 of the EC Treaty.

85/649/EEC (invalidated on procedural grounds and subsequently re-enacted in Directive 88/146/EEC) it had noted that "the aim of the Directive, according to the recitals in its preamble, is to protect human health and consumer interests with a view to eliminating the distortion of conditions of competition and bringing about an increase in consumption of the product in question".

4.21 Furthermore, the European Communities asserted that the historical record clearly demonstrated that the purpose of the EC measures was to protect human and animal health from risks arising from the use of the hormones at issue. The European Communities noted that the European Parliament had proposed a ban on imports of meat from animals treated with growth promoting hormones primarily because "scientific information about these substances is far from complete and that considerable doubt therefore exists about the desirability of their use and of their effect on human health".[38] Serious health concerns had been clearly stated in different MEP reports, including the "Nielsen Report", the "Pimenta Report" and the "Collins Report", and the European Parliament had remained constantly opposed to the authorization of all these hormones for animal growth promoting purposes for reasons of possible hazards to human and animal health. The Economic and Social Committee had also rejected the use of these hormones for growth promotion purposes on health grounds. The European Communities claimed that, from the above sequence of events which had eventually led to the adoption of Directive 88/146/EC, it was clear that the European Communities had examined carefully the potential risks to human and animal health from the use of these hormones for animal growth promotion purposes; considered that scientific evidence, whilst suggesting that these substances, if used in accordance with good veterinary practice, did not seem to pose risks to human and animal health, did not exclude beyond doubt that they posed no potential risks to human health; examined carefully all of the available options for harmonizing the conditions of use of these substances before concluding that, at present, the ban on their use was the only scientifically, technically and economically feasible option.

4.22 The European Communities rejected the US references to milk quotas and observed that the increase in the EC intervention stocks of beef was unrelated to the objective and purpose of the challenged measure. Such high intervention stocks of beef did not exist in the EC member States that introduced the prohibition on the use of these hormones as early as 1961; such high intervention stocks of beef did not exist in 1981 when this prohibition was for the first time imposed at EC level; and such high intervention stocks of beef did not exist in April 1996 when the European Communities adopted Directive 96/22/EC which re-enforced the prohibition on the use of these hormones. The European Communities further submitted that the fact that the Directive offered equal access to the EC market for third-country meat was additional proof that there was no protectionist pur-

[38] Point E of Parliament's Resolution, *EC Official Journal* No 288, 11 November 1985, p.158.

pose in the EC measures. Statistics showed that the European Communities had continued to import about the same quantities of meat as before the application of the ban, it was, however, meat from animals to which hormones for growth promotion purposes had not been administered.

(a) Article 2.2 of the SPS Agreement

4.23 The **United States** recalled that Article 2.2 required Members to ensure that any sanitary measure was applied only to the extent necessary to protect human or animal health, based on scientific principles and not maintained without sufficient scientific evidence. The United States argued that the European Communities had failed to follow scientific principles, and lacked any scientific evidence to give credence to its asserted health concerns. The European Communities presented no evidence to contradict the long established scientific determination that the six hormones were safe for use as growth-promotion substances and that consumption of meat containing the minute quantities of residues from treated animals was not harmful to consumers.

4.24 The United States claimed that while the negotiators had not defined precisely "scientific principles", at a minimum this term incorporated the scientific method, which represented those principles and processes universally regarded as necessary for scientific investigation, in particular procedures for:

(i) the observation of phenomena in nature or under controlled conditions;

(ii) the systematic classification of empirical data;

(iii) the measurement of empirical quantities and for calculating probable errors and significant deviations;

(iv) forming a hypothesis;

(v) analysing experimental results using logic and mathematics; and

(vi) many other related techniques and processes.

4.25 The **European Communities** responded that the US explanation of the concept of "scientific principles" was a caricature of "the scientific method" which could have been taken straight from a school textbook circa 1960. There was absolutely no reason to suppose that the Members of the SPS Agreement had the list presented by the United States in mind when signing it. There were many theories of science and the "scientific method"; the European Communities relied on biological principles when assessing the risks of using hormones for growth promotion. Measures must be based on *scientific* principles, as opposed to non-scientific ones, such as superstition. If a measure was aimed at reducing or eliminating a risk to health, then it must actually address that risk in a manner which could be scientifically justified. If, for example, the measure was aimed at eliminating a pathogenic organism from a food, there were several methods, e.g. heating, salting, pickling, etc. which could be scientifically proven to be effective. If, however, a Member required prayers to be said over the food, or a ritual

dance to be performed around it, that would not be compatible with the SPS Agreement because such methods could not be scientifically proven to be effective.

4.26 The European Communities further argued that during the meetings of the Panel with scientists on 17 and 18 February 1997, a number of experts advising the European Communities explained their views on the potential dangers to human and animal health from the use of these hormones for growth promotion. None of the experts advising the Panel argued that the experts referred to by the European Communities did not employ scientific principles in their research. The US Statement of Administrative Action stated that Article 2.2 of the SPS Agreement did not require the best science nor the weight of scientific evidence to be taken into account; it only stipulated that there should be "scientific principles" and "sufficient" (not absolute) scientific evidence. The European Communities further argued that for example, Dr. Lucier had agreed with the conclusions of the EC scientists that both the natural and synthetic hormones were carcinogenic at low levels (the natural hormones are carcinogenic even at existing physiological levels). Some of the scientists who attended the meetings of the Panel (and those of JECFA 1988) might not agree with the conclusions of the scientists advising the European Communities or with Dr. Lucier, but this was not relevant for the purposes of Articles 5.2, 2.2 and 3.3 of the SPS Agreement. What was important was whether, in the scientific research employed by the EC scientists (or the scientific reports to which they made reference in their reports), the *minimal attributes of scientific inquiry* were respected. The European Communities had not heard the opposite from any of the scientists advising the Panel nor from the United States and Canada. Therefore, the European Communities was allowed to take into account their scientific views (or the views of the scientists to which they referred in their reports) in its assessment of the risks of these hormones for growth promotion.

4.27 The European Communities indicated that a logical consequence of the requirement for measures to be based on scientific principles was that they must not be *maintained* without scientific *evidence*. All Members had measures in place before the SPS Agreement was drawn up, and in the absence of this requirement it could have been argued that the requirement for basing measures on scientific principles could not be applied retrospectively. The SPS Agreement understandably did not define the term "scientific evidence". It was easier to argue that there were scientific principles, scientific methods, scientific experiments and scientific data. But it was difficult to define what was "scientific evidence", since its content was relative in terms of time and was dependent on the principles, methods, experiments and data mentioned. For example, what might be an acceptable scientific method for one scientist might not satisfy another, who might be more interested in certain other scientific principles or aspects totally neglected or only partially examined by the first scientist. For that reason the

SPS Agreement only required "sufficient", not clear or certain, scientific evidence (Article 2.2).[39] The SPS also required Members, in their risk assessment, to taken into account "*available*" scientific evidence". But from the "available" scientific evidence, a Member was entitled to rely on that which its own scientists said was appropriate and sufficient, and disregard other available evidence. It followed that neither the Panel nor any other member might judge the adequacy of the scientific evidence upon which a Member based its measure in order to achieve its level of sanitary and phytosanitary protection. For the same reasons, a Codex group of scientific experts could not judge the adequacy of the scientific evidence used by a Member of the SPS Agreement.[40] In other words, if the "weight" of available scientific evidence indicated that a substance was not dangerous to human health, but another small or minority part of available scientific evidence (of the same Member) argued that there may be potential risks to human health, that Member was entitled under the SPS Agreement to take a precautionary approach and base its measure on the latter part of the available scientific evidence. As the United States has said in the Statement of Administrative Action, it is sufficient if the "government maintaining the measures has *a* scientific basis for it" (emphasis added).

4.28 The scientific basis of the EC Directives 81/602 and 88/146 were the following:

(i) the 1982 Report of the Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the basis of the Report of the Scientific Group on Anabolic Agents in Animal Production (the Lamming Report);

(ii) the 1983 OIE Scientific Conference Report;

(iii) the 1988 JECFA Report;

(iv) the various works of relevant international institutions, such as the International Agency for Research on Cancer (IARC);

(v) the scientific works by individual scientists relevant to the issue of use of hormones in general and for animal growth in particular; and

(vi) information on the use of these hormones for growth promotion available from other countries, when relevant.

4.29 For the adoption of Directives 81/602/EEC, 88/146/EEC and 92/22/EC, apart from the above scientific evidence, additional technical information had been taken into account. This information consisted mainly of the internal studies of the EC Commission, the reports of the European Parliament, the reports of the Economic and Social Committee and the deliberations of the Council of Minis-

[39] On the other hand, the European Communities noted that the term "scientific evidence" had a different meaning from the requirement to provide "evidence" in a legal trial.

[40] See, for example, the article by D.A. Wirth (1994), "The role of Science in the Uruguay Round and the NAFTA Trade Disciplines", 27 *Cornell International Law Journal*, 817-859, at 856-57.

ters. For their deliberations, the Ministers were assisted by scientific groups and individual scientific experts, including experts from the relevant administrations of the EC member States. For the adoption of Directive 96/22 of 29 April 1996, the 1995 EC Scientific Conference Proceedings had also been taken into account.

4.30 The European Communities noted that in its first proposal to the Council on these substances, the EC Commission had explained that controls were needed "... in view of the effects of these substances in relation to carcinogenicity, physiological effects and meat quality. The latter aspect is also important as regards use of natural substances since physiological effects may also occur when exposure to exceptional levels incidentally takes place".[41] In its second submission to the Council of Ministers the EC Commission had explained the (zero) tolerance levels which were being proposed and the need to take into account the natural levels of the endogenous hormones which might occur in animals.[42] In its third expanded submission to the Council of Ministers, the EC Commission had explained the proposed therapeutic and zootechnical uses of the natural hormones, including the system of control of use and marketing.[43]

4.31 The European Communities indicated that, with respect to Directive 88/146/EEC in 1982, the Commission had created an ad-hoc Scientific Committee of Experts on Anabolic Agents in Animal Production (chaired by Professor Lamming). This Committee had issued an interim report on 22 September 1982 (the "Lamming Report"). The EC Scientific Veterinary Committee gave its reaction on 9 November 1982. This was followed by the EC Scientific Committee on Animal Nutrition on 17 November 1982, and by the EC Scientific Committee for Food on 4 February 1983. In essence, these Committees supported *controlled* use of natural hormones, but were opposed to the use of trenbolone and zeranol. On 12 June 1984, the EC Commission published its proposal (COM(84)295) which envisaged the controlled use of the three natural hormones for growth promotion and proposed re-visiting the prohibitions on the two synthetic hormones after completion of their scientific evaluation.

4.32 The European Commission's proposal was rejected by the European Parliament based on the report of the Committee on the Environment, Public Health and Consumer Protection and on the opinion of the Committee on Agriculture, Fisheries and Food.[44] The European Parliament, which did not approve the proposed authorization of the three natural hormones except for therapeutic purposes, had explained that:

> "... Considering that scientific information about these substances is far from complete and that considerable doubt therefore exists

[41] COM(80)614 of 31 October 1980.
[42] COM(80)920 of 6 January 1981.
[43] COM(80)922 of 6 January 1981.
[44] European Parliament Doc. A2-100/85 of 11 October 1985.

> about the desirability of their use and of their effect on human health ...
>
> "... whereas, in particular, there seems to be doubt as to the effects on the immunity against various diseases of animals treated with hormone cocktails and that this in turn may lead to an increased use of antibiotics ...
>
> "... Recognizes that there is considerable difficulty involved in checking whether such substances have been used because, where they have been properly administered, the measurable residue concentrations are well within normal physiological limits relatively soon after application;
>
> "Believes, therefore, that the permitted use of hormones for therapeutic purposes must be strictly controlled and documented.
>
> "Rejects the authorization of artificial and natural hormones as growth promoters".

4.33 The European Communities concluded that, therefore, the European Parliament and the scientific experts advising their members had carefully reviewed the scientific evidence presented to it by the European Commission and by its own expert committees, and had decided to reject the Commission's proposal. The Economic and Social Committee had also reviewed the European Commission's proposal, taking into account a very wide range of technical and scientific expertise, and in its opinion (29 November 1984) stressed that:

> "... even the lifting of the bans on the three endogenous anabolics (oestradiol-17β, testosterone and progesterone) in respect of foodstuffs of animal origin cannot be regarded as unobjectionable from the point of view of the safety, health and well-being of the population, until they have been proved harmless on the basis of sound experience covering, inter alia, conditions of use ..."

4.34 The European Commission's proposal was also rejected by the Council of Ministers. As a result, the Commission amended its proposal and on 31 December 1985 the Council adopted Directive 85/649/EEC. This Directive confirmed a ban on the use of all the substances concerned for growth promotion purposes and established more detailed provisions concerning authorized therapeutic use. This Directive was challenged in the European Court of Justice, which annulled it on purely procedural grounds. Re-introduced, the proposal was re-adopted by the Council on 16 March 1988 (Council Directive 88/146/EEC), prohibiting the use in livestock farming of substances having a hormonal action.

4.35 The European Communities noted that in 1987, Professor Lamming had published an account of further work undertaken by members of his group on zeranol and trenbolone which concluded that these substances would probably be

safe when used in accordance with "accepted husbandry practice".[45] The European Communities argued that the report had not defined this concept, and that its conclusion was based on the unsupported assumption that their carcinogenicity was related to their hormonal effects.

4.36 The European Communities indicated that subsequently, in 1988, following discoveries of significant use of illegal growth-promoting hormonal substances in certain EC member States, the European Parliament had established a "Committee of Enquiry into the Problem of Quality in the Meat Sector". This Committee had received submissions from a wide range of scientific experts, organisations and institutions, including meat trade and farmers' organisations, third country producers, the pharmaceutical industry and consumers' organizations. The outcome of the work of the Committee of Enquiry into the Problem of Quality in the Meat Sector (the "Pimenta Report"), was adopted by the European Parliament on 29 March 1989. The report observed that there was no discernable health risk in the use of the three endogenous hormones at issue where these were, in particular, administered to castrated steers and where they were administered in the form of slow-release implants in a part of the animal which was not consumed (e.g. the ear) and where a specific withdrawal period was observed before slaughter. Of the two other hormonal substances, zeranol was regarded as being as safe as the three endogenous hormones referred to, while with regard to trenbolone acetate, a small residual doubt regarding potential long-term carcinogenicity persisted. The Pimenta Report also indicated that the Committee had been impressed with the thoroughness and objectivity with which the scientists concerned had produced and presented their findings. Nonetheless, the Committee endorsed the ban on the use of hormones, noting examples where scientific knowledge on the safety of substances had subsequently been reversed and that "[t]he scientific evidence does not address the question of potential interaction of these substances with other substances or the multiplier effect of these substances in a worst-case scenario (e.g. the administering of hormones to an animal with an already high level of endogenous hormones and the ingestion of the meat (or milk) of that animal by a female taking the oestrogen-based contraceptive pill" (page 6).

4.37 The European Communities noted that the Pimenta Report had concluded that successful regulations could not be based solely on scientific information, partly because of the "current state of knowledge" argument, and partly because the regulatory process had to resolve social and political conflicts that extended beyond scientific considerations. Although the decision-making process in controversial socio-economic and environmental issues had to take into account the scientific evidence, it was essential that the final decision rest with society itself through its elected representatives. The report noted that what might appear to be a public rejection of science was more plausibly related to a question of confi-

[45] *The Veterinary Record*, 24 October 1987, p.389.

dence in the adequacy of regulatory control. The Committee was unconvinced that the legalization of the five natural/nature-identical hormones for growth-promotion would prevent the use of harmful black-market alternatives. It observed that producers were still using easily-detectable synthetic substances because of the continued attractiveness of these products and the economic gain to be obtained from their use. These were also incentives not to follow the conditions for administration specified by the Lamming Committee.

4.38 In this respect, the Pimenta Report noted that "upstream" controls were essential, beginning with testing blood and urine samples of live animals on the farm. The processes of metabolism, dilution and excretion in the living animal meant that the longer the interval between administration of the substance and testing of the live animal or carcass, the more difficult it was to detect the metabolites characteristic of the use of illicit substances. In addition, once the carcass was slaughtered and butchered, detection of metabolites and tracing back to the animal became very difficult. However, testing for synthetic substances posed no significant problems, although the degree of capability and sophistication of detection varied enormously between EC member States. In addition, methods of chemical masking and other sophisticated techniques were being increasingly used. While testing for the three natural hormones posed a problem in that the range of levels of these hormones produced naturally in the body of the animal was so large and variable, ranges of levels could be drawn up, taking into account the sex, age, oestral cycle and condition of the animal. If tests showed that an animal, for no apparent reason, was at or above the upper limit, then testing on other animals in the herd could provide valid evidence since the statistical possibility of an entire herd possessing above-average hormone levels was minute.

4.39 The Committee reported that ten out of twelve veterinary authorities from the EC member States agreed that a total ban on administered hormones would be easier to police than a partial ban, because veterinarians could generally tell by visual signs when an animal had been treated with hormones (the shape of the animal and the sexual organs were altered) but not whether this had been a treatment with legal versus illegal substances. Furthermore, psychologically, a total ban was more effective than a partial one in that regulators, producers and consumers were left in no doubt that the administration of any hormonal substance for growth promotion purposes was not allowed. The control of the whole meat production chain in Europe would have to be equally rigorous whether all hormonal substances or only some hormonal substances were banned for growth promotion purposes. Inspection would need to be just as comprehensive and rigorous. The Pimenta Report concluded that severe sanctions would have to be imposed on those flouting the ban to overcome the strong economic incentives to use growth promotion substances, and that this problem had to be tackled in order for a ban to be effective and for confidence to be restored in the meat sector (page 13).

4.40 The European Communities added that the European Parliament had adopted another important report on the issue of use of hormones for animal growth promotion, the "Collins Report" of 7 February 1989.[46] This report proposed that the EC veterinary medicine licensing system be adapted to include a "fourth hurdle", entailing an objective socio-economic and environmental impact assessment in addition to safety, quality and efficacy criteria. It argued that the social, agricultural and environmental implications of the use of growth and yield promoting pharmaceuticals required a licensing system different from that which existed for these products when used for therapeutic purposes.

4.41 The European Communities indicated that the European Commission, in close cooperation with EC member States, had continued to review the application of Directive 88/162 in the appropriate scientific and management committees. After the entry into force of the SPS Agreement, the European Communities had decided to review once again the situation from the scientific point of view. For that reason, it had organized the 1995 EC Scientific Conference in Brussels. In light of the findings of that conference and other evidence, the European Commission had proposed to the Council of Ministers to maintain the prohibition on the use of these hormones for growth promotion, to further restrict their use for therapeutic or zootechnical purposes, to reinforce the provisions on control and testing, and to increase substantially the penalties and sanctions in case of violations.[47] Both the European Parliament[48] and the Economic and Social Committee[49] approved the Commission's proposal. The Council of Ministers adopted the new Directive 96/22 of 29 April 1996, which will replace Directive 88/146/EEC and the other relevant Directives as from 1 July 1997.

4.42 The **United States** argued that the European Communities had failed to comply with Article 2.2 which prohibited a Member from maintaining sanitary and phytosanitary measures "without sufficient scientific evidence". The proposal for a Council Directive submitted by the EC Commission on 13 June 1984 explicitly admitted that "on scientific grounds, it appears that the use of oestradiol-17ß, testosterone and progesterone, and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application, would not present any harmful effects to the health of the consumer nor harm the consumer by altering the characteristics of meat when used under the appropriate conditions as growth promoters in farm animals".[50] The United States added that there was absolutely no new scientific evidence considered by the Commission prior to the change in the proposed Directive to ban the use of these hormones.

---

[46] European Parliament, Committee on the Environment, Public Health and Consumer Protection, Report on "The USA's Refusal to comply with EC Legislation on Slaughterhouses and Hormones and the Consequences of this Refusal", EP 128 381/B, 7 February 1989, named after its reporter Mr. Collins, MEP. See para. 2.32.

[47] *EC Official Journal* C 302, 9 November 1993, p.8 and C 222, 10.8.1994, p.16.

[48] *EC Official Journal* C 128, 9 May 1994, p.105.

[49] *EC Official Journal* C 52, 19 February 1994, p.30.

[50] COM(84)295 final, clause 13 of the preamble, 29 June 1984, *Official Journal* C 170, p.4 seq.

Indeed, in response to the 1995 EC Scientific Conference Proceedings, EC Agriculture and Rural Affairs Commissioner Fischler had confirmed that these hormones did not pose a danger to health when used in beef production. However, rather than deciding to modify the ban to reflect the scientific evidence, Mr. Fischler had indicated that this was a political matter and had noted that a 10 million ECU advertising campaign extolling the virtues of eating hormone-free meat had been launched and that the EC Council would be pressed to introduce tougher monitoring measures. The United States concluded that, in the absence of any identifiable risk from these hormones and without any supporting scientific evidence for the ban, the EC measures were not "applied only to the extent necessary to protect human, animal or plant life or health" and were not "based on scientific principles", contrary to Article 2.2. Indeed, the EC approach was contrary to scientific principles.

4.43 The **European Communities** responded that Members were not obliged to demonstrate a scientifically confirmed adverse effect from a particular hazard before they might take measures. The SPS Agreement could not have been intended to operate in such a way that Members must wait until people were actually sick or dying before being allowed to take measures. For example, it had been recently reported that scientists only now had discovered the exact mechanism by which smoking could cause cancer. But governments all over the world had been taking measures to prevent or reduce smoking, even in the absence of such clear scientific evidence.[51] The European Communities added that the closest the SPS Agreement came to defining sufficient "scientific evidence" was in the footnote to Article 3.3. It followed from that definition ~~in~~ that scientific justification required an examination and evaluation of available scientific information, based on scientific principles. But at the end it was still the prerogative of the Member in question to decide whether the international standard, guideline or recommendation was sufficient to achieve its appropriate level of sanitary protection. The level of protection was decided by the Member alone and it was not a judgment that must be based on scientific principles or scientific evidence. Moreover, it was incorrect to state, as the United States did, that the choice of a measure was a purely scientific judgement. Measures must be based on scientific principles and not maintained without scientific evidence (conditions which the EC measures clearly meet) but these conditions could be met by a number of measures which could all achieve the same level of protection. If a Member was faced with choosing between several equally effective and scientifically justified measures, the SPS Agreement laid down other criteria, i.e. degree of trade-restrictiveness and technical and economic feasibility. This was the choice faced by the European Communities in the present case; either a ban on use for growth promotion or the imposition of strict veterinary controls. An assessment of trade-

[51] The European Communities noted that, for example, the GATT panel on Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes (1991) had accepted that "smoking constitutes a serious risk to human health" and, therefore, fell within the scope of Article XX:B of GATT 47.

restrictiveness and technical and economic feasibility clearly showed that a ban on the use of hormones for growth promotion was the only measure available to achieve its chosen level of protection.

4.44 The European Communities indicated that Mr. Fischler had been much more cautious on the possible risks to human and animal health arising from the nature and improper use of these hormones for animal growth promotion than suggested by the United States.

4.45 The European Communities claimed that the question was whether the scientific evidence on which the contested measures were based was "sufficient" in the sense of Article 2.2. The European Communities observed that the term "sufficient" was nowhere defined in the SPS Agreement and noted that it was generally agreed that "sufficient" could not mean other than the "minimal" level of scientific evidence required.[52] None of the publicly available scientific reports established beyond doubt that the use of these hormones in animal production was safe for human health. The European Communities also claimed that as regarded the three so-called "natural" hormones, all of the scientific reports suggested that they were *unlikely* to pose a hazard to human health *if* used in accordance with good veterinary or animal husbandry practice. The scientific evidence for the necessity to maintain its measure was the evidence from the 1995 EC Scientific Conference that there was still a lack of information on, for example, the mode of action, the effect of administering combinations and the effect of ingesting residues over a long period. For example, the United States, in the Statement of Administrative Action, had chosen the so-called Delaney Clause to explain the differences between the basic concepts of the *level* of protection that a government chooses and the *measure* that the government used to achieve that level of protection:

> "[T]he Delaney Clauses, in the first instance, establish a level of protection. They reflect a decision by the Congress that there should be no risk of cancer to humans from the substances those clauses cover .... A determination that a particular food additive poses a health risk is made on scientific grounds... Importantly, "risk assessment" as used in the SPS Agreement is *not* limited to *quantitative* risk assessment, which is a particular type of risk assessment used to evaluate the potential for carcinogenesis. The Delaney Clauses are entirely consistent with the Agreement's requirements in this regard. The determination that a particular substance poses a risk of cancer is a scientific determination, based on an evaluation of the potential for a substance to induce cancer. Based on scientific principles, the United States has determined that *if a substance induces cancer in animals, it poses some risk of*

[52] D.A. Wirth (1994) "The role of Science in the Uruguay Round and the NAFTA Trade Disciplines", 27 *Cornell International Law Journal*, 817-859, p.856.

> *human carcinogenesis*. And since the level of protection under Delaney requires that there be zero risk of carcinogenesis, the United States prohibit the substance" (pages 94-95).

4.46 The **United States** replied that conclusions of any scientific review could not be absolute because science was not absolute. Experimental results might either disprove or lend support to a particular hypothesis, but never prove it, and certainly would never prove it "beyond doubt". Yet the European Communities appeared to claim for itself the right to maintain their ban because scientific reports had not "established beyond doubt" that the use of these hormones for growth promotion was safe. Science could be used to determine whether there was a risk associated with the use of a particular substance; it could not eliminate the possibility that a potential risk might be found in the future. The SPS Agreement required a Member to base its measures on a risk assessment and prohibited a Member from maintaining SPS measures without sufficient scientific evidence. The Agreement did not provide that measures might be maintained without scientific evidence of a risk until such time as science proved "beyond doubt" that there was no risk. Moreover the United States noted that the lack of knowledge could not itself be the basis for taking a sanitary measure. The SPS Agreement required the European Communities to demonstrate scientific evidence of a particular risk. Scientists did not claim to know everything about everything. Scientific knowledge was always progressing and evolving. Accordingly, to claim that a Member was justified in banning an activity wherever there were still areas for science to explore would be to render the SPS Agreement meaningless - there were always areas for science to explore. Furthermore, in the US view, scientists knew more about the nature and mode of action of hormones than they did about most, if not all, other classes of compounds.

4.47 The **European Communities** claimed that there were three possible methods by which it could achieve its chosen level of protection: by the imposition of controls on hormone use to prevent misuse, by a ban on hormone use, and by a combination of controls and a ban. After a careful and extensive evaluation of the risks to human health and the technical and economic feasibility of each, the European Communities had chosen the third option, for the reasons explained in paragraphs 4.127 to 4.201. The European Communities also argued that the US claim that "it is important to distinguish between *having* a risk assessment and *basing* a measure on that risk assessment" revealed nothing. The European Communities based its measures on the risk assessment it conducted for that purpose. Neither the 1982 EC Expert Report nor the 1988 Lamming Committee Report, nor the 1988 JECFA Report constituted in themselves "risk assessment" in the sense of Articles 5.1 to 5.6 of the SPS Agreement; they only formed part of "available scientific evidence." The other factors mentioned in Article 5.2 and in paragraphs 3 to 6 thereof, were not dealt with by the scientific reports on which the United States was basing its claim. Indeed, the assessment of these factors was not a scientific question in the strict sense, and thus they fell within the responsibility of the appropriate political authorities of each Member.

4.48 The European Communities further argued that the United States had failed to appreciate the difference between the risk assessment required by the SPS Agreement when adopting *measures*, and the hazards against which members set a *level* of protection. Paragraphs 4.127 to 4.201 examined the hazards from hormones which were a source of risk to human health, irrespective of the way in which they were used. The European Communities was not obliged by the SPS Agreement to set different levels of protection against hormones used for growth promotion and hormones used for other purposes; on the contrary, one of the few requirements in the SPS Agreement in respect of the level of protection was that it be consistent (Article 5.5). The SPS Agreement imposed more, and stricter, disciplines on measures than it did on the level of protection. This was because measures were capable of being judged against objective universal criteria, while the level of protection was not. The choice of the level of protection might legitimately be influenced by factors such as political and financial priorities. As the United States had said in its Statement of Administrative Action, "it is a societal value judgment". However, once a level of protection had been decided, the measures used to achieve it could be analyzed scientifically. The European Communities claimed that the point was not that science did not know *everything* about hormones. The point was that it knew a lot, including the fact that they were carcinogenic. The problem was that science did know exactly how, and under what circumstances, this carcinogenic effect occurred. This was why the European Communities took a precautionary approach.

4.49 The **United States** indicated that in the United States, as in other countries, hormones were regulated as animal drugs when they were intended for use in animals for either therapeutic or production purposes. The use of hormones for growth promotion purposes had been approved by more than 20 countries, including the United States, Canada, Australia, New Zealand, Japan, Korea, the Philippines, South Africa, Mexico and most Latin American countries, and had been under intense scrutiny by scientists world-wide for over 15 years. The United States affirmed that no scientific review had ever concluded that there was a basis for banning the sale of animals to which one of these hormones had been administered in accordance with good animal husbandry practice or for banning the sale of meat from such animals. The reports which the European Communities had relied on, including the 1983 OIE Scientific Report and the 1988 JECFA report, as well as its internal reports, had all concluded that these hormones were safe when used for growth promotion purposes in accordance with good animal husbandry practice. The fact that the scientists, in their study of these hormones, had also reviewed the data on the effects of hormones at high doses or under other methods of administration did not constitute evidence that the approved uses for animal growth promotion purposes were unsafe. The United States contended that the issue was not whether any hormone was safe for all conceivable purposes at any conceivable level of concentration. The issue was whether the EC ban on the importation of animals, and meat derived from such animals, that had been administered the hormones in accordance with good animal husbandry practice, was supported by sufficient scientific evidence. The European Commu-

nities had offered absolutely no evidence that such use of these hormones presented any risk to human health. The United States noted that the experts advising the Panel had confirmed that there was no scientific evidence to support the EC ban.

4.50 The United States pointed out the Lamming Committee report for the three natural hormones had found that: "Thus *no questions of safety arise* in relation to the proper use of oestradiol-17β, progesterone and testosterone in an appropriate form of preparation" (emphasis added, page 7). In this regard, Part B of the Pimenta Report stated on page 6 that:

> "The present scientific evidence indicates that there is *no discernable health risk* in the use of the three endogenous hormones where these are, in particular, administered to castrated steers (whose hormone levels are therefore considerably lower than normal) and where they are administered in the form of slow-release implants in a part of the animal which is not consumed (e.g. the ear) and where a specific period with no further administration of hormones is observed before slaughter."

As indicated in paragraph 2.33, the scientific experts and other interested parties which the European Communities had called together for the 1995 EC Scientific Conference had concluded that there was no evidence of possible health risks from the use of the natural hormones for growth promoting purposes.

The 1995 EC Scientific Conference had furthermore concluded that:

> "At the doses needed for growth promotion, residue levels [of trenbolone and zeranol] are well below the levels regarded as safe (the MRLs). There are, at present, no indications of a possible human health risk from the low levels of covalently-bound residues of trenbolone."

The United States claimed that these conclusions were consistent with other scientific reviews of the hormones by scientists around the world, including the reviews conducted for the Codex Commission.

4.51 The United States observed that the concept of the "appropriate level of sanitary or phytosanitary protection" or "acceptable level of risk" was one of the key concepts of the SPS Agreement. The level of protection or risk related to the chance or probability of an adverse health effect resulting from a particular activity. For example, a level of protection or risk might be expressed as a risk of 1 in 1 million, meaning that out of every 1 million humans in the relevant population, one person could be expected to suffer the adverse health effect from engaging in a particular activity. The *appropriate* level of protection or *acceptable* level of risk was the maximum level of risk that was considered tolerable. The United States repeated that the choice of what level of protection was appropriate was a social value judgement, not a scientific determination. There was no scientific basis for choosing one level of protection over another. For example, science could not say whether a risk of one in one million of kidney failure from a particular activity was acceptable, or whether a risk of one in 1,000 or one in 10

million should be acceptable. The level of protection was the *goal* the Member sought to achieve in terms of health protection. Sanitary and phytosanitary measures were the *means* to achieve that goal.

4.52 The **European Communities** claimed that the terms "appropriate level of protection" and "acceptable level of risk" were alternative ways of expressing the concept but they were not synonymous. In the case in question, the European Communities had a level of protection but no acceptable level of risk, because it did not accept *any* level of residues of added hormones in meat. It rejected the US suggestion that level of protection equalled level of risk; in the EC view, *it did not*. The level of protection was *not* the "chance or probability" of an adverse effect. It was particularly incorrect to say that the appropriate level of protection was the maximum level of risk that was considered acceptable. The European Communities did not "accept" any risk from adding carcinogens to food for the sake of a little extra profit for farmers and drug companies. The European Communities was aware, of course, that despite its measures there might be occasions when such contaminated meat slipped through its detection system, but that did not alter the fact that its *objective*, in setting its level of protection, was to prevent *any* such residues. The "risk" (i.e. the "potential for adverse effects on human and animal health") from the use of hormones had been explained in detail by the European Communities, especially in paragraphs 4.127 to 4.201. The 1988 JECFA, on which the United States was arguably basing its contention, had also found that there was a potential risk to human health: if there were no such potential risk, the JECFA would have recommended no ADI and MRL for the two synthetic hormones. For the three natural hormones, JECFA had not recommend ADIs and MRLs because of problems in detecting the level of residues in meat. The European Communities further claimed that an ADI or an MRL recommended by Codex could never be considered to be a measure for the purposes of the SPS Agreement. Thus, science might help in setting a standard, guideline or recommendation (i.e. ADI or MRL) designed to exclude the probability that an individual would develop cancer after a lifetime of exposure to a particular chemical substance, or to limit that probability to no more than one chance in a million. The choice of where to set the probability, for example the one-in-a-million as opposed to one-in-a-thousand or zero chance, was one of public policy and belonged to the competent democratic authorities of the Members. The level of protection was subject *only* to Articles 5.4 and 5.5, not to the whole of Article 5. Contrary to the US view, the European Communities argued that a sanitary measure was not a measure to "limit the risk"; it was a measure to *protect* human or animal life or health, etc. In the case in question, the EC measure was aimed at *eliminating* the potential for adverse effects by preventing the occurrence of residues in meat.

4.53 The United States claimed that the EC reliance on its supposed appropriate level of protection as a justification for their ban was misplaced. First, the European Communities had never articulated what their appropriate level of protection was in respect of the six hormones. The requirement of "no residues", which the European Communities claimed to be its level of protection, was a

measure (essentially a measure that set a maximum residue limit, or "MRL", of zero) not a level of protection. Moreover, this was a measure which in fact was not maintained by the European Communities. The European Communities permitted residues of these hormones in meat. First, all meat had residues of the natural hormones ("residues" included amounts in the meat resulting from the animal's natural production of hormones). Second, the EC derogation for herd management and other purposes meant that meat would also have residues of *administered* hormones. The United States observed that the experts advising the Panel had confirmed that there was no scientific justification, where the concern was with residues of a substance, for only banning one use of the substance and not regulating residues. The United States argued that the EC statement that the aim of the EC Directives was to protect human and animal health by "seeking a level of protection which requires the presence of no residues in meat" suggested that the EC purported "level of protection" was really a way to justify their total ban. In the US view, aside from the fact that it was physically impossible to require the presence of no residues of hormones in meat, this was a case of the measure driving the level of protection, rather than, as it should be, the other way around.

4.54 The **United States** submitted that a level of protection with respect to animal drug residues in meat might be "no risk of cancer in humans". If that were the EC appropriate level of protection, then the European Communities could assess whether there were any risks presented by hormone residues in light of this level of protection. But that was not the EC appropriate level of protection. The European Communities studiously avoided naming a *level of protection* (naming instead the measure it had established), perhaps because naming a level of protection made clear that the EC ban was unjustified. Indeed, there was no scientific evidence that there was a risk of cancer to humans consuming meat from animals to which any of the six hormones had been administered for growth promotion purposes in accordance with good animal husbandry practice. Quite the opposite, there was scientific evidence that the levels of residue under discussion did not pose a risk of cancer in humans. In other words, there was *no* appropriate level of protection that would justify the EC ban. A "zero risk" level of protection was the most stringent level of protection possible. Since the banned animals and meat already achieved this level of protection, then the ban could not be justified on the basis of the EC appropriate level of protection.

4.55 The United States further argued that the EC own guidelines for the control of residues of oestradiol and testosterone were inconsistent with the EC position in this dispute.[53] For oestrogen, the EC guideline was 40 picograms ("pg")/ml (40 parts per trillion); for testosterone, it was 10 nanograms ("ng")/ml (10 parts per billion) in male cattle younger than 6 months and 30 ng/ml in males

[53] "Residues in food producing animals and their products; Reference materials and methods", Final Report, Directorate-General for Agriculture, Commission of the European Communities, 1992. Discussed at p.552 of the *1995 EC Scientific Conference Proceedings*.

6-18 months; in non-pregnant females it was 0.5 ng/ml (no guideline level had been set for progesterone.) Many animals that had not been administered any of the six hormones for growth promotion purposes violated the EC guidelines. For example, recent data were available to suggest that the very means of slaughter might cause increases in these hormones above these identified limits. At the same time, levels of hormones in animals to which any of the six hormones had been administered for growth promotion purposes fell below the guideline levels set by the European Communities. This was because, as had been confirmed by the experts advising the Panel, the residues in meat of the three natural hormones, when administered for growth promotion purposes in accordance with good animal husbandry practices, were within the normal physiological levels.

4.56 The United States noted that this was in part related to the fact that producers in EC member States raised bulls (non-castrated adult male cattle) to maximize the growth of animals, whereas in the United States steers (castrated adult male cattle) were predominantly raised and hormones were administered to obtain more efficient growth. Bulls naturally had far higher levels of hormones than steers, including steers to which hormones had been administered for growth promotion purposes. Similarly, in the European Communities there were quite a number of pregnant animals entering the normal slaughter process.[54] Like bulls, pregnant animals also had far higher than average levels of hormones. In other words, the agricultural practices in the European Communities, in light of the ban, resulted in consumers being routinely exposed to far higher levels of natural hormones in their meat of EC origin than meat of other origins. The selective EC ban was not justified even under their own professed approach. If one were to accept the EC claim that *any* residue of these hormones would pose a risk of cancer, then the European Communities would be required to prohibit the use of the hormones for herd management and other purposes. However, the European Communities permitted these uses. The United States further noted that meat could have residues identical to those of zeranol, even though zeranol had not been administered to the animal, if the animal had eaten feed contaminated with the common mould Fusarium.

4.57 The **European Communities** claimed that there was no obligation to follow scientific principles or to use risk assessment in setting the level of protection. As the United States had said in the Statement of Administrative Action: "The SPS Agreement thus explicitly affirms the right of each government to choose its levels of protection, including a "zero risk" level if it so chooses. A government may establish its levels of protection by any means available under its law, including by referendum." It was, of course, implicit that in order to need

[54] B. Hoffmann "Problems of Residues and Health Risks of Anabolic Agents with Sex Hormone-like Activities", *1995 EC Scientific Conference Proceedings*, p.284. Note also the conclusion on that same page that: "Thus, due to the lack of formation of extra residues, in principle *no risk* for public health can be seen following the presently recommend use of endogenous sex hormones as anabolic agents, at least in cattle".

a level of protection there must be some hazard against which a Member needed to protect. However, this only implied the *identification* of a hazard, not an assessment of the probability that it would cause damage. Many different kinds of biological, chemical or physical hazards might occur in foods, and governments had to decide to what degree they aimed to protect their populations from these hazards. These decisions were taken, as were any political decisions, in the light of a number of factors including the potential danger to health and the cost and feasibility of achieving effective protection. For example, in the case of a substance which was fatally poisonous, or which caused a very serious or fatal condition such as cancer, governments would generally set a very high level of protection, i.e. they aimed to avoid the presence of such a substance in food altogether. However, in the case of a lesser hazard, such as an organism which caused an uncomfortable, but transient and non life-threatening effect, governments might set a level of protection which aimed to minimize, but not necessarily eliminate, the presence of the organism in food. There would obviously be differences between governments in their approach to setting a level of protection, as a function of their economic priorities and cultural habits. For example, a developed country might consider it desirable to set a high level of protection against contamination of foods by waste material from the chemical industry, whereas a developing country might consider it a higher priority to encourage the establishment of a chemical industry rather than, for the present, worry about some chemical residues in food. This was particularly the case for countries where food *supply* was more of a problem than food *quality*. Similarly, cultural habits such as the eating of certain foods in a raw state might cause a government to set a higher level of protection against some pathogens than would be the case for a government whose population cooked the same food thoroughly before eating it. For economic and cultural reasons, the decision on where to set the level of protection was not a purely scientific one, and it was not one which could be subject to international rules, given the great diversity among the Members of the WTO.

4.58 The European Communities pointed out that, contrary to the US allegations, it had stated clearly, on several occasions, that it aimed to avoid the presence of residues of added hormones in meat. The reference to "zero risk" was misleading. The EC interpretation of "zero risk" in this context was that it was not prepared to accept *any* residues of added hormones for growth promotion.

4.59 The European Communities further clarified that it had argued that the Codex recommendation was a level of protection as opposed to a *measure*. However, it was by no means clear that the MRLs were "standards", as they were adopted under a heading of "Standards and related texts"; they could better be regarded as guidelines or recommendations. It was interesting that now the United States did not refer to Codex MRLs as "measures" in the sense of the SPS Agreement.

4.60 The European Communities noted that the divergencies in the regulatory approach of Members regarding the use of the hormones at issue demonstrated that countries viewed and appreciated differently the potential risks to human and

animal health resulting from the use of these hormones for growth promotion purposes. While the United States allowed the use of all six hormones, Canada allowed the use of all of these hormones except trenbolone[55]; Australia, New Zealand and South Africa allowed the use of all of these hormones except MGA[56]; Argentina allowed the use of zeranol and trenbolone, but not the other four hormones; and at least 25 meat-producing countries (other than the 15 EC member States) prohibited the use of these hormones for growth promotion.

4.61 The **United States** claimed that the issue in this dispute was the EC ban, not the measures of other Members. Differences among countries in the regulation of these hormones were not scientific evidence supporting the EC ban. As Australia and New Zealand had indicated, a hormone might not be registered due, for example, to a lack of interest associated with differences in production practices. Moreover, it could not be ruled out that the EC ban had influenced other countries to forgo approving the use of the hormones for growth promotion purposes in order to ensure access to the EC market for meat.

4.62 The **European Communities** replied that what was significant was that by virtue of the fact that they regulated hormones, all of these countries must consider that a risk existed. The differences in regulation reflected different opinions about the degree of risk. It was untrue that the EC rules had influenced other countries due to fears about a trade ban; there was not, and never had been, a ban on trade. It was entirely possible that other countries had carefully considered the scientific evidence and come to the same conclusion as the European Communities.

(b) Article 2.3 of the SPS Agreement

4.63 The **United States** recalled that Article 2.3 required Members to ensure that their sanitary and phytosanitary measures (a) did not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevailed, including between their own territory and that of other Members; and (b) were not be applied in a manner which would constitute a disguised restriction on international trade. The United States argued that the EC ban arbitrarily or unjustifiably discriminated between Members where identical or similar conditions prevailed and discriminated against imported animals and meat, both compared to domestic products and to products imported from other Members. The EC ban discriminated between Members that permitted the use of the hormones for growth promotion purposes and those that prohibited their use or permitted the use of the natural hormones for therapeutic purposes (including the European Communities itself); the question for purposes of Article 2.3 was whether the discrimination was justifiable. The United States argued that there were no rele-

[55] Canada corrected the EC claim that Canada does not permit the use of trenbolone (see Section V, para. 5.12).
[56] *1995 EC Scientific Conference Proceedings*, pp.597-598.

vant differences in the conditions prevailing in the United States compared to the European Communities or other supplying Members with respect to these animals or meat and that there was no scientific or other basis for the European Communities' discrimination against US meat and animals. The EC ban was designed, in part, to remove any competitive advantage arising from the use of the hormones at issue for growth promotion purposes and to thereby protect domestic production. As the European Court of Justice had judged, "the possibility of a reduction in surpluses was indeed taken into consideration during the process leading to the adoption of the Directive".[57] Furthermore, the EC Parliament, in calling for the European Communities to adopt its ban, had explicitly cited the fact that "there is overproduction of meat and meat products in the European Communities which adds considerably to the cost of the CAP".[58] In March 1989, the draft of the Pimenta Report had also made it clear that control of beef supply was one of the true motives for this Directive: "The Inquiry Committee believes that only a total ban on the use of growth-promoters is concordant with the strategic aims now adopted for the Common Agricultural Policy, in particular the reduction of surpluses and the safeguarding of a viable regionally-diversified farming community". Finally, Directive 88/146/EEC itself cited the desire to alter the conditions of competition in the meat sector.

4.64 The **European Communities** responded that European Court of Justice had pronounced itself twice on the aim of Directive 88/146/EEC. In the first case, the Court of Justice found that the aim of the Directive was to protect human health and consumer interests.[59] This objective was pursued with a view to improving the quality of meat through regulating the conditions for the production and marketing of meat. The United States had totally disregarded this part of the Court's judgment and cited selectively from the other judgment of the Court.[60] Furthermore, the Court ruling cited by the United States had concluded that "it does not follow that such a reduction, which is not cited in the preamble to the Directive as one of the objectives pursued, was in fact the exclusive or main purpose of the rules adopted". This made evident that the reduction in meat surpluses was no more than a possibility, and any Member was entitled to evaluate the side effects of an act it adopted for other purposes. Moreover, surpluses of meat had not existed in April 1996 when the European Communities had decided to maintain the prohibition by adopting Directive 96/22/EC. Furthermore, the evidence clearly showed that even the first EC Directive 85/649/EEC, which had

---

57 "The Queen v. The Minister for Agriculture, Fisheries and Food and the Secretary of State for Health" (Case C-331/88), Judgment of the Court at p.I-4065.

58 Resolution "closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council for a Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having an hormonal action and of any substances having a thyrostatic action," para. I. (Doc. A2-100/85, 11 November 1985, *EC Official Journal* No. C 288, p.158 *et seq.*).

59 Case 68/86, United Kingdom v. Council (1988) *EC Reports* p.855, p.897, para. 20.

60 Case 331/88, Fedesa and others (1990) *EC Reports* p.I-4023, p.4065.

been replaced by Directive 88/146/EEC, had not in fact contributed to reducing the small beef surpluses. Statistics showed that the European Communities had continued to produce domestically about the same quantities and had continued to import from third countries about the same quantities of meat as before the prohibition. The only difference, after the adoption of these Directives, was that the nature and composition of meat destined for human consumption in the European Communities changed (i.e. came from animals to which no hormones for growth promotion had been administered).

4.65 The European Communities also noted that there were several countries which did not allow the use of any or most of these hormones for animal growth promotion, but some of them did not impose any restrictions on imports of hormone-treated meat because they hardly imported any meat as their domestic production sufficed to cover demand. Argentina, for instance, which was a major beef producer, did not allow the use of the three natural hormones for growth promotion (because residues of these hormones could not easily be detected), but did not apply a prohibition on imports of animals or meat treated with these three hormones as there were virtually no imports taking place. In contrast, the European Communities had always imported large quantities of meat and had to adopt the measures in question in order to ensure that the objectives of its domestic sanitary policy were not circumvented through imports from third countries.

4.66 The European Communities argued that its measures offered equal opportunities of access to the EC market for all third-country animals and meat from animals to which no hormones had been administered for growth promotion purposes. Of the 31 countries which were authorized to export meat to the European Communities, only six apparently allowed the use of some or all of these hormones for growth promotion purposes. All of these 31 countries (including the United States) had continued to export to the European Communities animals and meat from animals to which no hormones had been administered for growth promotion purposes. Thus, overall the same competitive pressure as before was maintained from third-country imports on domestic meat production and US allegations to the contrary were unfounded. The intention of the EC measures at issue, therefore, was not to shield domestic meat production from foreign competition. The EC legislation did distinguish between countries which permitted the use of hormones for growth promotion and those which did not, but this was a justified distinction in view of the chosen EC level of protection. The argument that its measures were a disguised restriction on trade was unsubstantiated. The EC measure did not, therefore, contravene Article 2.3.

4.67 The **United States** noted that the European Communities admitted to distinguish between Members that permitted the use of the hormones for growth promotion and those that did not. The United States considered that the EC claim that this distinction could be justified by its chosen level of protection was unfounded. The European Communities had not demonstrated any scientific basis or other basis for the discrimination, and it was not justified by any health risks. None of the experts advising the Panel gave any response which would justify a determination that animals to which any of the six hormones had been adminis-

tered for growth promotion purposes, and meat from such animals, should be considered "unlike" other animals or meat. The European Communities had admitted that residues of hormones resulting from implants could be impossible to detect, and scientists had concluded that such residues were meaningless given the variation in different meat sources and the levels of hormone production in humans. Moreover, the European Communities had not demonstrated that its chosen level of protection was any different from that of any of the Members who had approved the use of these hormones for growth promotion. More importantly, the right of a Member to select its own appropriate level of protection was not a justification for a breach of its obligations under Article 2.3. The United States concluded that the European Communities had failed to show how its asserted defense was even relevant. This discrimination was consequently not justified by any health risks, it was arbitrary and unjustifiable. Accordingly, the United States concluded that the EC ban unjustifiably discriminated between Members where identical or similar conditions prevailed and was inconsistent with the obligations of the European Communities under the first sentence of Article 2.3.

4.68 Furthermore, the United States contended, the ban constituted a disguised restriction on international trade, in breach of Article 2.3, as demonstrated by the record which showed that economic reasons related to reduction of meat surpluses and to altering the conditions of competition in the EC market were an important purpose of the ban. Moreover, the EC Directives required the EC member States to permit widespread use of hormones for purely economic reasons connected with efficient herd management. The EC measures depended on drawing a distinction between, for instance, domestic beef from cattle injected with hormones for herd-management purposes and imported beef from cattle implanted with hormones for growth promotion purposes. In this connection the United States noted that the doses of hormones used for therapeutic and zootechnical purposes were equivalent to, or in some cases higher, than the average daily dose used for growth promotion purposes. The United States stated that if low level residues of the hormones caused adverse health affects, as claimed by the European Communities, then therapeutic and zootechnical uses should be banned as well. These facts confirmed that the hormone ban was not a valid health-based measure, but an economic measure, and a means of protecting EC producers against imports. The EC measures were designed to protect domestic production. In sum, since the EC measures were not applied only to the extent necessary to protect human life or health, were not based on scientific principles, were maintained without sufficient scientific evidence, were not based on an assessment of the risks, and were more trade-restrictive than required to achieve the appropriate level of protection, it was apparent that the measures were not legitimate sanitary measures. Instead, they were measures designed to protect domestic production in the guise of sanitary measures. That was the essence of a disguised restriction on international trade.

4.69 The **European Communities** responded that, although the EC legislation permitted the use of the three natural hormones for therapeutic or zootechnical

reasons, this was allowed under strict conditions. Thus, the three hormones might be administered, for therapeutic or zootechnical reasons, (i) only by a veterinarian, (ii) only by injection or vaginal spiral (to the exclusion of implantation), and (iii) only to farm animals which had been clearly identified. Furthermore, such treatments must be registered by the veterinarian and these animals could not be slaughtered for meat production before a waiting period long enough to ensure that no residues were present in their meat. The doses of these hormones required for therapeutic or zootechnical purposes were several times lower than the doses required for effective growth promotion. In the case of animals which were at the end of their reproductive career, such treatments were prohibited during the fattening period following the end of their breeding life. All these conditions ensured that the hormones were administered properly and that no residues of hormones, other than those naturally produced by the animals themselves, were present in the meat destined for human consumption.

4.70 The European Communities noted that the 1988 JECFA Report had also recognized that a clear distinction should be drawn between the use of hormones for therapeutic or zootechnical reasons and animal growth promotion, indicating that "... residues left after the use of a drug for growth promotion should be considered *separately* from residues left after the use of that drug for other purposes".[61]

4.71 The European Communities claimed that it was misleading to state that there was widespread use of hormones for therapeutic or zootechnical purposes in the European Communities. Although the European Communities did not possess the exact figure of the number of animals treated for these purposes, of those EC member States which kept records[62], it was estimated that only between 1 per cent and 2 per cent of breeding cattle in the European Communities were treated each year for such purposes. This percentage corresponded to about the same proportion of total bovine meat of EC origin consumed in the European Communities, to which once in their breeding life such treatments may have been administered. Regardless of the insignificant quantities involved, what needed to be underlined was that allowing the administration of the three natural hormones for therapeutic or zootechnical reasons was in full compliance with the EC policy of ensuring no residues of hormones in meat for human consumption since the strict conditions imposed by EC law effectively ensured its policy objective (no residues at all). Furthermore, the European Communities pointed out that meat from animals which had, at some time in their life, been treated with hormones for therapeutic or zootechnical reasons, under the strict conditions laid down in the EC law, might be marketed for human consumption in the European Communities. Equally, animals treated for therapeutic or zootechnical reasons and meat of such animals were allowed to be imported from third countries under guarantees

[61] *1988 JECFA Report*, p.16.
[62] E.g. Denmark, the Netherlands and Finland.

which were equivalent to those applied for domestic animals and meat from such animals. Therefore, this provision of EC law applied regardless of the country of origin of the animals or meat of such animals. The United States had not brought forward any evidence to show that animals and meat from animals treated in the United States for therapeutic or zootechnical purposes, if they complied with the conditions laid down in EC law, were not allowed to be imported into the European Communities. The European Communities further contended that "identical or similar conditions" did *not* prevail between the United States and the European Communities in respect of the use of hormones for growth promotion. Neither were the products similar or identical. A measure might be applied only to the extent *necessary* to protect life or health. If, for example, it could be demonstrated that pasteurizing milk at 72°C for 15 seconds was sufficient to kill tuberculosis, a Member would not be justified in requiring milk to be heated to a higher temperature for a longer time for the purpose of protecting against the same hazard. But in this case, the European Communities had demonstrated that if it had followed the US example in applying the Codex recommended MRLs in the way they were applied in the United States, it would have certainly failed to achieve its level of protection, which was no residues of these hormones in meat for human consumption and also to protect animal health, in view of the very limited number of tests carried out by the United States and the number of violations found even in this limited number of tested samples.

4.72 The **United States** noted that the EC claims that it had no solid information about the percentage of meat produced in the European Communities from animals to which hormones had been administered for herd management and other purposes was at odds with the European Communities' constant reference to the strict controls on such use and the need to identify every single animal to which hormones had been administered. Industry sources in the European Communities had indicated to the United States that 3.75 to 4 per cent of all cattle were treated each year based on an average of numbers in Belgium, France, Germany, the Netherlands and the United Kingdom. In addition, about 6 per cent of sheep in the European Communities were treated each year. In 1995, from one company alone, 2 million doses of hormones had been sold (for sheep) and ½ million doses were sold for cattle. Furthermore, the one guess that the European Communities offered was misleading. By stating that hormones were administered to 1 to 2 per cent of the EC herd each year, the European Communities failed to note that this figure should be multiplied by the number of years that the animals in the herd remained in production in order to determine the quantity of the meat supply from animals that, during their lifetime, had been administered these hormones. For example, if the hormones were administered to different animals each year, then over the course of 5 years, 5 to 10 per cent of the herd would have been administered these hormones. Alternatively, if the hormones were administered to the same animals, then an animal might have received five separate sets of treatment. Furthermore, there was no requirement that the hormones administered always be the same substances. Nothing prevented an animal in the European Communities from having been

exposed to multiple hormones (or in the EC's words, "combinations" or "cocktails" of hormones).

(c) Article 3.1 of the SPS Agreement

4.73 The **United States** claimed that, contrary to the requirements of Article 3.1 to base its sanitary measures on international standards, guidelines or recommendations where they exist, the EC ban was not based on the relevant international standards. The relevant international standards in this respect were those of the Codex Commission. The Codex standards for oestradiol-17β, progesterone and testosterone in foods of bovine origin stated that there was no need to set any Acceptable Daily Intake level (ADI) or any Maximum Residue Limit (MRL).

4.74 Codex had based its decision not to set ADIs and MRLs for these three hormones on the basis of the 1988 JECFA Report[63], which had found that residue levels in treated animals fell well within the normal range of levels found in untreated bovine animals of different types and ages. JECFA thus deemed it unnecessary to set an ADI for hormones that were produced endogenously in human beings and showed marked physiological variations in levels according to age and sex, and had concluded that residues arising from the use of oestradiol-17β, testosterone and progesterone for growth promotion purposes in accordance with good animal husbandry practice were unlikely to pose a hazard to human health. JECFA, in its assessment of the hormones, had defined what was meant by an MRL not specified. It meant that: "Available data on the identity and concentration of residues of the veterinary drug in animal tissues indicate a large margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the Committee has concluded that the presence of drug residues in the named animal product does not present a health concern and that there is no need to specify a numerical MRL".[64]

4.75 With respect to trenbolone and zeranol, the United States noted that the Codex standards specified both an ADI and an MRL. The Codex definition of an MRL was as follows:

> "... the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or μg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food.
>
> "It is based on the type and amount of residue considered to be without toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI

63 *1988 JECFA Report*, p.19.
64 Fortieth report of the Joint FAO/WHO Expert Committee on Food Additives, pp.5-6.

> that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects.
>
> "When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available."[65]

The Codex standard for trenbolone and zeranol was an MRL of 10 µg/kg of bovine liver and 2 µg/kg of bovine muscle.

4.76 The United States noted that as early as December 1987, the CCRVDF agreed on MRLs for trenbolone and zeranol, and agreed that no MRLs were necessary for the three endogenous hormones. At the June 1991 biennial meeting of the Codex Commission, four of the hormones (oestradiol, progesterone, testosterone, and zeranol) were at the end of the lengthy 8-stage approval process of which the decision by the CCRVDF was a key point. At that stage in the process, the science on a particular drug had been thoroughly reviewed, and Codex Commission members had been provided numerous chances to voice concerns about the scientific assessment of these hormones - either in writing to the Codex Commission secretariat or at CCRVDF plenary meetings. So, the United States contended, the scientific consensus on the four hormones was clear by the time they came before the Codex Commission. However, the issue continued to become politicized. The United States stressed that in 1994, the Codex Alimentarius Executive Committee (which includes a member from the European Communities) developed four principles clarifying, *inter alia*, that "[t]he food standards, guidelines and other recommendations of the Codex Alimentarius Commission shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply." Despite the EC opposition, these principles were adopted by the Codex Commission in June 1995. This paved the way for the Codex Commission to finally adopt standards for the five hormonal substances (by this time, trenbolone was also at the Step 8 of the Codex Commission procedures) recommended by the CCRVDF. Notwithstanding the adoption of the standards, the United States noted that the European Communities had maintained its ban and, in fact was expanding its ban for example by expanding it to new species.

4.77 The **European Communities** argued that at the time it had adopted and applied Directive 88/146/EC (1 January 1989), there existed no Codex standards on the hormones. Moreover, the Codex had never studied scientifically the hormone MGA and had never adopted any standard on its use. Furthermore, the European Communities argued that the Codex standards on the five hormones at

[65] Codex Alimentarius, Vol. 3, Residue of Veterinary Drugs in Foods, Rome 1993, pp.65-66.

issue had been adopted by a majority of only 33 votes in favour, 29 votes against and 7 abstentions (i.e. a minority of those participating), that was a very close vote in favour of the adoption of the standards. There were, therefore, at least 14 countries other than the 15 EC member States which had voted against the standard. This close vote clearly indicated that the issue of hormones had been, and continued to be, very controversial both from the scientific and the regulatory policy point of view. The European Communities argued that, despite the fact that the United States knew of the strong and wide opposition to the adoption of these recommendations on hormones for growth promotion purposes throughout the preparation of the Codex Commission's decision of July 1995, it had still insisted on and pressed, the issue for economic reasons, and despite the long established practice of the Codex Commission to adopt decisions on MRLs by consensus. In fact, the unusual procedure of voting by secret ballot had been requested in this case by the United States.[66] The European Communities argued that even today, no Codex member had notified Codex of its acceptance of the standards adopted in July 1995 on the hormones.[67] The United States itself seemed to support Codex standards, guidelines and recommendations on a very selective basis, only when they favoured their strict economic and trade interests.[68]

4.78 The European Communities added that Article 3.1 made it plainly clear that there was no absolute obligation on Members to always follow standards on SPS measures adopted by Codex. There was no doubt that the two systems of the Codex and the SPS Agreement did not interact properly, because a member of Codex, which had different views about other considerations (e.g. health concerns of consumers) and in good faith abstained from blocking the adoption of a Codex standard knowing in advance that in doing so it would not be required to follow the standard whose adoption it did not block, would later find itself to have an obligation to follow under the SPS Agreement. This was an inherent contradiction in the functioning of the two systems, of which both Codex and WTO Members were well aware and efforts were now being made to resolve it in an appropriate way.

4.79 The European Communities further observed that JECFA could not propose an ADI for natural hormones because when it had considered the matter, in the early and mid-1980s, the technology for measuring increases in levels of the natural hormones was not sufficiently advanced to be appropriate for routine use.

---

[66] Report of the 21st Session of the Codex Alimentarius Commission, Rome, 3-8 July 1995, Alinorm 95/37, paras 45-46.

[67] In the meantime, South Africa notified acceptance of the MRLs for veterinary drugs (Codex response to written questions raised by the Panel.).

[68] The European Communities noted that a Codex press release (Codex Facts, 05-95) had explained that "[t]he countries which voted in favour of the hormone MRL are primarily meat-producing/ exporting countries where the cost of production is either not subsidised or is subsidised to a lesser extent than in the EU. Production efficiencies, therefore, exercised a major influence on the Codex Commission. The animal health industry (commercial producers of the hormones) was also pleased with the Commission's decisions for obvious reasons".

Noting that the United States itself set limits for levels of the natural hormones in meat above those naturally present, but did not check annually for the presence of residues from these hormones, the European Communities further argued that the only "international standard, guideline or recommendation" relevant to the EC *measure* was the "Codex Code of Practice for Control of the Use of Veterinary Drugs". The MRL laid down by Codex was a *level* of protection, *not a measure*, and there was no obligation in the SPS Agreement to adopt Codex recommended levels of protection. The European Communities recalled its earlier arguments that neither the Panel nor any other Member, nor a Codex Alimentarius group of scientific experts, could judge the adequacy of the scientific evidence used by a Member. In view of the potential hazards to human health presented by the misuse of hormones in food animals, the European Communities considered that they should only be administered for the purposes and under the conditions defined in Directive 96/22/EC, which were in accordance with the "Codex Code of Practice for Control of the Use of Veterinary Drugs".

4.80 With respect to the synthetic hormones, the European Communities observed that JECFA (on whose scientific advice Codex had based its recommended MRLs) had established an ADI for zeranol of 0 - 0.5 µg/kg body weight, and for trenbolone of 0 - 0.02 µg/kg body weight. The European Communities was therefore justified, in respect of zeranol and trenbolone, in accepting the lower limit, *i.e. an ADI of zero*. Codex had made no recommendation for MGA. The European Communities argued that it was contrary to common logic to claim (as it was argued by the United States) that an MRL of 2 mg/kg of bovine meat for zeranol was a "measure" in the sense of the SPS Agreement. Scientists had defined the MRL as the quantity of a particular residue in meat that would not exceed the ADI for the particular substance concerned, if its administration was done in accordance with the required practice. The decision where to set the level, i.e. at 2 mg/kg or at 10 mg/kg of bovine meat, was a decision on the level of protection, not a "measure" as defined in Annex A of the SPS Agreement.[69] Moreover, the European Communities claimed that as there was no international standard relevant to its measure, there was no contravention of Article 3:1. Codex had not established standards for five of the hormones at issue; all it had done was to recommend maximum residue levels for the two synthetic hormones and decided that it was too difficult to do so for the three natural ones. Maximum residue levels were only of relevance to Members which accepted residues of these hormones in meat. The European Communities did not. Furthermore, as six of the scientists advising the European Communities had pointed out in their

[69] The definition of SPS measures in Annex A of the SPS Agreement specifies that "(...) [s]anitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including inter alia end product criteria; processes and production methods; inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety."

written opinions to the Panel[70], the JECFA Report on the basis of selected studies in laboratory animals had "concluded" that the carcinogenic effect of progesterone (and oestradiol and testosterone) was linked in some way to its hormonal effect, so that if it was present in a concentration insufficient to produce a hormonal effect in animals it would not be carcinogenic; they had then extrapolated this assumption to humans. But the JECFA Report had no scientific basis for making this assumption; contrary to their own stated intent (section 2.1.2 of the 1988 JECFA Report) they had not known (and a decade later it was still not well known) how these hormones produced their effects. Nevertheless, on the basis of these unjustified extrapolations and assumptions, and because detection was too difficult, they had "deemed" it unnecessary to set an ADI.

4.81 The **United States** claimed that the European Communities appeared to misunderstand Article 3 and confused a level of protection with a measure when it claimed that the MRLs established by Codex were a "level of protection" rather than a measure. The United States submitted that an MRL was a measure, not a level of protection. If a government wished to ensure, for example, that its public was not exposed to a risk of more than 1 in 10 million of nerve damage from lead in food, the government could establish an MRL to limit total exposure. However, the MRL was not the level of "protection", it was the maximum limit of residue. What level of protection it achieved would depend in large part on where the MRL was set. In other words, the level of protection determined where to set the MRL.

4.82 The United States rejected the EC argument that Article 3.1 did not apply to its ban because Codex did not have a standard for the use of these hormones, only for their residues. The United States argued that a requirement to base a measure on the relevant international standard included a requirement to base the form of the measure on the international standard. Otherwise, it would be easy to evade the requirements of Article 3.1 by deliberately adopting a measure different in form from the international standard. Under that approach, as soon as a Member had chosen to adopt a measure different from the international standard, there would no longer be any requirement to base its measure on the international standard. In other words, Article 3.1 would cease to apply as soon as a Member acted inconsistently with it. The United States added that to claim, as the European Communities did, that since the Codex ADI was a range from zero to 0.5 µg/kg body weight, setting an ADI of zero was "based on" the Codex standard,

[70] Dr. Liehr, Adlercreutz, Cavalieri, Letzler, Pinter and Epstein. The European Communities indicated that Dr. Liehr, for example, in his scientific advice on this issue had stated the following:

> *"In the 1988 JECFA Report, the authors considered only the hormonal receptor-mediated activities of the natural hormones. In view of the considerable amount of scientific evidence which has accumulated since the release of that Report, particularly in respect of the genotoxicity of oestradiol, the Report can no longer be considered applicable to a risk assessment of the use of hormone growth promoters."*

was a distortion of the international standard. The ADI was expressed as a range because it referred to the "acceptable" daily intake. In that regard, an intake of zero of these residues was acceptable, but it was not the Codex standard.

4.83 The **European Communities** responded that international standards, guidelines or recommendations were based on a certain concept of level of sanitary protection. The SPS Agreement explicitly allowed Members not to follow the international standards, guidelines or recommendations in order to achieve their appropriate level of protection. The objective of Article 3.1 was to harmonize, as far as possible, the sanitary or phytosanitary *measures* of Members, given that a different *level* of protection might require different types of measures. An ADI or MRL recommended by Codex could therefore, never be considered to be a measure, because measures were adopted by Members. Science might help in setting a standard or recommendation (i.e. ADI or MRL) designed to exclude the probability that an individual would develop cancer after a lifetime of exposure to a particular chemical substance, or to limit that probability to no more than one chance in a million. But the choice where to set the probability, for example one-in-a-million as opposed to one-in-a-thousand or zero chance, was a choice of public policy, and belonged to the competent democratic authorities of the Members. It was a goal of public policy, not of scientific nature. The EC policy in case of potentially carcinogenic substances like these hormones aimed to avoid exposing consumers to them. Therefore, the European Communities would not consider a level of protection of 1 in one million to be acceptable. That was why its level of protection in this case aimed at reducing that probability to zero.

4.84 The European Communities argued that the "appropriate level" a Member decided to apply in its territory did not have to be expressed in the same technical fashion, i.e. as an MRL. There were usually several ways of dealing with any given hazard, and the SPS Agreement did not require Members to change the type of measures they chose. For example, one of the many ways of tackling pathogenic organisms in food was irradiation, and some Members allowed it to be used for certain foods. Codex had adopted standards for irradiation of foods but this did not mean that every Member was now obliged to allow irradiation of foods. Similarly, if a Member chose a level of protection against a contaminant on the basis of an MRL, this did not mean that it should set its MRL at the level recommended by Codex. Also, if a Member chose not to allow any residues of dangerous substances in food, this did not mean that it was obliged to base its protection on the concept of an MRL recommended by Codex, if there existed one for that substance. One of the weaknesses of the SPS Agreement was that a measure in conformity with a Codex standard or recommendation was deemed to be consistent with Article 3.2. Unfortunately, many Codex standards were quite out of date, having been adopted decades before the development of sophisticated analytical methods.

(d) Article 3.3 of the SPS Agreement

4.85 The **European Communities** argued that Article 3.3 permitted Members to "... introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate ..." The Codex recommendations were designed to achieve a level of protection which was lower than that applied in the European Communities for the hormones at issue. Moreover, Codex and the other relevant international organisations mentioned in the SPS Agreement might issue standards, guidelines or recommendations, but they were relevant only for those Members which chose to follow them and base their measures on them. If a Member elected not to follow them because it had a different level of sanitary protection, the Member was entitled to take another type of measure necessary to achieve its chosen level of protection. In such a case the SPS Agreement only required the Member to respect the provisions of Articles 5.1 to 5.8 thereof.

4.86 The European Communities claimed that the "Codex Statements of Principle Concerning the Role of Science in the Codex Decision - Making Process and the Extent to which other Factors are taken into Account", approved on July 1995, explicitly recognized that other legitimate factors, relevant for the health protection of consumers, could be taken into account when elaborating and deciding food standards.[71] In addition, Members which had different views about other considerations (e.g. health concerns of consumers) could abstain from accepting the relevant standards. The SPS Agreement permitted departure from international standards for the same reasons for which Codex standards, guidelines or recommendations were voluntary and could not be made legally binding, i.e., because each Member was free to decide its appropriate level of sanitary or phytosanitary protection. This was not a scientific judgment and scientific com-

[71] Alinorm 95/37, Appendix 2. The *"Statements of Principle"* is an annex to the report of the 21st Session of the Codex Alimentarius Commission. The "*Statements of Principle*" provide:

> "1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
>
> "2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
>
> "3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
>
> "4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex."

mittees or expert groups could not replace the democratically elected authorities of Members.

4.87 The **United States** argued that the EC ban was not covered by the exceptions in Article 3.3 to the requirements of Article 3.1. The European Communities had not shown that its level of protection was different from that achieved by applying the Codex standards. In fact, the European Communities had not even identified its own level of sanitary protection. Noting that the SPS Agreement defined "appropriate level of sanitary or phytosanitary protection" as "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory", the United States submitted that "level of protection" referred to protection from a particular sanitary or phytosanitary *risk*. For the level of protection to form the basis for taking action, there must first be identified some activity which gave rise to the identified risk, and the activity must present a level of such risk higher than the level deemed acceptable by the Member.

4.88 The United States submitted that the level of protection did not refer to protection from foreign competition, nor did it refer to protection from a particular substance or activity *per se*, only from the *risk* associated with that activity. Thus, for example, a Member might deem a chance of 1 in 1 million to be the appropriate level of protection from the risk of the establishment of a particular plant pest, or 1 in 10 million to be the acceptable level of risk of harm to nerves from the ingestion of lead in food. In contrast, the *measures* taken to achieve that level could for example, in the case of the plant pest risk, involve quarantine to ensure the pest was not harboured on imported plants or plant material, or fumigation. In the case of the nerve damage risk, the *measures* could consist of a maximum residue limit for lead in foods, or a prohibition on the use of lead in ceramic glazes for food utensils such as pitchers or glasses. Finally, the United States agreed that the choice of the appropriate level of protection was a societal value judgment. The SPS Agreement imposed no requirement to establish a scientific basis for the chosen level of protection because the choice was not a scientific judgment.

4.89 The **European Communities** responded that the United States' arguments were contradictory. It followed from these arguments that for the United States, the concept of "measures" for the purpose of the SPS Agreement included quarantine, fumigation or prohibition on the use of a substance. In criticizing the EC formulation of "no residue at all", the United States had also admitted that this was also a measure, not a level of protection. However, the United States had also argued that an MRL was a measure. If an MRL was a measure, then what was a prohibition laid down in law on the use of hormones for growth promotion?

4.90 The European Communities noted that there were two exceptions provided in Article 3.3. The first exception was fulfilled when the international standard was inadequate, faulty or obsolete from a scientific point of view. According to the second exception, a Member was in any case entitled to introduce or

maintain measures which aimed at achieving its appropriate level of protection, to be determined in accordance with Article 5 of the SPS Agreement. The European Communities agreed that to invoke either of the options in Article 3.3, which were available to a Member when taking a sanitary or phytosanitary *measure*, there must exist "a potential risk for adverse effects". But the SPS Agreement left Members free to define *the level of probability* they wanted to assume: this might range "from zero to infinite" and it also left them free to decide the *type of measure* they might choose to ensure that the level of protection they considered to be appropriate was achieved. The European Communities further agreed that the choice of the appropriate level of protection was a social value judgement and that the SPS Agreement did not impose a requirement to establish a scientific basis for the chosen level.

4.91 The **United States** argued that both exceptions contained in Article 3.3 had the same effect, since both referred to a situation where the basis for departing from the relevant international standard was that the international standard was not sufficient to achieve the Member's appropriate level of protection. The concept of the appropriate level of protection interlaid a number of the provisions of the SPS Agreement. For example, Article 5.6 used the appropriate level of protection to determine if sanitary or phytosanitary measures were more trade-restrictive than required. Article 3.3 also used this concept in permitting a Member to introduce or maintain a sanitary or phytosanitary measure that was more stringent than the relevant international standard where the international standard would not be sufficient to achieve the Member's appropriate level of protection. In the US view, none of the different EC formulations for the purported level of protection was appropriate for purposes of the SPS Agreement. For example, on the one hand, the European Communities had stated that its appropriate level of protection was "the assurance that meat will not contain residues of administered hormones". Elsewhere the European Communities had stated that its level of protection was the "guarantee that EC consumers did not ingest residues of added hormones in meat". In yet another place, the European Communities had stated that its level of protection was "no residue at all".

4.92 The United States argued that the first formulation, "the assurance that meat will not contain residues of administered hormones" was *not* a level of protection from sanitary risk. Prohibiting certain residues was a *measure*, not a level of protection. This formulation said nothing about whether those residues posed a risk. In fact, the United States could only assume that it was a misstatement since the European Communities permitted hormones to be administered for herd management and other purposes. Nor did this formulation say anything about how any residues from administered hormones compared to other residues, such as residues of hormones that were naturally occurring in meat. The second formulation, "guarantee that EC consumers did not ingest residues of added hormones in meat", suffered from the same deficiencies and misstatement as the first formulation. The third formulation, "no residue at all" was also a measure, not a level of protection. The United States also assumed that this so-called "level of protection" applied only to the synthetic hormones since meat would always have resi-

dues of the naturally occurring hormones. In fact, the EC measure was not a requirement that there be no residue of these substances. The EC measure was a ban on the *use* of the substances for growth promotion irrespective of any residue.

4.93 The **European Communities** contended that it was obvious that the EC level of protection in this case was no residue of added hormones in meat. This level resulted from the provisions of the EC Directives which prohibited the administration to farm animals, by any means whatsoever, of "substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action"; or the slaughter or sale of any animal to which the above-mentioned substances had been administered, or of the meat or meat products from such animals. The aim of these provisions was to protect human and animal health by seeking a level of protection which required the presence of no residues in meat. In contrast, the level of protection of Codex was the recommended MRLs. The European Communities noted furthermore that its measure applied not only to the six hormones in dispute, but to all hormones, substances and combinations thereof which exerted the above-mentioned action on all farm animals (i.e. not only on beef cattle). Conversely, the MRLs recommended by Codex did not exclude, when followed by a Member, that thyrostatic, oestrogenic, androgenic and gestagenic actions could be exerted on farm animals. Moreover, the EC level of protection was concerned only with *added* hormones, over and above those which occurred naturally; the reference to natural levels was irrelevant to this case. Its rule were strict and avoided the presence of residues in animals treated for therapeutic or zootechnical purposes. So the fact was that the EC rules did not permit residues of added hormones at all.

4.94 The **United States** claimed that the EC ban was not designed to, nor did it, achieve any particular level of protection. Meat naturally had widely varying residues of the endogenous hormones, and many foods had levels of residues which were orders of magnitude greater than that found in the banned meat (as shown in the following tables).

Comparative androgen intakes

Food	Weight of portion (g)	Androgen intake (ng)
Unimplanted bull meat	500	1,560
Steer or female implanted w/ trenbolone[1]	500	135-150
Heifer implanted w/ testosterone	500	35

[1] Assuming 25 per cent fat, 75 per cent muscle
ng = nanograms

Comparative oestrogen intakes from food sources

Food	Weight of portion (g)	Oestrogen intake (ng)
Unimplanted steer meat[1]	500	61.1
Oestradiol-Implanted steer meat[1]	500	11.4
Zeranol-Implanted steer meat[3]	500	7*
Cow meat[1,2]	500	75 (7.2-540)*
Hen's egg	50-60	1,750*
Cabbage	100	2,400*
Peas	100	400*
Wheat germ	10	200*
Soybean oil	10 ml	20,000*
Milk	500 ml	75*

E.g. 1 egg equivalent in oestrogen content to 76.5 kg of implanted steer beef
1 Assuming 25 per cent fat, 75 per cent muscle
2 Oestrone only
3 Muscle tissue only
* Oestradiol equivalents
ng = nanograms

4.95 The United States noted that the European Communities permitted the sale and consumption of meat without regard to the levels of endogenous hormones; did not regulate exposure to hormones found in any other foods, and finally, permitted the sale and consumption of meat from animals that had received the natural hormones for purposes other than growth promotion. If the supposed health problem was exposure to residues of any of these hormones, then the European Communities should regulate dietary exposure to residues of the natural hormones. For the same reasons, the European Communities could not claim that its appropriate level of protection was "zero", since if "zero risk" was intended to refer to the five categories of risk identified by the European Communities (discussed in paragraph 4.126 below), then achieving zero risk was impossible. For example, two of the categories referred to by the European Communities were risks arising from detection and control (or more accurately arising from difficulty in detecting the presence, or controlling the use, of these hormones) and risks arising from the administration and use of hormones (or more accurately from incorrect administration or misuse of these hormones). In both cases the activity of concern to the European Communities was already illegal in the European Communities and with respect to exports to the European Communities. As a result, there was no reason to believe that lifting the ban would mean that there would be a risk that was not now already present. The United States stated that it would also be interested in the EC explanation of how it could guarantee that there was a zero probability that illegal activity would occur. The United States argued that history (including the history of the European Communities' own failure to prevent illegal use of hormones by EC producers) showed

that it was impossible to guarantee that there was a zero probability that illegal activity would occur.

4.96 The **European Communities** claimed that it did not insist on "zero risk"; it *aimed* to prevent *any* residues. The European Communities have never claimed to "guarantee" a "zero probability that illegal activity will not occur". There was always a possibility that any controls would be evaded but that did not mean that the controls should be abandoned. For example, there were measures in the United States which banned murder, and the sale of heroin, but apparently these measures were sometimes evaded. This did not mean that the measures should be dropped. The European Communities contended that the sixth preambular paragraph of the SPS Agreement made clear that it did not require Members to change their appropriate level of protection or to "downward" harmonize them to less stringent Codex sanitary and phytosanitary measures. Also Article 3.3 clearly indicated that a Member was *not* required to accept international standards that would result in a lower level of protection than the Member had determined to be appropriate. Under Article 3.2, if a sanitary or phytosanitary measure conformed to a relevant international standard, it was then *deemed* to be necessary to protect human health, and *presumed* to be consistent with the relevant provisions of the SPS Agreement and of GATT. However, as the USTR itself had stated: "... the fact that a sanitary or phytosanitary measure differs from a relevant international standard, guideline, or recommendation *does not, in itself, create any adverse presumption concerning that measure"*.[72]

4.97 The European Communities noted that the approach adopted by the SPS Agreement was in conformity with previous GATT law and practice, and was a sensible approach for the purpose of establishing multilateral rules and disciplines to guide the development and progressive harmonisation in order to minimize the negative effects on trade from national sanitary and phytosanitary measures. This approach was also in conformity with democratic regulatory procedures, where frequently a dichotomy was operated in the decision making process between *risk assessment*, which established strictly the scientific basis for regulatory action and *risk management* which was the process by which the competent authority of a Member decided what action to take in the face of the assessment submitted to it by the scientists. Such action was based on factors such as public health and environmental protection, relevant legislation and legal precedent, application of social, economic and political values and consumer concerns. The European Communities argued that the risk management phase, therefore, in a democratic legislative system, expressly recognized the importance of social value choices.

4.98 The European Communities argued that its interpretation of the disciplines the SPS Agreement imposed on Members was apparently also supported by the United States in the US Statement of Administrative Action, presenting to

[72] *US Statement of Administrative Action*, p.92.

the US Congress the results of the Uruguay Round for approval, which stated as follows:

> "The S&P Agreement thus explicitly affirms the right of each government to choose its levels of protection, *including a "zero risk" level if it so chooses. A government may establish its levels of protection by any means available under its law, including by referendum. In the end, the choice of the appropriate level of protection is a societal value judgement*. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific judgement"[73] (emphasis added).

In another public document also submitted by the USTR to Congress it was stated that:

> "... the requirement for a scientific basis applies to SPS *measures*; it does not apply to the *level of food safety* that those measures are designed to achieve. The SPS Agreement explicitly recognizes the right of governments to choose the level of food safety that they consider appropriate.
>
> "... Moreover, by requiring that a measure be based on scientific principles (rather than, for instance, requiring that a measure be based on the "best" science or on the "weight of evidence") the Agreement recognizes the fact that scientific certainty is rare and many scientific determinations require a judgement among differing scientific views. The SPS Agreement preserves the ability of governments to make such judgments."

4.99 The European Communities argued that the table of foods such as potatoes and Lima beans was irrelevant. In the first place, consumers had always been exposed to a certain amount of hormones, or hormone-like substances in their diet; humans evolved alongside them and could cope with them. This was not the case for *added* hormones. Secondly, the figures in the table were fictitious, in the sense that they were examples and might bear little or no relation to the situation where growth hormones were used in practice. Thirdly, plant substances were not identical to the animal hormones (see in this regard the statement of one of the

---

[73] *US Statement of Administrative Action*, point 3(b). The European Communities noted that this Statement used the example of the so-called "Delaney clause" to illustrate the point :

> *"The Delaney clauses are entirely consistent with the Agreement's requirement in this regard. The determination that a particular substance poses a risk of cancer is a scientific determination, based on an evaluation of the potential for a substance to induce cancer. Based on scientific principles, the United States has determined that if a substance induces cancer in animals, it poses some risk of human carcinogenesis. And since the level of protection under Delaney requires that there be zero risk of carcinogeneses, the United States prohibits the substance."* (point 9).

EC scientific experts, Dr. Liehr, in the transcripts of the meeting of 18 February 1997, paragraphs 757-758. The European Communities also claimed that the comparison which the United States cited in its table was incorrect because it compared meat from a treated *heifer* with meat from an untreated *bull*. The correct comparison (which had been omitted in the table) must be with an untreated *heifer* (not bull). This comparison could be found in the 1995 EC Scientific Conference Proceedings (page 278, table 3):

- meat from untreated bull - 1 560 ng;
- meat from untreated heifer - 8 ng;
- meat from treated heifer - 35 ng.

The human diet normally contained a variety of meat; evidently if all the meat came from treated animals the amount of hormone residue ingested would be significantly increased (more than fourfold on the above comparison). If a proper comparison were to be made involving male animals, it would have to be between treated and untreated males to see how much the levels of female hormones were increased in male animals. According to the US argument, heifer meat would be "within the normal range" if it contained as much testosterone as bull meat.

4.100 The **United States** insisted that the US Statement of Administrative Action (SAA) did not support the EC ban. The US position in this dispute was fully consistent with the SAA. The United States explained that the SAA was a communication between the President and the Congress of the United States describing the President's interpretation, and intentions with respect to the implementation, of the Uruguay Round Agreements. It was not a document that was applicable for purposes of the generally accepted rules of treaty interpretation embodied in Article 31 of the Vienna Convention on the Law of Treaties. For example, it was not part of the text of the Marrakesh Agreement Establishing the World Trade Organization ("WTO Agreement") nor was it an international agreement made in connection with the WTO Agreement. However, the SAA confirmed the understanding of the US negotiators that an SPS measure must be based on scientific principles, have a basis in science, be based on an assessment of the risks, and not be maintained without sufficient scientific evidence. But these obligations were clearly set forth in the SPS Agreement itself, which should be construed in accordance with the ordinary meaning to be given to the terms of that Agreement in their context and in the light of its object and purpose. The EC ban failed to meet any of these obligations, and nothing in the SAA relieved the European Communities of those obligations. In contrast, the SAA clearly reflected the US understanding that the SPS Agreement fundamentally required an examination of whether a measure was adopted with a basis in science and based on a risk assessment, rather than as a protectionist measure. The United States noted that this dispute would not have arisen if the European Communities had followed the SPS rules referred to in the SAA. The European Communities had not articulated its appropriate level of sanitary protection, nor had it based its ban on scientific grounds. In contrast, the SAA noted that the determination that a

particular substance "poses a health risk is made on scientific grounds". The United States consequently claimed that, for all these reasons, the EC ban was inconsistent with Article 3 (and Articles 2 and 5) of the SPS Agreement.

4.101 The **European Communities** responded that the Statement of Administrative Action itself explained that it "represents an authoritative expression by the Administration concerning its views regarding the interpretation and application of the Uruguay Round Agreements, both for purposes of US international obligations and domestic law", and that the "Administration will observe and apply the interpretations and commitments set out in it". When approved by the US House of Representatives, the SAA was said "to carry particular authority". The European Communities concluded that the SAA was a highly informative piece of evidence which indicated the way the SPS Agreement had be interpreted officially by the United States in *tempore non suspecto*. The European Communities did not contest that Article 3.3 required a scientific justification for the *measures* taken by a Member as a consequence of the level of protection it deemed appropriate. However, the footnote to Article 3.3 confirmed the prerogative which the SPS Agreement left to Members to make risk management decisions that reflected social value choices distinct from the strict scientific process of risk assessment.[74] The purpose of the footnote to Article 3.3 was to clarify what was meant by "scientific justification" in Article 3.3, not to define the justification for choosing a level of protection. The level of protection was decided by the Member alone and it was not a judgement that must be based on scientific principles or scientific evidence. The European Communities noted that the SPS Agreement specified that sanitary and phytosanitary measures must be "necessary for the protection of human, animal, or plant life or health", must be applied only to the extent necessary to protect human, animal or plant life or health", must not "arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail", must not "be applied in a manner which would constitute a disguised restriction on international trade", and must not be "more trade restrictive than required to achieve [a Member's] appropriate level of protection, taking into account technical and economic feasibility". The application of these requirements did *not* address the scientific underpinnings for a national regulatory requirement. Instead, these tests targeted the choice by national regulatory authorities among a variety of potential measures, as determined by such factors as impacts on international trade, discriminatory effect, economic efficiency and technical feasibility, and the relationship between the regulatory goal and the measure chosen.

[74] Footnote 2 to Article 3.3 reads as follows: "For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection".

4.102 The European Communities further argued that under Article 13, national governments were fully responsible for the observance of the Agreement by sub-national governments. However, nothing in the SPS Agreement required that state or local governments adopt, or comply with, *federal* sanitary or phytosanitary measures. The reasons for this were twofold. First, because it was quite possible that within a single Member with federal constitutional structure there could exist different levels of protection and different types of sanitary and phytosanitary measures. Second, the inability of the federal government of that Member and of the WTO dispute settlement panels to substitute their scientific judgment for that of the local government on the level of protection and the measures applied to achieve its chosen level of protection. The European Communities claimed that if such differences might exist within one single Member, it was obvious that such differences were also likely to exist between different Members with different perceptions of what constituted risk to public health.

4.103 The European Communities argued that the United States attacked not only the *level* of protection chosen by the European Communities, but also its measures, by insisting that residues of hormones above naturally present levels did not pose any risk to health and, therefore, did not warrant the application of any measures to control them other than the MRLs recommended by Codex. If this argument were to be accepted, then it would in the future be open to any country to oppose any health measure which was based on the precautionary principle. There were very few examples of health hazards where all scientists agreed on the degree of risk, and countries must be allowed to make judgments as to what degree of risk they were willing to accept. The European Communities argued, by way of example, that there was no scientific proof that bovine spongiform encephalopathy (BSE) was transmissible to humans; there was only a "likelihood" based on the appearance of a very small cluster of human cases in the only country with a high incidence of the disease in cattle. Nevertheless, the European Communities (and most other countries) had taken severely trade-restrictive measures to protect public health as a precaution, because if BSE were transmissible to humans the consequences would be devastating.

4.104 With regard to MGA, the European Communities noted that it was authorized for growth promotion only in the United States and Canada, but apparently nowhere else. Codex had never scientifically examined this hormone and had never recommended any standard. Still, the United States in essence argued that the European Communities should accept meat treated with MGA and check only for residue limits *as they were set by the United States*. This argument flew in the face of the SPS Agreement, which explicitly allowed the European Communities to adopt a *level* of protection which it deemed appropriate (in this case, no residue at all).

4.105 The European Communities insisted that the US position in this case contrasted sharply with the legal position of the United States when it had presented the SPS Agreement to Congress for approval, and was dictated by short-sighted economic interests (of maximum US$80 per animal), regardless of the danger to human and animal health posed by the use of these hormones for growth promo-

tion. All countries, including the United States, regulated the use of hormones in farm animals, and the difference between the European Communities and the United States in this respect was the extent to which their use was regulated. The European Communities concluded that this difference in degree of regulation was a reflection of the different levels of consumer protection adopted by the European Communities and the United States. The European Communities had taken a precautionary approach, placing the attainment of a high level of consumer protection before the commercial interests of farmers and pharmaceutical companies. Where there existed a doubt over the safety of a product, the European Communities gave the benefit of doubt to the consumer, especially in cases where the potential risks might affect very large parts of the population. The European Communities claimed that, in the case of growth hormones, the United States had taken an opposite approach, giving the benefit of doubt to the producer. It noted that a 1986 report on Human/Food Safety and Regulation of Animal Drugs, approved by the US House of Representatives, had concluded that "the Food and Drug Administration (FDA) has consistently disregarded its responsibility, because it has repeatedly put what it perceives are interests of veterinarians and the livestock industry ahead of its legal obligation to protect consumers thus jeopardizing the health and safety of customers of meat, milk and poultry".[75] These criticisms appeared equally valid in the present case.

4.106 The **United States** rejected the EC argument that because there was no guarantee that science would not one day identify a risk associated with residues resulting from the use of the six hormones for growth promotion purposes, the European Communities were justified to use a "precautionary approach" to ban such use. Speculation that some day there might be a risk identified, even if there was none now, was not a basis for banning something. If it were, then Members could ban anything. To invoke the precautionary principle, there still must be some scientific information indicating a risk, not just mere speculation, but the European Communities had produced no such scientific information with respect to their ban. On the other hand, to invoke the exception of Article 3.3, the European Communities was required to compare its level of protection against that afforded by a measure based on the Codex standard and show that its ban was a consequence of the EC level of protection being more stringent than the level achieved by use of the Codex standard.

4.107 The United States also stated that the final sentence of Article 3.3 provided, however, that even if Article 3.3 applied, the measure at issue might not be inconsistent with any other provision of the SPS Agreement. Thus, Article 3.3 was limited only to justifying a departure from international standards and did not justify a breach of any other obligation arising under the SPS Agreement. As a result, the fact that the EC ban was inconsistent with Articles 2 and 5 of the SPS Agreement meant that the EC ban was not justified under Article 3.3 even if the

[75] US Committee on Government Operations, 27th Report, 99th Congress, 31 December 1985.

European Communities could establish that the Codex standards would not achieve the EC appropriate level of sanitary protection.

4.108 The **European Communities** responded that a hazard (cancer) had been identified and a lack of scientific knowledge on the exact mechanisms by which it arose was not a sufficient excuse for failing to take strict measures to prevent it. Article 5.7 was not applicable to this case because EC measures were not based on insufficient knowledge and were not temporary. The European Communities *knew* about the hazard and had taken measures to prevent it. In fact, there was clear evidence, from IARC, JECFA and others, that these hormones were carcinogens. They posed a risk and the European Communities was therefore justified in acting. There was not enough scientific evidence to conclude that these hormones, particularly when used by farmers without any official control, did not pose a risk to human health. The European Communities added that international standards, guidelines or recommendations were based on a certain concept of level of sanitary protection. But a different level might require different type of measures. This was what the European Communities applied in the case of these hormones: to achieve its level of protection, the only reasonably available and less restrictive measure was to apply a prohibition on the use of these hormones for growth promotion. The Codex recommendations were designed to achieve a level of protection which was lower than that applied in the European Communities.

(e) Articles 5.1 and 5.2 of the SPS Agreement

4.109 The **United States** recalled that Article 5.1 reads as follows:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations".

The United States claimed that the central concept underlying the SPS Agreement was "risk". With limited exceptions not applicable to this dispute, a government must scientifically demonstrate the existence of an identified risk to the life or health of humans, animals or plants resulting from a specific activity before that government could impose or maintain a sanitary measure. While the SPS Agreement did not define "risk" as such, it defined "risk assessment" with respect to food safety as "the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs" (Annex A of the SPS Agreement). The United States concluded that, as a result, in the context of the present dispute "risk" consisted of the "potential for adverse effects on human health" arising from the presence in meat of residues resulting from the administration to animals of any of the six hormones for growth promotion purposes.

4.110 The United States claimed that the European Communities had never performed any risk assessment, or relied on any risk assessment, that could serve as a basis for its ban with respect to the six hormones. If there was no risk from a substance, then it could not be said that a sanitary or phytosanitary measure was necessary to protect against a risk posed by the substance. By definition, in order to be a legitimate "sanitary" measure, a measure must protect against one or more specified risks. The United States submitted that the remarkable characteristic of the public debate in the European Communities on these hormones was that the "risk" was usually described in terms of consumer anxieties rather than any observable adverse effect on human health. During the consultations, the European Communities had failed to identify any specific risk to human or animal life or health against which the ban was designed to protect. On two occasions, the European Communities had formed groups of scientists to examine the safety of the hormones (excluding MGA), but both the Lamming Group convened in 1982 and the 1995 EC Scientific Conference had concluded that these hormones were safe when used for growth promotion purposes in accordance with good animal husbandry practice. The United States submitted that the European Communities had failed to identify a risk assessment on which its ban was based and, while suggesting that a risk assessment (or risk assessments) had been performed by "scientific groups and/or conferences" or by "groups of experts established by the EC member States and the European Communities", they had failed to provide the time or place of any such risk assessment, the names of the scientists who had conducted the risk assessment, or the documentary evidence of the results. Furthermore, although the European Communities had argued before the Panel that there was new scientific evidence now available, the European Communities had not relied on any of the studies of the scientific experts whom it claimed had new or differing evidence when it introduced the ban in 1989, nor when it had promulgated its new Directives in 1996. Indeed, the European Communities had apparently not consulted any of those scientists until it was well into a WTO dispute settlement proceeding to review its ban. A risk assessment by the European Communities' own regulatory scientists had never been produced.

4.111 The United States claimed that the European Communities could not just assert that there was a risk associated with these six hormones when used for growth promotion and then prohibit their use. Article 5.1 required that a Member base a sanitary measure on an assessment of the risks to human or animal life or health. The European Communities had failed to produce anything resembling an assessment of the risks that would form the basis for its ban. The European Communities had in fact rejected every scientific review of the six hormones and had been unable to produce any scientific risk assessment of these hormones that it did accept. It was important to distinguish between *having* a risk assessment, and *basing a measure* on that risk assessment. This was not a situation in which there was no risk assessment. To the contrary, the European Communities certainly had risk assessments available for its use.

4.112 The United States noted that during the Article XXIII consultations, the European Communities had stated that the risk assessment on which it had based

its ban was the report of the 1995 EC Scientific Conference. Subsequently, the European Communities had indicated that the 1995 EC Scientific Conference "was not to perform for it a risk assessment, but to provide a public forum for discussion of the scientific aspects of the use of growth promoters", a statement which concurred with the US view of the Conference. In any case, the United States argued that the 1995 report failed to satisfy the requirements of Article 5.1 in at least two key ways: first, the 1995 EC Scientific Conference had found that the five hormones it reviewed were safe for use as growth-promoting hormones and that there was no basis for banning animals, or meat from animals, to which these hormones had been administered for growth promotion; and second, the 1995 EC Scientific Conference had not looked at all six hormones - it had not discussed MGA. Accordingly, it could not constitute a risk assessment for MGA. In fact, the 1995 EC Conference did not appear to have actually performed a risk assessment on any of the hormones; it simply "discussed the safety assessment" of the five hormones. The United States contended that in the case of the six hormones, since the European Communities had failed to establish through an assessment of the risks that there was in fact any identifiable risk posed by these hormones, there was no basis for the EC ban on the importation of animals to which had been administered these hormones or meat from those animals. The United States consequently claimed that the EC ban was not supported by an assessment of risk and was consequently inconsistent with Article 5.1.

4.113 The **European Communities** responded that Codex had not developed risk assessment techniques. In the absence of such international guidelines, each Member must apply its own methodology. That followed by the European Communities was, and had been throughout the consideration of the hormone issue, to obtain the best scientific information available, to have that information evaluated by technical experts and for the EC Commission to make a proposal based on an assessment of that scientific and technical advice. In assessing the advice and drawing up its proposals, the European Communities also took account of the factors set out in Article 5.2, including "relevant processes and production methods". Livestock production in the European Communities and in most of the countries which exported to the European Communities was characterized by large-scale intensive production in a free market. If producers were at liberty to administer hormone growth promoters at their own discretion there was a considerable risk that mistakes and misuse would occur. There was no guarantee that the correct products or doses would always be used or that animals would be injected or implanted in the correct site. There was also a risk that animals would be slaughtered for human consumption soon after treatment if, for example, the market price suddenly became favourable. Article 5.2 also required Members to take into account "relevant inspection, sampling and testing methods". Due to the scale of livestock production, it was not possible to carry out regular inspections of livestock holdings to check that universally available growth promoters were being used properly. Sampling and testing for these substances was extremely expensive and time-consuming and, in the case of substances analogous to endogenous natural hormones, it might be difficult to distinguish marginal cases of

misuse. Moreover, there was nothing in the text of the contested measures, the legislative history or in any other document to suggest that "consumer anxieties" was *the* purpose for which the measures were adopted, although it was likely that consumer concerns had been taken into consideration during the "risk management" phase, since consumer concerns on potential risks to human health resulting from the use of hormones were very high at that time (and they were even higher today). There was little question that consumer concerns about safety and other issues also influenced the US agencies' decisions, even where there was arguably little, if any, basis for those concerns.

4.114 The European Communities argued that it had considered a number of scientific reports and judgements regarding the potential risks from the hormones at issue. As previously indicated[76], this included:

(i) the 1982 Report of the Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the basis of the Report of the Scientific Group on Anabolic Agents in Animal Production (the Lamming Report);

(ii) the 1983 OIE Scientific Conference Report;

(iii) the 1988 JECFA Report;

(iv) the various works of relevant international institutions, such as the International Agency for Research on Cancer (IARC);

(v) the scientific works by individual scientists relevant to the issue of use of hormones in general and for animal growth in particular;

(vi) information on the use of these hormones for growth promotion available from other countries, when relevant.

For the adoption of Directives 81/602/EEC, 88/146/EEC and 92/22/EC, apart from the above scientific evidence, additional technical information had been taken into account. This information consisted mainly of the internal studies of the EC Commission, the reports of the European Parliament, the reports of the Economic and Social Committee and the deliberations of the Council of Ministers. For their deliberations, the Ministers were assisted by scientific groups and individual scientific experts, including experts from the relevant administrations of the EC member States. For the adoption of Directive 96/22 of 29 April 1996, the 1995 EC Scientific Conference Proceedings had also been taken into account.

4.115 The European Communities submitted that it had based its measures on the risk assessment it had conducted for that purpose. Neither the 1982 Lamming Report, nor the 1988 JECFA Report constituted in themselves "risk assessment" in the sense of Articles 5.1 to 5.6 of the SPS Agreement. They only formed part of "available scientific evidence." The other factors mentioned in Article 5.2, and in paragraphs 3 to 6 thereof, were not dealt with by those scientific reports on

[76] See paras. 4.28-4.29.

which the United States had based its claim. The assessment of these factors was not a scientific question in the strict sense, and thus they fell within the responsibility of the appropriate political authorities of each Member.

4.116 The European Communities further argued that the 1988 JECFA Report had found that there was a potential risk to human health because if there were no such potential risk, the JECFA would not have recommended any ADI and MRL for the two synthetic hormones. For the three natural hormones, JECFA had not recommended an ADI and MRL because of problems in detecting the level of residues in the meat on a routine basis. Moreover, the 1988 JECFA Report, apart from being deficient in several respects from the scientific point of view, had not performed a "risk assessment" in the sense of Article 5. All it had done was to "evaluate the safety of hormones used for growth promotion". This evaluation was not a proper risk assessment for the purposes of Article 5, since it dealt only with one of the elements required by Article 5.2, i.e. it formed part of the "available scientific evidence" but did not constitute the only relevant scientific evidence available. In addition, it did not take into account relevant process and production methods, relevant inspection, sampling and testing methods and relevant ecological and environmental conditions, as required by Article 5.2. Even if the European Communities was to assume that they did (quod non), still the European Communities considered that Article 3.3 explicitly permitted it to adopt a level of sanitary protection it determined to be appropriate in its territory. The European Communities added that it had explained in the scientific opinions which it had submitted to the Panel and in the meetings of 17 and 18 February several defects of the 1988 JECFA Report from the scientific point of view, in particular the so-called hormonal effect level at which these hormones considered to be carcinogenic, its failure to set ADI values for the three natural hormones and its incorrect figures cited for the daily production of oestradiol-17β for prepubertal boys. (See transcript of the meetings with scientific experts, paragraphs 315-318. See also paragraph 740 with regard to prepubertal boys).

4.117 The European Communities claimed that another point where the JECFA Report was deficient related to the question whether ADI (and consequently MRL) values could eve be fixed for the three natural hormones. The European Communities referred to an official letter which the European Communities received from the US Government in 1988, where it was stated that tolerance levels were set in the United States even for the three natural hormones, but meat would not be monitored for residues. The European Communities further claimed that as Dr. Lucier had argued on 18 February, ADIs could have been established in the 1987 JECFA Report. But they had not been established precisely because the scientific approach of JECFA was to examine only the hormonal effect levels of these hormones, because only at such levels were they supposed by JECFA scientists to be carcinogenic. But this line of argument had been shown to be incorrect or at least there was a substantial part of the scientific community which did not agree with this view (see also paragraphs 469-479 of the transcript of the 17 February meetings with scientific experts) The European Communities added that in this case the quantification of the risk was said by Dr. Lucier, one of the

scientific experts advising the Panel, to range between 0 and 1 per one million. This was the minimum risk from the use of these hormones *in accordance with good veterinary practice*. The European Communities argued that this risk would certainly be higher if good veterinary practice was not respected, and would be even much higher if synergistic and long-term exposure risks were taken into account. (See the statement of Dr. Lucier in this regard in paragraph 742 of the transcript of the 18 February meetings with scientific experts. See also the opinion of Dr. Epstein, a scientist advising the European Communities, in the case of prepubertal boys in paragraph 214. As regards the quantification of the risk of cancer, the European Communities also drew the attention of the Panel to the opinion of the Panel expert, Dr. Lucier, reflected in paragraphs 6.110 and 6.111, as well as to the opinion of Dr. Liehr, an EC scientist, in paragraph 330 of the 17 February meeting with the scientific experts.

4.118 The European Communities noted in this regard that scientists had said that "the ADI-model is not a risk model and does not predict the risk of the occurrence of adverse effects, when ADI-values are exceeded".[77] The same was basically true for the MRL-model, "which specifies the quantity of a particular residue in meat that, even in dietary extremes, would not exceed the ADI for the particular substance concerned".[78] The European Communities concluded that the MRL was based on the notion that there was a risk, but if the proposed threshold was observed the *probability* of the adverse effect arising from the use of hormones would not materialize. In this case, the JECFA recommended standards which would achieve "a level of protection" against the risk. But the SPS Agreement allowed Members to determine *another* level, i.e. the level *they* deemed appropriate. This level might be higher or lower. The European Communities argued that all the above scientific data, reports, papers, conferences and other relevant information constituted a body of scientific evidence which was carefully considered by the competent EC institutions and the EC member States.

4.119 The European Communities claimed that there were substantial differences in the arguments not only between the European Communities and the United States and Canada, but also in the arguments between Canada and the United States. Canada had argued on 19 February that the European Communities did not have any of the scientific evidence presented to the panel by the scientists advising the European Communities in this case, when it decided to perform a risk assessment. Canada said that the European Communities had discovered this scientific evidence some weeks earlier, searching for an ex post facto justification of the measures it had taken before. The European Communities claimed that this argument of Canada was not correct and did not corroborate with what the United States had said, because as the

[77] H.A. Kuiper, "Risk Assessment Strategies for Xenobiotics", *1995 EC Scientific Conference Proceedings*, p.375.
[78] "Report and Conclusions", *1995 EC Scientific Conference Proceedings*, p.4.

United States had explained that the views of Dr. Liehr were already mentioned twice in the 1988 JECFA report (footnotes 34 and 35). Dr. Liehr was also mentioned in the 1995 EC Scientific Conference Proceedings (e.g., at page 386). The views of Dr. Liehr were therefore known to the European Communities before, and were not discovered some weeks earlier as Canada had argued. The work of almost all of the scientists that provided advice to the European Communities in these disputes were aware to the responsible EC authorities, such as the work of Dr. Epstein and Dr. Hertz who were mentioned in the book of Orville Schell of 1985, Dr. Liehr was already mentioned in the 1988 JECFA Report and in the 1995 EC Conference, Dr. Metzler who has been doing research in this area since a long time and Dr. Adlercreutz.

4.120 The European Communities said that the reason why the United States had never requested Codex to set a "standard" *for MGA* was that MGA was possibly even more dangerous than the other five hormones. The European Communities noted that the United States applied a so-called "safety factor" of 200, instead of the usual 100, and argued that, apart from its carcinogenicity, MGA exerted a more powerful progestagenic effect than progesterone. Its principal use was in fattening heifers which were kept under abnormally intensive conditions and could injure themselves or their inexperienced handlers when they came into oestrus and start mounting each other. MGA, although not a very effective growth promoter, was very effective at suppressing oestrus and was added to the feed mainly for this purpose. Although it had a withdrawal period, there was a strong incentive on the handlers not to observe it since the heifers would start coming into oestrus before going to slaughter. It was, therefore, probable that meat from heifers regularly contained significant residues of this powerful sex hormone. The European Communities also claimed that as regarded oestrogens, progestins and combinations thereof (i.e. mainly oestradiol-17β, progesterone and MGA), the 1987 IARC Report explained that "Steroid hormones are essential for the growth, differentiation and function of many tissues in both animals and humans. It has been established by animal experimentation that modification of the hormonal environment by surgical removal of endocrine glands, by pregnancy or by exogenous administration of steroids can increase or decrease the spontaneous occurrence *of tumours or the induction of tumours by applied carcinogenic agents .... The incidence of tumours in humans could be altered by exposure to various exogenous hormones, singly or in combination*" (emphasis added). The European Communities further claimed that the United States was offering a solution to safeguard against the potential risk to human health from the use of these hormones for growth promotion which the European Communities had considered carefully and rejected, because it did not meet its appropriate level of protection. It stressed that the hormone MGA was authorized for growth promotion only in United States and Canada, but apparently nowhere else. Codex had never scientifically examined this hormone and had never recommended any standard. Still, the United States in essence argued that the European Communities should accept meat treated with MGA and check only for residue limits *as they were set by the United States*. The Euro-

pean Communities submitted that this argument contradicted the SPS Agreement, which explicitly allowed the European Communities to adopt a *level* of protection which it deemed appropriate (no residue at all).

4.121 The European Communities argued that the Lamming Committee had not considered itself competent to make recommendations to the European Commission on the conditions under which these hormones could be allowed to be used for growth promotion purposes. This showed that the Lamming Committee could not be considered competent to perform a risk assessment for the European Communities in the sense of Article 5, because risk assessment could only be performed by the governments of Members. The Lamming Committee had not provided anything other than scientific advice, which the responsible EC institutions had used as *part* of the available scientific evidence in their risk assessment. The European Communities further argued that the US claim that the European Communities stated during the consultations that it based its "ban" on the 1995 EC Scientific Conference was clearly wrong. As the purpose of the 1995 EC Scientific Conference was not to perform for it a risk assessment, but to provide a public forum for discussion of the scientific aspects of the use of growth promoters, the reference to Article 5.1 and related comments were irrelevant as well as inaccurate.

4.122 The **United States** claimed that the Codex risk assessment and other scientific reviews stood in sharp contrast to the EC purported risk assessment. Yet the European Communities took the curious position that the Codex and other scientific reviews were not "risk assessments" for purposes of the SPS Agreement because they did not "constitute the only relevant scientific evidence available". The United States argued that, first, under the SPS Agreement, a risk assessment was to "take into account" available scientific evidence (Article 5.2); it was not supposed to "constitute" scientific evidence. Second, the European Communities suggested that Codex had not taken into account all the elements listed in Article 5.2, without explaining why elements which were omitted would be relevant to the risk assessment. Yet the elements listed by the European Communities were taken into account by Codex, as reflected in the Codex definition of an MRL. The United States observed that the experts advising the Panel confirmed that there was no scientific basis for the EC refusal to use the Codex standards as a basis for the EC measures. Third, under Article 3.2, measures that conformed to Codex standards were presumed to be consistent with the relevant provisions of the SPS Agreement. This would include Articles 5.1 and 5.2, so that the Codex risk assessment might be presumed under the SPS Agreement to be consistent with those Articles. Fourth, the EC approach was to selectively misquote parts of various risk assessments while ignoring the conclusions of those risk assessments as well as those portions and the scientific evidence that did not support its ban. The European Communities did not explain how this approach of selectively ignoring the scientific evidence could be considered to take into account the relevant scientific evidence. Furthermore, the European Communities could not establish that the Codex standards would not achieve the EC appropriate level of sanitary protection. The European Communities had suggested that it had

adopted "zero risk" as the appropriate level of protection, and this "zero risk" level would justify its measures under Article 3.3. The United States submitted that an "appropriate level of sanitary protection" was a level of protection *from a risk* and that the European Communities had not identified any particular risk from these hormones, which were all safe.

4.123 The **European Communities** claimed that it was not required to accept only the two scientific reports which the United States contended had carried out a proper risk assessment, i.e. the Lamming Report and the Codex assessment. These were just two reports of a certain scientific orientation, but there were other scientific reports by individual scientists, scientific conferences, (e.g. the 1995 EC Scientific Conference) and responsible international institutions (eg. IARC) which did not entirely agree with them. Some of the scientific reports on which the European Communities had based its measures questioned the very basic scientific assumptions on which the reports supported by the United States were founded, including the carcinogenic effects of these hormones when used for animal growth promotion. The EC scientific evidence was therefore constituted by the scientific studies which concluded that these hormones could be carcinogenic irrespective of the dose administered because they may alone or in combination be "genotoxic" (i.e. act directly on the genome to cause cancer). The European Communities added that this was exactly what some scientists had feared for the hormone DES. It had warned the US authorities at an early stage, but those authorities had failed to pay attention in time.[79] Moreover, the sanitary policy of the European Communities on these hormones for animal growth promotion purposes was exactly the policy pursued by the United States under the so-called Delaney Clause for dangerous food additives.

4.124 The European Communities noted that the "Delaney Clause" was the most notable example of the adoption by the United States of a zero-risk policy. Enacted in 1958 in the context of public fear over the growing incidence of cancer, the Delaney Clause provided that "no additive shall be deemed to be safe if it found to induce cancer when ingested by man or animal."[80] *The Delaney Clause*

[79] The European Communities explained that Diethylstilboestrol (DES) was a synthetic hormone which improved both rate of gain and feed efficiency in poultry, cattle and sheep. DES was perhaps the most widely known of oestrogenic growth promoting agents. It was first used in the US therapeutically in pregnant women in the 1940's to prevent abortion. The US Government approved its use as a feed additive for poultry in 1947, for cattle in 1954 and later for sheep. In 1971, its carcinogenic effects in humans and in laboratory animals was clearly established. Additional studies showed that DES had other effects on daughters and sons of mothers treated with it, the most common being vaginal adenosis and other gross abnormalities of the reproductive tract. At the time (1976) these studies were published, an estimated 25 million cattle and 7 million sheep were being treated with DES. Still, its complete withdrawal from the US market was achieved only in 1978, while in the meantime the US FDA was trying to discover and fix acceptable "no residue" limits.

[80] 21 U.S.C. § 348(c)(3)(A). The European Communities noted that the Delaney Clause also applied to colour additives (U.S.C. § 379e(b)(5)(B)) and compounds administered to food-producing animals (21 U.S.C. § 360b(d)(1)(I)). On 3 August 1996, new legislation had been enacted which changed US regulation of pesticides and encouraged international harmonization of pesticide toler-

required that all carcinogenic food additives be banned, regardless of their degree of risk or offsetting benefits. The Delaney Clause had become an increasing burden to regulatory agencies since its passage in 1958. The scientific methods available then did not have the sensitivity of today's technology, which could detect minimal carcinogenic effects or minimal "migration" of substances from packaging materials to food. The Delaney Clause therefore banned chemicals with insignificant carcinogenic properties, without permitting agencies to conduct the usual risk/benefit analysis employed when considering approval of new substances. The United States had - with only modest exceptions - an inflexible, *zero tolerance policy for carcinogenic substances* added to the food supply. No matter what its concomitant benefits, a substance having a possible carcinogenic effect could not be approved as a food additive.

4.125 The European Communities argued that none of the scientific reports the United States had cited had concluded in favour of an unqualified use of these hormones for animal growth promotion. All these reports had concluded that all these hormones individually were potentially dangerous to human and animal health in general as well as when used for growth promotion purposes and that all these hormones individually were not likely to pose risks to human or animal health only if used in accordance with good agricultural/animal husbandry/veterinary practice. Moreover, the 1982 Lamming Report and the 1988 JECFA Report had not examined the potential risks arising from these hormones when used in combination with other hormones, and had not explained what constituted good agricultural/animal husbandry practice.

4.126 The European Communities contended that available scientific evidence showed the use of the natural and synthetic hormones subject to this dispute could be dangerous to human and animal health. The potential danger resulted from (i) their nature and mode of action; (ii) the action of their metabolites; (iii) combinations of hormones and multiple exposure; (iv) problems linked to their detection and control; and (v) problems linked to their administration. In submitting its supporting arguments, the European Communities indicated that it focused on the potential risks to human beings, but that this did not imply that there were no risks for animal health.

(i) Nature and Mode of Action of the Hormones

4.127 The **European Communities** claimed that even though the precise mode of action of the hormones at issue had only been partly understood, all scientists agreed that these hormones were dangerous. The principle sex hormone in men, testosterone, contributed to acne, baldness, prostatic disease, coronary heart disease and peptic ulceration. Oestrogens, and to a lesser extent progesterone, ex-

---

ances (Food Quality Protection Act of 1996, Pub. L. No 104-170). This new legislation did not affect food additives other than pesticides residues. Thus, the Delaney Clause still governed the regulation by FDA of food additives and compounds administered to food-producing animals.

posed women to premenstrual tension, dysmenorrhoea, some disorders of the reproductive system and an increased tendency to develop gallstones. More importantly, these hormones also played a major role in the development of tumours in sex-hormone dependent tissues (for example prostatic cancer, breast cancer, cancer of the uterus and neoplastic liver disease).

4.128 The European Communities noted that the carcinogenic risks from these hormones was well known. For instance, in the 1983 OIE Scientific Report a scientist had concluded that "although it is unlikely that the small amounts of anabolic steroids which might be ingested in agricultural produce could (cause cancer), this possibility should not be ignored entirely". Moreover, the same 1983 OIE Scientific Report stated that: "... However, as pointed out by Williams, the initiation-promotion concept does not adequately explain all carcinogenic mechanisms. Therefore, it is not possible to state with any certainty that anabolic steroids act *only as promoters in induction of cancers in other hormone dependent tissues such as prostate, uterus and breast, although present evidence suggests that levels of endogenous steroids are probably not sufficient to initiate carcinogenesis in those tissues"* (emphasis added).

4.129 The European Communities further noted that the carcinogenic effects of hormones on humans (and animals) had been documented by several reports of the International Agency for Research on Cancer (IARC). IARC had classified steroidal oestrogens (including oestradiol) in Group 1, meaning the agent *was* carcinogenic to humans; androgenic (anabolic) steroids (including testosterone) in Group 2.A, agents *probably* carcinogenic to humans and progestins in Group 2.B or agents possibly carcinogenic to humans.[81] A 1987 IARC Report indicated that, in the case of androgens:

> "The fact that castration palliates prostatic cancers suggests that testosterone may be involved *in the genesis* of these tumours, and a number of epidemiological observations suggest that increased testosterone levels may increase the risk for prostatic cancer" (page 96). ... The *evidence* that anabolic steroids can *cause* both benign and malignant liver tumours *is quite strong*. However, because no analytical epidemiological study has been done, the Working Group felt constrained to classify the evidence for carcinogenicity in humans as no more than "limited" (page 97).

The European Communities noted that, according to the same IARC Report, in the case of oestrogens, however, the evidence was clear:

> "A number of studies, utilizing a variety of designs, have shown *a consistent, strongly positive association between exposure to a number of oestrogenic substances and risk of endometrial cancer*,

[81] *IARC Monographs*, Supplement 7, pp.31, 96 and 280 (1987).

> with evidence of positive dose-response relationships both for strength of medication and duration of use" (page 280).

The European Communities added that in a recent article published in the review Science[82], the author argued that oestrogen's (natural hormone) mode of action may be different from what it was thought to be until now:

> "... while it is still too early to tell just how many alternate paths there are, other recent results are further undermining the idea that there is a single main pathway for oestrogen action."

4.130 The European Communities asserted that the scientific assumption that, despite their carcinogenic potential, these hormones were not likely to cause problems to human health was based on the assumption that "the carcinogenic effect of these hormones is related to the hormonal activity of these compounds, i.e. an increase in tumour incidence in tissues of animals with high levels of specific hormone receptors, which would not occur at normal physiological levels".[83] But scientists could not define what those "normal physiological levels" were since they varied widely from animal to animal, and for that reason these hormones were considered by some scientists to be "promoters rather that primary inducers of cancer in hormonally sensitive tissues".[84] According to the European Communities, it was on this assumption that was also based the 1988 JECFA Report, on which Codex had based its recommendations. With regard to oestradiol-17β, the 1988 JECFA Report stated that "[t]he results of studies ... [showed that] .... [o]ral and parenteral administration of oestradiol -17ß can increase the incidence of tumours in experimental animals. These tumours largely occur in tissues with high levels of specific hormone receptors that are normally responsive to stimulation by the particular hormone concerned. The Committee concluded that the carcinogenic response was related to the hormonal activity of oestradiol-17ß at levels considerably higher than those required for a physiological response" (page 18).[85]

4.131 The European Communities argued that the general scientific assumption was that these substances were not "genotoxic"[86], but exerted only "epigenetic"

---

[82] *Science* Vol. 273, 30 August 1996.

[83] H.A. Kuiper, "Risk Assessment Strategies for Xenobiotics", *1995 EC Scientific Conference Proceedings*, pp.370-371.

[84] H.A. Miller, J.K. Leighton, "Risk Assessment Strategies for Hormones and Hormone-like Substances", *1995 EC Scientific Conference Proceedings*, p.386, and *1983 OIE Scientific Report*, p.339 sqq.

[85] The European Communities noted that the same assumptions were made in the *1988 JECFA Report* for progesterone (p.20), testosterone (p.22), trenbolone acetate (p.24), and zeranol (p.27).

[86] "Genotoxic carcinogens" were defined by the European Communities as "chemicals whose mode of action is mediated by a series of molecular events, initiated by direct interaction of the compound or activated reactive intermediate species with cellular DNA eventually leading to uncontrolled cell replication and formation of tumours". The European Communities added that the concepts of NOEL (no observed effect level) and ADI (acceptable daily intake), on which for instance was based the 1988 JECFA report, were not applicable to such genotoxic agents Recently (1990),

action. But this was an assumption which had not yet been clearly proved. Scientists had agreed that "further development of metabolic studies is required, particularly with regard to exogenous anabolic agents (synthetic hormones). Such advanced studies would lead to a better understanding of their mechanism of action and any toxic effects".[87] The European Communities also claimed that the distinction between agents which acted as tumour initiators and those considered as tumour promoters was over-simplistic. This distinction permitted some scientists to make some predictions by extrapolating tumour incidence observed in test animals at high exposure levels to potential human exposure to low levels of such hormones. However, other scientists had agreed that "these models do not indicate a true risk but provide a calculated risk for the occurrence of the (carcinogenic) effect. The relevance of these models is questionable since the biological basis for high to low dose extrapolation is lacking".[88] The European Communities submitted that it was on this disputed extrapolation, based on the no hormonal effect level, that JECFA had based its 1988 Report and Codex its July 1995 recommendations. The example of DES illustrated the danger of such an approach (see paragraph 4.123, footnote 79).

4.132 The **United States** rejected the EC claim that "all scientists agree that the six hormones are dangerous" and submitted that instead, hormones used for growth promotion purposes were not inherently safe or dangerous, but protection of public safety depended upon the dose of the compound, its toxicity and the manner of human exposure. Under the conditions of use in the United States, these hormones were safe when used for growth promotion purposes. The safety of the hormones as growth promotants was confirmed by the fact that they had been registered for use in more than 20 countries (including the largest meat-producing countries). These countries had strong food safety laws. The 1983 OIE Scientific Report had reviewed trenbolone and zeranol and had also come to the conclusion that these hormones were safe when used for growth promotion. The 1983 OIE Scientific Report had concluded that:

> "1. Hormones generally pose no cancer risk where exposure is to levels below those required for detectable hormonal activity.
>
> "2. Mutagenicity and carcinogenicity test data for trenbolone and zeranol suggest that these agents and their metabolites are neither mutagenic nor clastogenic and that they would only influ-

---

oestrogen induction of DNA adduct formation had been described (*1995 EC Scientific Conference Proceedings*, Kuiper, p.373, Miller and Leighton, p.386, with a reference to a study by J.G. Liehr, "Genotoxic Effects of Oestrogens", 1990). "Epigenetic" agents were believed not to induce gene mutations but to operate via other mechanisms like cytotoxicity, cell proliferation, peroxisome proliferation or hormone disbalance, and interference with hormone production. These effects were considered as dose-dependent for which a threshold level (NOEL) might be established (*ibid*, Kuiper, p.374). Once a NOEL had been set up, then an ADI level or MRL (maximum residue limit) was usually established.

87 *1983 OIE Scientific Report*, pp.263-269.

88 *1995 EC Scientific Conference Proceedings*, p.373.

> ence cancer risk - either increase it or decrease it - if there was exposure to hormonally effective levels.
>
> "3. Therefore, in judging whether it is safe to use trenbolone or zeranol as anabolic agents in meat production the emphasis needs to be on making sure that any residue of these agents in meat are below the levels that could have any hormonal effect on the meat-eater. ..."[89]

4.133 Furthermore, the United States noted that the IARC work had been reviewed by JECFA.[90] IARC's work did not support the EC argument because IARC had not looked to see if there would be a risk at the low levels of residues involved in this dispute. The IARC had specifically stated that "[t]he operating principle is to determine the ability of the chemical to produce cancer or other genetic and related effects *without the strictures of mode of human use or the magnitude of the doses"*[91] (emphasis added). The IARC work involved looking at much higher doses, and different modes of administration, than those involved in the use of hormones in livestock for growth promotion purposes. The United States explained that for these six hormones, one could not extrapolate from high doses to low doses. In scientific terms, this was referred to as high-to-low dose or linear extrapolation, and it was not a general principle of toxicology or pharmacology but was instead one model used to explain experimental observations. This model was also used in some approaches to risk assessment. An alternative approach to explain scientific data would be to use a threshold model. Under a threshold model some minimal amount of a compound was necessary before any response occurred. These were not contradictory models; experimental data for some compounds were better explained by linear extrapolation whereas data for other compounds, including the hormones involved in this dispute, could be better explained using a threshold approach. The threshold approach implied that a no-effect level could be determined through scientific studies, an approach that had been determined to be valid for the implant hormones used for growth promotion by the Lamming's Committee[92] and the 1995 EC Scientific Conference.[93] MGA had not been not examined in those reports, but the US Food and Drug Administration had conducted scientific reviews of MGA and had determined that the threshold approach applied to MGA as well.

4.134 The **European Communities** noted that the IARC tests were not necessarily only at high doses. IARC did not differentiate between the effects of the substance at high doses versus low doses. With regard to oestrogens, progestins and combinations thereof (i.e. mainly oestradiol-17β, progesterone and MGA), the 1987 IARC Report explained that:

---

89 F.J.C. Roe, "Anabolics in Animal Production", Symposium held at OIE, February 1983, p.339.
90 *1988 JECFA Report*, pp.17, 20 and 21.
91 *IARC Monographs*, Supplement 7, p.272.
92 *Veterinary Record*, 24 October 1987, pp.389-392.
93 Assessment of Health Risk Working Group II, pp.19-21.

> "It has been established by animal experimentation that modification of the hormonal environment by surgical removal of endocrine glands, by pregnancy or by exogenous administration of steroids can increase or decrease the spontaneous *occurrence of tumours or the induction of tumours by applied carcinogenic agents... The incidence of tumours in humans could be altered by exposure to various exogenous hormones, singly or in combination*.
>
> "These statements make explicit the facts that oestrogens and progestins occur naturally, and that the hormonal milieu and dose-effect relationships are generally inextricably involved in the carcinogenic effects of oestrogens and progestins.
>
> ...
>
> *"Thus, there is a basic incongruity between the human data and the animal carcinogenicity data. As noted earlier, however, the effects of these chemicals in humans appear, at least in most cases, to be linked to the hormonal milieu"* (emphasis added).

It followed that the findings of the IARC reports aimed at establishing the carcinogenic or other effects of these substances irrespective of the modes of human use and the magnitude of the doses. Furthermore, the phrase "at least in most cases" did not mean in "all cases" and under all conditions.

4.135 The European Communities argued that the US statement that the threshold approach implied a "no-effect" level deliberately concealed the fact that in respect of the hormones under discussion the scientific groups to which the United States referred looked *only* for a "no *hormonal* effect" level. They did not look for a "no *toxic* effect" level; the JECFA report stated that no toxicological monograph was prepared for any of the hormones which they considered. The "rationale" for this approach was that any toxic effects in humans, including cancer, would be linked to the hormonal effects in laboratory animals; without the latter the former would not occur. However, this was a mere guess. There was no scientific justification for such an assumption. Noting that the United States had banned DES *without* requiring such a link, the European Communities concluded that if the hormones exerted their carcinogenic effects by acting directly on the genome, there was no "safe" level. The evidence for this was increasingly strong, particularly in the case of oestradiol.

4.136 The **United States** contended that an international scientific consensus had evolved on the safety and efficacy of the natural hormones (oestradiol, progesterone and testosterone) and their mimics (zeranol, MGA and trenbolone) for use as growth promoting agents in bovine animals when used according to good veterinary practice. The United States recalled that after imposing the ban, the European Communities had twice convened groups of scientific experts to review the use of these hormones (except MGA) and that on both occasions the European Communities' own chosen scientific experts had concluded that it was safe to use these hormones for growth promotion purposes (as reflected in the Lamming Report and in the 1995 EC Scientific Conference proceedings). Moreover,

Codex had reviewed these hormones, with the exception of MGA for which JECFA had never been requested to perform a safety assessment, and had concluded that they were safe to promote growth in cattle. Codex standards had been adopted[94] after an extensive review of the relevant science including studies on biological activity, carcinogenicity, embryo toxicity, and mutagenicity; use patterns; residues in animals; analytical methodology; toxicological data from laboratory animal experiments; and observations in humans. The Codex process had afforded the opportunity for input by scientists around the world.

4.137 The United States added that after thorough review, the US Food and Drug Administration (FDA) had also approved oestradiol, progesterone, testosterone, trenbolone and zeranol for use as ear implants to promote growth in cattle and, in addition, FDA had approved MGA for use as a feed additive for increased weight gain, improved feed efficiency and suppression of oestrus. Oestradiol, progesterone, and testosterone had been approved in the 1950's, zeranol had been approved in 1969, trenbolone in 1987, and MGA in 1968. In the case of the three synthetic hormones, the FDA review had included a standard battery of toxicology tests including studies designed to assess each compound's toxicity, carcinogenicity, mutagenicity and any reproductive effects. FDA had also required special studies designed to examine the hormonal action of the compound.[95]

4.138 The United States claimed that oestradiol, progesterone and testosterone occurred naturally in all mammals and that the amount produced daily varied widely among species and among animals of the same species, and was influenced by factors such as age and breed. Furthermore, endogenous hormonal substances were also found in a variety of non-meat foods that formed a part of the normal human diet. Over 300 species of plants that were used for food were recognized as having oestrogenic substances, including soybeans, cherries, apples, green beans, alfalfa, palms and licorice. Moreover, these hormones occurred at much higher levels in some of these other foods. For example, a hen's egg had a higher concentration of oestradiol equivalents than meat from an implant-treated steer. The relative concentration in an egg was more than one thousand times higher than that in the steer, and the total amount ingested by consuming a hen's egg, even considering the difference in quantity consumed, was slightly greater than 600 times that from consuming meat from an implant-treated steer.[96] Many

---

[94] ALINORM 91/31 APPENDIX IV, as adopted by the 21st Session of the Codex Alimentarius Commission.

[95] The United States submitted an explanation of the FDA review of these hormones as well as a table providing details on the approved uses of these hormones in the United States.

[96] J. Riboleau (1983), "Teneur en substances oestrogènes de l'oeuf vierge et l'oeuf faconde des pietaux". Compt. Redn. Sco. Biol, 129-914; V.C. Craknell, and F.L. Mauld "Anabolic Agents in Animal Production" (unpublished Lilly Research Ltd.); J.B. *et al*. Tarr (1984), "Pharmaceutical metabolic and tissue residue studies of 3H-Zeranol in cattle" (unpublished).

fruits, vegetables, grains and nuts contained substantial quantities of phytoestrogens.[97]

4.139 The **European Communities** argued that consumers had always been exposed to a certain amount of hormones, or hormone-like substances in their diet; they had evolved alongside them and could cope with them. This was not the case for *added* hormones. Furthermore, the plant substances referred to by the United States were not identical to the animal hormones.

4.140 The **United States** further observed that wide variations occurred in the production of oestradiol, progesterone and testosterone in humans and at amounts considerably greater than the amounts of these hormones in meat from treated animals. While human production of oestradiol, progesterone and testosterone was measured in micrograms per day, ingestion of these hormones was measured in nanograms or picograms (one thousand to one million times less, respectively, than a microgram). Thus, ingestion of residues of oestradiol, progesterone and testosterone in meat was very small when compared to those amounts produced by humans, whether or not the meat was from an animal to which hormones had been administered. These amounts were so small that they did not have any effects on humans. In addition, the residues of the natural hormones had very low biological activity when ingested because more than 90 per cent of the residues (including metabolites of the three natural hormones) passed through an individual and were rapidly excreted. Thus over 90 per cent of the residues were not absorbed, so they could not have any effect on the consumer. Finally, the United States submitted that any residues of the natural hormones in meat from animals to which one of these hormones had been administered could not be distinguished from the residues resulting from the endogenous production of these hormones.

4.141 The **European Communities** argued that the various assessments or reviews undertaken by groups of scientists, conferences, etc. were not a risk assessment in the terms of Article 5. Article 5 required *Members* to ensure that their measures were based on a risk assessment. It did not provide for them to delegate this responsibility to scientific groups. Article 5.2 specifically required *Members* to "take into account available scientific evidence" as one of a number of factors. It did not say that Members should adopt without question the conclusions of whatever scientific group had happened to pass an opinion on the subject. No democratic system of government could abdicate its responsibilities to technicians in this manner. Moreover, the conclusion of *all* scientific experts did *not support an unqualified and free use* of these hormones for growth promotion, as

[97] K. and R. Vertual, D.S. (1990), "Naturally Occurring Oestrogens in Plant Foodstuffs-A Review". *Journal of Food Production*, Vol. 43, pp.577.581; A.N. Booth, S.M. Tithoff, and C.M. Hehier, (1960), "Oestrogen-like Activity in Vegetable Oils and Milk By-products",. *Science*, Vol. 131, p.1807; E.L. Monk, R.E. Erf, and T.A. Mellest (1975), "Relationships between Immunoreactive Oestrone and Oestradiol in Milk, Blood and Urine of Dairy Cows", *Journal of Dairy Science*, Vol. 44, pp.34-40.

was the practice in the United States. They all concluded cautiously that, under the present state of scientific knowledge, the use of the five hormones for growth promotion *was not likely* to pose risks to human or animal health, *if used in accordance with good agricultural husbandry (veterinary)* practice.

4.142 The European Communities contended that the United States apparently sided (as had done the 1988 JECFA report and the Codex) with those scientists who believed that these hormones caused cancer due to their hormonal activity and that, therefore, they were promoters rather than inducers of cancer in hormonally sensitive tissues. But this was the belief of just one part of the scientific community. In the absence of clear evidence to the contrary, the European Communities considered that it was entitled to follow a cautious approach and sided with the other body of scientists who placed more attention on the carcinogenic risks arising from the possible "genotoxic"[98] action of these hormones, irrespective of the dose in which they were administered to animals for growth promotion. This choice was in compliance with the proper definition of the concepts of "risk" and "risk assessment" which the SPS Agreement had explicitly established in Articles 5.1 to 5.6 and in Annex A(4). In this respect, the European Communities referred to a number of scientific opinions.

4.143 The European Communities observed, for example, that Dr. Liehr argued that "oestrogens have been implicated for some time in the induction of human cancers, and there is increasing evidence of a similar role for progesterone and testosterone".[99] In particular, Dr. Liehr had stated:

> "In the case of oestradiol, experiments have shown that its hormonal potency is *not* linked to its carcinogenic activity. Investigations of the metabolic pathways of oestradiol have revealed that free radicals are continuously produced, and DNA damage by these free radicals, as well as DNA adduct formation, has been demonstrated in a range of tissues. As damage to DNA and DNA adduct formation are known to be associated with tumour formation, these experiments provide strong evidence that oestradiol is a genotoxic carcinogen. In the case of progesterone and testosterone, it is not clear whether their carcinogenic effects are mediated by their action on specific receptors in target tissues or due to mutagenic DNA damage.
>
> "In the present state of knowledge, it is very difficult and in any case not advisable to determine a safe threshold dose of hormone below which tumour formation will not occur. Hormone-associated tumours in the breast, uterus or prostate may be induced by a combination of exogenous and endogenous hormones and/or their me-

[98] J.G. Liehr (1990), "Genotoxic effects of oestrogens"; and the *1995 EC Scientific Conference Proceedings*, p.386.
[99] J. Liehr, "Potential genotoxicity of Hormones", 23 December 1996.

> tabolites. As the total amount of hormone or metabolite necessary for tumour induction is not known, the amount of exogenous hormone or metabolite necessary for tumour induction in addition to unknown amounts of endogenous hormone or metabolite has not yet been determined. In the 1988 JECFA report, the authors considered only the hormonal receptor-mediated activities of the natural hormones. In view of the considerable amount of scientific evidence which has accumulated since the release of that Report, particularly in respect of the genotoxicity of oestradiol, the Report can no longer be considered applicable to a risk assessment of the use of hormone growth promoters."[100]

4.144 In addition the European Communities argued that Dr. Adlercreutz indicated that:

> "... the 1987 JECFA report must now be regarded as too old. The main problem with this report is that it relates any negative effects of hormonal drugs to their hormonal effects, i.e. if a compound occurs in amounts not giving clear "hormonal" responses it is regarded as safe. The anabolic steroid trenbolone has both anabolic and oestrogenic effects and it is not clear which effects are considered. It is frequently used in combination with oestradiol and also with zeranol, which are oestrogenic. Furthermore, testosterone and trenbolone seem also to affect the glucocorticoid receptor and testosterone increases growth hormone and growth factor concentrations and both affect steroid biosynthesis. Many other hormonal effects of the five compounds dealt with are known. When studying hormonal effects only gross effects are considered, but nowadays it is obvious that effects may occur at the cellular level at low concentrations of hormones and without being observable by the relatively coarse methods used in toxicology in vivo studies. Such effects may be observable in human subjects first after many years or even longer time. Another problem is that the JECFA report does not deal with or discusses very little the carcinogenicity of metabolites of hormones, particularly those of oestrogens. At the time when the 1987 JECFA Report was written very little was known about the genotoxic effects particularly of estrogen metabolites. Since the report was written it has also been more and more obvious that hormones have nongenomic effects not related to their hormonal effect via the receptors and that steroid hormone metabolites may be as important or even more important with regard to various effects on biochemical or genotoxic events than the parent compound.

[100] J. Liehr, "Potential genotoxicity of Hormones", 23 December 1996.

> "All these hormones have been shown to cause cancer in various experimental systems if given in high amounts but it is obvious that the effect is not always due to their hormonal activity. For oestrogens and trenbolone it has been shown that also other mechanisms occur and the mechanisms by which the other hormones cause cancer is far from clear.
>
> (...)
>
> "Anabolic steroids in meat has been shown to result in positive doping tests. A compound giving positive doping tests cannot be administered for meat production because these may result in lifetime problems for any sportsman or sportswomen who is caught with a positive doping test without having used any doping agents.
>
> "The 1987 JECFA report is definitely too old and does not take into account recent scientific evidence changing our view on the carcinogenicity of oestrogens and does not take into account non-hormonal and other negative effects of the administration of steroids to animals intended for human consumption".[101]

4.145 The European Communities also presented the argument of Dr. Cavalieri that:

> "... the presently available knowledge about tumour induction in hormone-responsive tissues suggests a specific pathway of oestrogen metabolism, namely 4-hydroxylation followed by oxidation to E-3, 4-Q and reaction DNA. This DNA damage is responsible for generating the critical mutations that can lead to tumour formation, if the appropriate mechanisms of promotion occur. Therefore, oestrogens, in particular oestradiol, have genotoxic effects and no threshold dose can be established. In addition, the effects of the other natural and synthetic hormones used for meat production on the metabolism of oestrogens are not known. Thus, Acceptable Daily Intakes and Maximum Acceptable Levels cannot be established for residues of these hormones in meat for human consumption.
>
> "The 1988 and 1990 FAO/Codex Alimentarius expert group reports recommended ADIs and MRLs for these hormones based on their hormonal effects. Genotoxic effects were unknown at that time and, thus, were not considered. In light of the new knowledge about the genotoxic effects of oestrogens, the entire subject of

[101] H. Adlercreutz, "Evaluation of the Thirty-Second Report of the Joint FAO/WHO Expert Committee on Food Additives, and Discussion of Dr. J. Liehr's Report on this Topic", 7 January 1997.

these residues in meat for human consumption must be reassessed."[102]

4.146 Furthermore, the European Communities argued that Dr. Metzler reported that the available data show that:

> "17β-oestradiol, 17β-trenbolone and zeranol can be metabolically activated to products capable of covalent DNA binding. The level of DNA binding is low as compared to typical chemical carcinogens, but may have significant toxicological implications, as discussed below.
>
> "17β-oestradiol and some of their metabolites have the potential to cause aneuploid and are therefore chromosomal mutagens. For 17β-trenbolone, the reports about aneuploidogenic potential are controversial. For zeranol and its metabolites, aneuploidogenic potential has not been studied adequately.
>
> "The metabolism of 17β-trenbolone and zeranol in humans and the genotoxicity of the metabolites have not been fully elucidated.
>
> "The mechanisms of hormonal carcinogenesis are not yet fully understood. The hormonal and genotoxic effects of an agent may well act in concert. Therefore, it is conceivable that an hormonally active compound is retained in target cells by the hormone receptor and stimulated cell division, which in turn makes the cell more vulnerable for the induction of gene mutations and aneuploid. Xenobiotic hormones have longer half-life and may accumulate to higher levels after repeated exposure.
>
> "The standard systems used in toxicology for assaying genotoxicity may not be suitable to detect the rather subtle genotoxic effects of carcinogenic hormones. As the hormones under consideration and/or some of their metabolites exhibit both DNA-damaging and aneuploidogenic potential, it is not permissible to establish values for No-Adverse-Effect-Levels and for Acceptable Daily Intake. The conclusions and recommendations of the 1988 and 1990 FAO/Codex Alimentarius Reports are solely based on the hormonal activities of the agents under consideration. As the evidence for genotoxic effects of these agents has increased considerably over the past years, an update is required which takes these recent findings into account."[103]

---

[102] E. Cavalieri, "Genotoxicity and Potential Carcinogenicity of Hormones Administered to Animals for Promotion of Growth in Meat Production", 7 February 1997.

[103] M. Metzler, "Genotoxic Potential of the Natural Sex Hormones 17β-oestradiol and Testosterone, and of the Synthetic Compounds 17β-trenbolone and Zeranol", 6 February 1997.

4.147 The European Communities also referred to the report submitted by Dr. Epstein in which he argued that:

> "... there is substantial evidence challenging the validity of classifying carcinogens as epigenetic, for which thresholds or Acceptable Daily Intake (ADI) levels are claimed, or genotoxic. Apart from this, hormonal anabolics are mutagenic in mammalian test systems and are thus genotoxic. There is also substantial scientific evidence challenging the existence of thresholds for any carcinogen. This evidence is even more persuasive for exposures involving infants and young children, in view of their enhanced sensitivity to carcinogens and for exposures involving unpredictable synergistic interactions. There is no scientific basis for claims that ADI levels can be set for natural and synthetic anabolic carcinogens, or for claims that ADI levels can be based on "no-hormonal-effect levels" of synthetic anabolic carcinogens (FAO/WHO, 1990).
>
> "These conclusions on the hormonal effects of anabolics are consistent with, and an amplification of, those detailed in an earlier review of endocrine factors in human carcinogenesis. In almost all cases two postulated mechanisms: "alteration of the susceptibility of tissues to the initiation of cancer" and "promotion of the development of cancer from initiated cells", could not be separated. The carcinogenic effects of DES in relation to breast cancer were considered to be "more in keeping with an effect on initiation rather than on promotion". It may further be noted that no mechanism of action, whether promotion, initiation or other, could be determined for the carcinogenic effects of oestrogens on salivary, ovarian, renal and thyroid cancers, and malignant melonoma in humans. A most recent report has further summarized evidence that parent oestrogens and their catecholamine metabolites induce several types of DNA damage, adduct formation, and gene mutations. Additionally, the author concluded, on the basis of experimental evidence, that "hormonal activity of oestrogens was considered to be necessary but not sufficient for tumour induction to occur".
>
> "There is no scientific basis for making distinctions between genotoxic and epigenetic carcinogens on the basis of available bioassay data. Thus, there is no basis for attempts to derive threshold levels for hormonal anabolics, or other carcinogens, from such data. ...
>
> "It should further be emphasized that extrapolation from high dose bioassay data is likely to underestimate, rather than overestimate, the carcinogenic effects of low dose chronic human exposure. A recent publication endorsed this conclusion with particular reference to metabolic considerations. "Limited evidence would indi-

cate that proportionately less active metabolite is formed at high concentrations where Phase 2 enzymes predominate, while at lower concentrations pathways leading to active metabolites are favoured. The overall effect would lead to an underestimate of risk from high dose animal experiments when extrapolating to low level, chronic human exposure".

"Apart from the invalidity of distinctions between genotoxic and epigenetic carcinogens, it is generally accepted that threshold levels cannot be determined for genotoxic carcinogens. While hormonal anabolics are inactive in bacterial gene tests, and hence dismissed as epigenetic, they are nevertheless clastogenic in mammalian evidence of genotoxicity is clearly more relevant to human cancer than are data based on bacterial gene tests.

"There are other cogent reasons for rejecting the threshold hypothesis. These include:

- The enhanced sensitivity of neonatal rodents to the carcinogenic effects of anabolic hormones, supported by substantial evidence on the increased susceptibility of infant rodents and humans to a wide range of carcinogens, including natural anabolics and diethylstilbestrol. (IARC, 1989, NRDC, 1989)
- Synergistic interactions between different anabolics administered in combination. Illustrative, are the synergistic effects of oestrogen and progesterone in the induction of mammary tumours in mice. (IARC, 1987)
- The possibility of additive and/or synergistic interactions between natural and synthetic anabolic carcinogens and endogenous hormones, particularly in infants.
- Synergistic interactions, not as yet investigated, between anabolic carcinogens and carcinogenic and/or xenoestrogenic contaminants in meat products, such as chlorinated hydrocarbon pesticides.
- The absence of routine monitoring and residue analysis for parent anabolics following their legal administration, and of sensitive and practical analytic techniques further preclude attempts to estimate threshold or Acceptable Daily Intake levels for hormonal anabolics. Still further complicating problems of residue analysis is the impracticality of assaying for biologically active oestrogen metabolites."[104]

[104] S.S. Epstein, "Report to the EC on Cancer Risks from Hormonal Meat Products", 5 February 1997.

4.148 The European Communities also presented the arguments of Dr. Pinter that:

> "... there is evidence that endogenous and exogenous hormones represent potential carcinogenic risk to humans. The risk is associated with the level of hormones, the time of exerting the hormonal effect and the general status of the hormone-responsive organs. Exogenously administered hormones have been proved to be carcinogenic to experimental animals and there is also evidence for hormones to be casually associated with human tumours. In contrast to many animal carcinogens, in the case of hormones, one has to bear in mind that we deal with "human" carcinogens. Therefore, any consideration should be dealt with more seriously than with "animal" carcinogens. Although the level of endogenous hormones varies greatly during the life time, there is no evidence that low level of additional hormones do not represent additional risk.
>
> "Oestrogens and/or their metabolites can react with DNA causing DNA damages, can alter proteins including tubulin, resulting in aneuploid. There is also evidence that this effect is different from the hormonal one, therefore relying on no-hormonal effect might be inappropriate. Administration of oestrogens and progestins in humans is proved to be tumorigenic. In case of hormone mixtures and their residues, it is possible that similar risks exists. Although the level of administered or ingested mixtures may be different, the tumorigenic hazard should not be excluded.
>
> "All effort should be made to avoid additional hormonal effect unless it is absolutely necessary (mediation, etc.). The risk associated with consumption of hormone-containing meat products can be regarded as unnecessary risk which can be avoided."[105]

4.149 The **United States** argued that the work referenced by the European Communities did not provide evidence of any risk involving residues of the six hormones when used for growth promotion purposes. Contrary to the EC suggestion in submitting the reports it had requested from individual scientists, oestradiol-17ß was not genotoxic when administered by the oral route. Most of the studies cited in these reports involved compounds that were genotoxic but were not related to oestradiol-17ß (or to any of the other five hormones involved in the dispute) either structurally or biologically. The only studies presented as evidence that oestradiol-17ß was genotoxic discussed a Syrian hamster model system. The hamsters were given oestradiol-17ß at doses millions of times higher than the levels present in food, as shown below. The route of administration was directly into the animal (systemic) not oral. The purported DNA damage (adduct formation) was attributed to a minor metabolite of oestradiol-17ß, not oestradiol-

[105] A. Pinter, "Some Aspects of Hormonal Carcinogenesis", 5 February 1997.

17ß per se. The studies failed to demonstrate that the adducts were permanent and irreparable- a necessity for compounds that were genotoxic. Rather the studies suggested that the DNA changes were secondary to the cell's inability to inactivate these extremely high doses of oestradiol-17ß, a common finding in toxicology.

4.150 The United States observed that the dosage used in Dr. Liehr's study was 61µg/day in male Syrian hamsters weighing approximately 100 g. This was 610 µg/kg/day. For a 60 kg adult human male, this was the equivalent to 36.6 mg/day. On average an adult male produced 48 µg of oestradiol/day. This meant that Dr. Liehr's study involved delivery to male hamsters of 762.5 times more than the comparable average daily production rate in adult men. The average daily production rate in men was, in turn, 15,000 times more than the residue of oestradiol in meat from treated animals. The difference between the dose used in treatment of Syrian hamsters and the residue in 500 g of meat from treated animals was approximately 11.5 million. In other words, if one extracted all the oestradiol out of 11.5 million 500 g portions of meat, and injected all this quantity of oestradiol every day for a number of months into human males, one would replicate the dose used by Dr. Liehr.

4.151 The United States maintained that the final step in the scientific process was to determine that the data generated in a model system accurately predicted the adverse effects in humans. The scientific data on the oral activity of oestradiol-17ß demonstrated that the results obtained in the Syrian hamster model system were not relevant for assessing the toxicity of oestradiol-17ß administered orally to humans.

4.152 The United States argued that a more definitive test, a two-year rodent bioassay, had already been conducted for oestradiol-17ß and the results of the bioassay together with the results of other short-term tests had been reviewed by various scientific experts and used in determining the safety of oestradiol-17ß. Based on the results of these tests and other relevant scientific data, it had been determined that oestradiol-17ß was not a genotoxic carcinogen. Since long-term *in vivo* carcinogenicity tests had already been conducted for these hormones, the results of additional short-term assays were of little value. The full scientific process necessary to make the regulatory decision that oestradiol-17ß was not a genotoxic carcinogen had been completed. The very low levels of oestradiol-17ß present in food were not adding to the cancer risk of women, children or men.

4.153 Furthermore, the United States observed that oestradiol was the same whether produced endogenously in women, naturally present in food of animal origin, or present as a result of treatment of animals for therapy or growth promotion. Oestradiol-17ß was present in milk, including human breast milk. Oestradiol content was very high in human breast milk early in lactation. Although infants and young children were very susceptible to genotoxic agents, there was no evidence that oestradiol-17ß was genotoxic in this very sensitive population. Genotoxic agents caused irreparable damage to cells. Newborn human infants

were orally exposed to relatively large doses of oestradiol-17ß in human breast milk with absolutely no evidence of genotoxic or other harmful effects.

4.154 The United States also argued that there was no evidence that use of the hormones in question resulted in adverse health effects to treated animals.

4.155 The United States acknowledged that scientists did not claim to know everything about everything and noted that scientific knowledge was always progressing and evolving. However, lack of knowledge could not itself be the basis for taking a sanitary measure. The SPS Agreement required the European Communities to demonstrate scientific evidence of a particular risk. Accordingly, to claim that a Member was justified banning an activity wherever there were still areas for science to explore would be to render the SPS Agreement meaningless: there would always be areas for science to explore.

4.156 The **European Communities** responded that it had not argued in this case that lack of knowledge by scientists of all aspects of hormones' mode of action could alone justify the prohibition on their use for growth promotion. What the European Communities had argued was that it was concerned with substances which scientists knew were potentially carcinogenic. This scientific evidence, coupled with the other possible sources of risks, enabled a Member to adopt a precautionary approach by prohibiting their use for growth promotion. This was all the more so when under a proper risk assessment, performed in accordance with what was now required by Articles 5.1 to 5.6, the European Communities had concluded that no other measure was reasonably available to it, taking into account technical and economic feasibility, that would have achieved its appropriate level of sanitary protection and which would have been significantly less restrictive to trade.

4.157 The European Communities emphasized that the real policy question on how regulatory authorities should treat hormones depended on the definition of the terms "harm" and "risk". If risk was defined as "the probability (either measured or estimated) that harm might occur from exposure to these hormones"[106], Members were free to decide whether such measured or estimated risks were desirable from their regulatory policy point of view. No scientific report to date, including the 1988 JECFA Report on which Codex had based its recommendations, had ever suggested that there was no potential risk from the use of these hormones. The simple fact that Codex had considered it necessary to recommend MRLs for some of these hormones was sufficient proof in itself that there was such a risk. Such a risk might also result from their administration, if this were not done in accordance with good veterinary practice.

4.158 The **United States** argued that the European Communities attempted to imply that there were large gaps in the knowledge about hormones, and that this

[106] J. Bridges and O. Bridges, "Hazards of Growth Promoting Agents and Strategies of Risk Assessment", *1995 EC Scientific Conference Proceedings*, p.247 seq.. and "Risk Assessment Strategies for Xenobiotics", *1995 EC Scientific Conference Proceedings*, p.365 seq.

gap compared unfavourably to scientific knowledge about other types of compounds. However, in the US view, scientists knew more about the nature and mode of action of hormones than they did about most, if not all, other classes of compounds. The United States asserted that the European Communities was wrong in claiming that the fact that there were ADI levels or MRLs for a substance was evidence that there was a risk from the substance at levels below that ADI or MRL. The concept of ADIs and MRLs was only applicable to residues of substances that did not occur naturally, such as trenbolone and zeranol. The United States explained that using laboratory animals, scientists determined at what level the hormones had any effect on animals (not necessarily an adverse health effect, but simply where the hormone started to have a hormonal effect). Then, using a large safety margin (100 times or even 200 times), the scientists calculated what level of these hormones the most sensitive member of the human population could be exposed to every day of their lives and still have no effect. This was the ADI level (acceptable daily intake level). The scientists then determined what was the maximum residue level (MRL) that food could contain and still ensure that the ADI was met. This MRL was calculated using conservative consumption estimates, for example assuming that a person ate 500 grams of beef per day. There were no evidence that there was any risk of harm to human health at levels below the ADI and MRL. Moreover, the European Communities' claim assumed that if there was any risk of harm from hormones at high levels of consumption, then there must be a risk, albeit smaller, from low levels. The United States argued that this was unsupported by evidence and was also untrue in the case of a number of common foods. These common foods were safe at normal levels of consumption, but posed a risk of harm to human health at very high levels. Some examples of this were potatoes, which contained alkaloids which were toxic in high quantities; lima beans, which contained cyanide which was toxic in high quantities; and rye and other small grains, which in Europe often contained ochratoxin-A that at high levels could cause kidney disease and cancer.

4.159 The **European Communities** responded that the "safety factor" applied when setting the values of ADI and MRLs did not provide the necessary protection, especially in the case of potentially carcinogenic substances whose mode of action was not clear, as the example of the hormone DES had shown. The "safety factor" was in reality no more than a useful tool and applied to those scientific reports which depended on extrapolations from imperfect data on laboratory animals to setting ADIs and MRLs for human beings. The European Communities argued also that the use of simplistic examples of a number of common foods (eg. potatoes, lima beans, rye and other small grains) bore no relevance whatsoever to the scientific issues in discussion. The United States had not explained how many kilogrammes of potatoes one would have to consume first before absorbing alkaloids in toxic quantities. Conversely, a very minuscule portion of meat from an animal to which these hormones had been improperly administered might contain a very high dose of residues which were dangerous to human health. The European Communities argued that the example of the premature

sexual development and ovarian cysts involving about 3,000 Puerto Rican infants and children demonstrated the above point.[107] In addition, potatoes, lima beans and the other products mentioned by the United States had always formed part of the normal diet of human beings and naturally-occurring substances in these products had entered the metabolism of the human body throughout the course of human evolution and could not be compared with exogenously administered carcinogenic substances given to animals for growth promotion purposes. The European Communities argued that, faced with the identified cancer risks, it was entitled to be as cautious as possible and noted that the United States actually applied the same type of sanitary and phytosanitary policy with regard to potentially carcinogenic food additives through the "Delaney clause".

4.160 The **United States** clarified that it did not apply a zero risk policy to all potential risks presented by the use of a food additive. To receive approval for use in the United States, the sponsor of a food additive must demonstrate that the additive was "safe" for its intended uses. Under US law, "safe" did not mean the absence of all risk but rather a "reasonable certainty" that no harm would result from the intended use of the additive. The same standard also applied to the setting of tolerances for pesticide residues in raw agricultural commodities and processed foods. This concept of safety was articulated in both the US Senate and House reports to the 1958 bill enacting the Food Additives Amendment, which stated that "[t]he concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not - and cannot - require proof beyond any possible doubt that no harm will result under any conceivable circumstance".[108]

4.161 The United States noted that the European Communities in essence had argued that there was not a threshold level below which residues of these hormones would be safe.[109] In other words, the European Communities claimed that *any* residue, no matter how infinitesimal, posed a risk of carcinogenicity. Yet the European Communities had not provided scientific evidence to support this position. Moreover, if the European Communities truly believed that there was no threshold, and were unwilling to accept any risk from residues of these hormones, then the European Communities would have to ban the use of hormones for herd management and other purposes. But the European Communities did permit the use of hormones for herd management and other purposes. In the US view, the European Communities' own arguments belied its position. For example, the European Communities had claimed that the levels of hormones that occurred naturally in meat and other foods were not a risk to human health because hu-

[107] A. Pérez-Coma, C.A. Saenz, "Anomalous Sexual Development in Puerto Rico - 28 Years of Experience".
[108] H.R. Rep. No. 2284, 85th Cong., 2d Sess. (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. (1958).
[109] See para. 4.135 with respect to EC arguments regarding the threshold approach.

mans evolved alongside them. This conclusion, while lacking any scientific foundation, nonetheless demonstrated that the European Communities believed that there was a threshold of exposure below which there was no risk.

4.162 The **European Communities** contended that it did not permit the administration of the three natural hormones "to entire herds of cattle". Although the European Communities did not possess the exact figure of the number of animals treated for therapeutic or zootechnical purposes, partly because some of the EC member States did not keep such a detailed statistical record, it could be estimated from those EC member States which did keep such records (e.g. Denmark, The Netherlands and Finland) that only between 1 per cent and 2 per cent of breeding cattle in the European Communities were treated each year for such purposes. This percentage corresponded to about the same proportion of total bovine meat of EC origin consumed in the European Communities. This might be partly explained by the fact that there were now better treatments available which were not based on these hormones. Regardless of the insignificant quantities involved, what needed to be underlined was that allowing the administration of the three natural hormones for therapeutic or zootechnical reasons was in full compliance with the European Communities' policy of ensuring no residues of hormones in meat for human consumption since the strict conditions imposed by EC law effectively ensured its policy objective (no residues at all).

4.163 The **United States** responded that it was wishful thinking, not fact, to think there were no residues present at the end of a withdrawal period. As had been confirmed by the experts advising the Panel, residues might be below the level of detection, but there would always be some amount left. This was because hormones (as almost all compounds, with very few exceptions) depleted by first-order kinetics. This meant that after one half-life, only 50 per cent of the original amount remained; after 2 half-lives, 25 per cent of the original amount remained, and so on until the amount remaining became vanishingly small but still present. The EC claim only demonstrated the overbroad nature of the EC ban. If the European Communities had been correct in thinking that there were no residues after a particular waiting period, then the European Communities at a minimum would not have been entitled to prohibit all imports of meat from animals to which any of the six hormones had been administered for growth promotion purposes, but only meat from animals that had not been subject to a sufficient waiting period. Similarly, instead of prohibiting imports of all animals, the European Communities could have prescribed a waiting period for those animals prior to slaughter. The EC view would have meant there was no basis for an absolute ban with respect to the three synthetic hormones either, since under that view there would be no residue of these hormones after a sufficient waiting period.

4.164 The United States also responded that the EC claim that it had no solid information about the percentage of meat produced in the European Communities from animals to which hormones had been administered for herd management and other purposes was at odds with the constant EC reference to the strict controls on such use and the need to identify every single animal to which they had been administered. Industry sources in the European Communities informed the

United States that 3.75 to 4 per cent of all cattle were treated each year, based on an average of information, known in Belgium, France, Germany, the Netherlands and the United Kingdom. In addition, about 6 per cent of sheep in the European Communities were treated each year. In 1995, from one company alone, 2 million doses of hormones were sold (for sheep) and ½ million doses were sold for cattle. Furthermore, by stating that hormones were administered to 1 to 2 per cent of the EC herd each year, the European Communities failed to note that this figure should be multiplied by the number of years that the animals in the herd remained in production in order to determine the quantity of the meat supply from animals that, during their lifetime, had been administered these hormones. For example, if the hormones were administered to different animals each year, then over the course of 5 years, 5 to 10 per cent of the herd would have been administered these hormones. Alternatively, if the hormones were administered to the same animals, then an animal may have received five separate sets of treatment. Furthermore, there was no requirement that the hormones administered always be the same substances. Nothing prevented an animal in the European Communities from having been exposed to multiple hormones (or in the EC view, "combinations" or "cocktails" of hormones).

(ii) Metabolites

4.165 The **European Communities** argued that other risks arose from the hormones at issue because of their metabolites. When drugs were introduced into the body, their pharmacological and toxic effects were directly correlated to their concentration in tissues and fluids. The concentration of a drug was a function of its resorption, excretion and metabolism. Drugs were metabolized (broken down) and their metabolites might also have pharmacological effects, which might differ from the effect of the parent drug. Metabolites might have different side or toxic effects. Anabolic steroids had a large variety of metabolites, some of which were only recently identified. The pharmacological and toxic behaviour of many of these metabolites were still unknown. In addition, the same parent substances might produce different metabolites in different species, making the extrapolation from studies on laboratory animals to humans unreliable.

4.166 The European Communities asserted that there were scientists who argued that knowledge about the toxicity of the metabolites of these hormones was as yet very limited. Moreover, metabolites of such substances which, even in low concentrations, might have highly toxic effects were generated in the human body.[110] These scientists argued that "the use of hormones in growth promotion of animals should not be allowed, as it cannot be excluded that unchanged agents, their metabolites and, above all, unknown highly effective and toxic metabolites are dis-

[110] W. Schänzer, "The Illegal use of Anabolic Agents in Sport", *1995 EC Scientific Conference Proceedings*, p.352.

tributed with the meat which is purchased by consumers".[111] Moreover, in some of the experimental studies on which the 1988 JECFA Report was based, no extensive research and risk assessment of the potential risks arising from the metabolites of the hormones under consideration had been carried out.[112] Noting that despite all the uncertainties, JECFA had decided to establish a temporary ADI for trenbolone acetate while requesting additional information to be submitted to it by 1990, the European Communities argued that in light of the arguments advanced by some scientists, it was questionable whether the decision of the JECFA could be regarded as a reasonable one. The European Communities remarked that the United States had already approved the use of trenbolone for livestock growth promotion in 1987, whereas Codex had established its final recommendation only in 1995. In 1987, the Standing Commission on Hormone Toxicity of the German Society for Endocrinology and the Commission for Toxicology of the German Society for Pharmacology and Toxicology had stated that "the present information in respect to a likely genotoxic potential did not allow a final evaluation for trenbolone".[113]

4.167 The **United States** argued that EC claim that there were health risks arising from metabolites of the hormones were unfounded. The European Communities appeared to simply rely on the fact that "there are scientists who argue" that "knowledge is very limited" and metabolites "may have adverse effects", with no evidence of any such adverse effects, much less in relation to specific hormones or to the levels of exposure from the use of hormones for growth promotion purposes. Furthermore, the European Communities cited studies on the illegal use of anabolic hormones in athletes which had nothing to do with residues of hormones in meat. The United States disagreed that Codex had failed to examine potential risks from metabolites. The additional studies on metabolites requested by the 1988 JECFA report had been performed and accepted in 1989. The Lamming Committee had also examined the safety of the metabolites for the hormones it had reviewed and had found them to be safe. Moreover, in the United States, metabolism of a compound was an integral part of the safety assessment of all animal drug products prior to approval of the drug or the setting of a final MRL for the hormone products. All scientific evidence showed that there were no risks of harm to human or animal health due to residues of any metabolite of the six hormones when used for growth promotion.

---

[111] W. Schänzer, "The Illegal use of Anabolic Agents in Sport", *1995 EC Scientific Conference Proceedings*, p.353.

[112] As an example, the European Communities noted that, as regards trenbolone acetate (TBA), the JECFA had stated that "[i]n the absence of satisfactory toxicological data the Committee was unable to establish a separate no-effect level for the a-TBOH metabolite. It also noted that this metabolite was not produced in significant amount in the rat, which made it inadvisable to extrapolate from data generated from ß-epimer, experiments in that species".

[113] B. Hoffmann, "Problems of Residues and Health Risks of Anabolic Agents with Sex Hormone-Like Activities", *1995 EC Scientific Conference Proceedings*, p.291.

4.168 The **European Communities** responded that data derived from the directly-observed effects of these hormones on human beings (whether for therapeutic purposes or by athletes) was equally or even more important than data derived from laboratory animals. The fact that these anabolic steroids were used "illegally by athletes" did not diminish the relevance of the EC argument, since the metabolites of these substances, whether used legally or illegally, were the same. The 1988 JECFA Report on which the United States based its contentions in this case stated that information from human case reports on drugs also used therapeutically in human beings "may provide important evidence of possible adverse effects in human beings that are not detectable in animal models". The Codex had also noted that "[h]uman data of insufficient extent may be considered in the setting of [a Codex Acceptable Daily Intake] on the basis that extrapolation of data from animal studies contain greater uncertainty".

(iii) Combinations of Hormones and Multiple Exposure

4.169 Referring to scientists' reports at the 1995 EC Scientific Conference of evidence of the illegal use of growth-promoting substances in many European countries and elsewhere[114], the **European Communities** submitted that the illegal use of mixtures of veterinary drugs and growth promoters might result in unpredictable residue levels in edible foods, which might constitute a risk for the consumer. This might be due to variations in physiological and pathological parameters, altering drug disposition and elimination. Biotransformation patterns of synthetic drugs and hormones might differ markedly depending on the animal species and gender. Interactions might occur between compounds as had been reported for sulphadimidine and oestrogenic and androgenic hormones administered to dwarf goats. This might require longer withdrawal times in order to arrive at safe residue levels. For those reasons, the 1995 EC Scientific Conference had concluded that "the use of combinations (or cocktails) of hormones poses serious risks for the health of consumers because the use of mixtures, which usually contain illegal substances, is made in the form of injections, rather than implants, and this is an impediment to their detection at slaughter. This potentially allows the sale of meat containing very high concentrations of hormones".[115]

4.170 In the European Communities, the terms "combinations" and "cocktails" were used interchangeably to denote the higher potency and multiplied negative effects that such substances exerted when used in combination, compared to when used individually. Whether the combinations were legally marketed was irrelevant, as there was nothing to prevent an unscrupulous farmer from admin-

[114] "Report and Conclusions", Steering Committee, *1995 EC Scientific Conference Proceedings*, p.9.
[115] *Ibid.*, page 9, and H.A. Kuiper, "Risk Assessment Strategies for Xenobiotics", *1995 EC Scientific Conference Proceedings*, p.376.

istering one, two, three or even more of these legally available substances, in an attempt to yield potentially higher growth rates. The European Communities stressed that the use of cocktails in the United States did not appear to be subject to strict control, since a number of products were freely available on sale in the market. On the other hand, several of the licensed products in the US market were commercially manufactured combinations of hormones, with adjuvants (i.e. additives used to speed up or slow down the active element of the combination).

4.171 The European Communities argued that when JECFA had established its recommendations on the ADIs and MRLs of the hormones at issue, it had considered only information on the single substances, although scientists had agreed that the concept of ADI was not applicable to assess the risk from exposure to mixtures (or cocktails) of compounds. The 1988 JECFA Report had, however, pointed clearly to the need to examine the effects of combinations:

> "The Committee noted that several of the hormonally active substances on the agenda were used in combination one with another, and recommended that, where substances having similar physiological activities were combined, evidence that their hormonal effects were additive, rather than synergistic, should be provided. The Committee agreed that data on the residues of each of the substances that are used in combination should be available for evaluation, whether or not their physiological activities were similar."

The European Communities concluded that there was considerable potential risk arising from the use of combinations, containing authorized or unauthorized hormones, and that existing international rules did not deal adequately with this potential source of risk.

4.172 The **United States** submitted that the EC claims regarding health risks arising from the use of hormones in combination were unfounded. There was a difference between combinations of hormones and the so-called "cocktails." Combination products contained only authorized hormones and adjuvants. The product intended for commercial sale was the product tested and reviewed in the United States and subjected to both animal and food safety analysis prior to release for commercial purposes. Furthermore, they were manufactured according to required good manufacturing practices so that they were consistent in identity, strength and purity. Since hormones might be legally purchased in formulations that had been demonstrated to be safe and efficient, there was no reason for a farmer or a rancher to buy other combinations and use them illegally. Furthermore, because approved formulations were tested for optimal growth promotion effects, the addition of other hormones or higher dose levels, under conditions different from the label, did not result in additional growth effects. Accordingly, such use would result in increased economic costs with no accompanying economic gain.

4.173 On the other hand, the United States observed that the term "cocktails" had no legal definition and was generally used to refer to the mixture of illegal

drugs prepared in unlicensed facilities that were sold on the black market in EC member States. The United States agreed that the use of such cocktails was dangerous and stressed that they were illegal for use in the United States. Finally, it was not clear how concern over the use of illegal "cocktails" could justify the EC ban on the use of strictly regulated single or combination products, or even how the concern over "cocktails" could justify the EC ban on the use of all hormones for growth promotion purposes, including the administration of single hormones.

4.174 The **European Communities** claimed that illegal marketing of hormones and veterinary drugs in general in the United States might be as great as, or even greater than, in the European Communities. The European Communities referred to a 1985 report produced by the US Congressional Committee on Government Operations, entitled "Human Food Safety and the Regulation of Animal Drugs". This report noted that "... the problem of illegal veterinary prescription drug sales is of such magnitude and pervasiveness that it threatens the credibility of the veterinary drug approval and the regulatory process". These conclusions were based on a focused investigation by the US Food and Drug Administration which found that "indiscriminate sale of prescription veterinary drugs" was "pervasive" throughout eastern Iowa, and that other, ongoing investigations seemed to confirm that "... the illegal sales problem was probably nationwide in scope".

4.175 The European Communities contended that the risks that might potentially arise from the multiple exposure of humans to hormones and other chemical substances were similar to those resulting from the illegal use of combinations (or cocktails) of hormones. All foodstuffs, whether of animal or plant origin, were likely to contain trace amounts of several substances derived from various sources, a fact currently not addressed in any risk assessment strategy for food. Because the ADI and MRL assessed the safety of a single compound and not the exposure to mixtures of compounds, a sufficient protection of humans was only guaranteed if the MRL was not exceeded. Thus, there was a substance-related risk to consumers if the acute ingestion of a residue amount exceeded the established MRL and possibly the ADI. But the question also arose on how to protect consumers from a potential adverse effect resulting from long-term treatment with growth- promoting substances. Such adverse effect was the possibility that the biotransformation of other compounds might be altered, as had been shown in the case of steroids. This might result in altered residue kinetics for those compounds.[116] The European Communities claimed that the idea that there might be a risk associated with the long-term exposure to a mixture of substances, resulting in a possible biotransformation of other compounds, was a precursor to the so-called "precautionary" principle and it was at the heart of the policy followed by the European Communities on such issues.

[116] Working Group II, "Assessment of Health Risk", *1995 EC Scientific Conference Proceedings*, p.20.

4.176 The **United States** claimed that with respect to multiple exposure, the European Communities had once again failed to identify any particular risk or provide any evidence or risk assessment demonstrating a risk. Instead, the European Communities had simply mused about the "idea that there may be a risk". In this musing, the European Communities had also chosen to ignore the fact that one of the reasons for applying a safety factor of 100 (200 in the case of MGA) was to take into account, among other things, the possibility of exposure to more than one compound over a life time.

4.177 The **European Communities** responded that the Codex itself had noted that "[u]ncertainty in the safety evaluation process is primarily addressed through the use of safety factors. Their respective values are arbitrary and have no measured biological significance, however, their appropriateness is somewhat borne out by experience".[117] The safety factor, therefore, might not provide the necessary protection, especially in the case of potentially carcinogenic substances whose mode of action was not clear, as the example of the hormone DES had shown. The "safety factor" was in reality no more than a useful tool and applied to those scientific reports which depended on extrapolations from imperfect data on laboratory animals to set ADIs and MRLs for human beings. Although these concepts had served well in the past and would continue to do so in the future, a Member was entitled to deviate from these concepts as used by Codex in establishing recommendations. Codex had proven to be useful in setting guidelines and recommendations for food additives precisely because it had left its members free to decide whether they would accept its recommendations. The SPS Agreement was cast largely on the same basis, because it allowed Members to depart from international standards, guidelines or recommendations under the conditions laid down therein (e.g. Article 3.3).

(iv) Detection and Control

4.178 The **European Communities** noted that none of the scientific conferences and expert review groups (including the Lamming Report and the 1988 JECFA Report), which had examined the potential risks from the use of these hormones for animal growth, had concluded in favour of an unqualified use of these hormones for growth promotion purposes. This was because the administration of these hormones to laboratory animals, at high doses but also at low doses in some experiments, had caused serious health effects, including cancer. Furthermore, all the scientists which had expressed themselves in favour of allowing the use of these hormones at low doses for growth promotion purposes did not exclude risks to human and animal health from improper administration or from combinations and metabolites of hormones and multiple exposure. This critical caveat on conditions of use had been recognized in the EC Commission proposal

[117] Codex Alimentarius Commission (1993), "Risk Assessment Procedures used by the Codex Alimentarius Commission and its Subsidiary Advisory Bodies", p.11.

(COM(84)295 final) which finally led to the adoption of Directive 88/146/EEC. This Directive proposed to allow the use of the three "natural" hormones only under the following conditions in order to safeguard public health:

(i) only in the form of an implant to be administered in a part of the animal discarded at slaughter (usually the ear);

(ii) to an identified animal only, to allow control of the withdrawal period;

(iii) only by a veterinarian;

(iv) substances allowed to be administered must be on an EC list, setting out clearly conditions of use; and

(v) these substances must be shown to be effective and safe.

4.179 The European Communities observed that the Lamming Report had also urged the attention of the European Commission to the need to lay down certain essential provisions before the three natural hormones could be used for growth promotion, in particular as regarded the following:

"(a) Instructions for use:

1. Specification of the doses, the type of pharmaceutical preparation, the number and frequency of administrations.

2. Association of anabolic agents.

3. Localization of implant and ablation of zone treated.

4. Withdrawal period before slaughter.

5. Identification of animals treated, with indication of the period of treatment.

(b) Surveillance programme and analysis methods

1. Control of production and trade in anabolic agents.

2. Veterinary control of authorized uses.

3. Means and methods of control."

4.180 The European Communities noted that JECFA had recognized that the use of these hormones was unlikely to pose a hazard to human health *if* used in accordance with good animal husbandry practice, but that there were no internationally agreed rules on what constituted "good animal husbandry practice" for the administration of these hormones. As far as "good veterinary practice" was concerned, the 1988 JECFA Report had noted that the Code of Practice for the Use of Veterinary Drugs was under preparation by the Codex Committee. This Codex Code of Practice had finally been adopted in 1993.[118] However, it was not clear how strictly this Code was adhered to by countries. The European Commu-

[118] International Code of Practice for Control of the Use of Veterinary Drugs, adopted by Codex in 1993.

nities wondered what concrete measures the United States had taken in the case of hormones to comply with the Codex Code.

4.181 The European Communities submitted that difficulties arose because the identification of animals or meat from animals which had been treated with the three natural hormones was difficult due to the wide variation in natural levels of these hormones arising because of factors such as sex, age, diet, physiological condition, etc. While residue analysis for natural hormones in treated animals could experimentally show differences between them and untreated animals, it was currently not possible through routine tests to identify treated animals on the basis of assays of edible tissue samples, and it was also difficult using blood, urine or faeces. A country allowing imports of animals and meat from animals treated with hormones would have to rely largely on checks and controls on use of hormones carried out by the exporting country if trade was not to be impeded, but the importing country would also have to carry out checks and controls in order to ensure that its consumers ate meat which conformed to the requisite standards. Detection and surveillance of hormones was based on screening methods, principally immunoassays (radio or enzyme immunoassays) because they were rapid, relatively low cost and could be applied simultaneously to a large series of samples.[119] However, the European Communities claimed that all the available methods used for detection and control had their limits and drawbacks. Furthermore, although Codex had established an *ad hoc* working group on the matter, there were still no internationally agreed rules for the methods to be used for residue control programmes.[120] The European Communities argued that in light of the potential risks to human and animal health resulting from the uncertainties in residue control programmes and the absence of internationally agreed rules, any Member (including the European Communities) was entitled to adopt a regulatory system to achieve the level of protection for its public that it considered to be appropriate.[121]

4.182 The **United States** claimed that the European Communities had moved to a discussion of "control, inspection and approval procedures" which were covered in Article 8 and Annex C of the SPS Agreement, because it had been unable to produce any risk assessment or evidence with respect to the substances themselves to support its ban. The experts advising the Panel had confirmed that even where there was a failure to follow good animal husbandry or veterinary practice, resides of the three natural hormones administered for growth promotion pur-

---

[119] M-L Scippo and G Maghuin-Rogister, "Methods of Detection and Surveillance of Natural Sex Steroid Hormones", *1995 EC Scientific Conference Proceedings*, p.541 seq.

[120] The European Communities stressed that in 1991 the Codex Commission had only established *provisional method*s to serve as a potential source of use. See Joint FAO/WHO Food Standards Programme, Residues of Veterinary Drugs in Food, Vol. 3, 2nd Ed., 1993.

[121] The European Communities noted that, for example, Argentina prohibited the use of the three natural hormones (while allowing the use of the two synthetic ones), citing as an essential motive for the restriction the lack of suitable methods for measuring hormone residue levels in meat. *1983 OIE Scientific Report*, p.411.

poses might well still be within the normal physiological range. The European Communities was unable to identify any particular risk or provide any evidence or risk assessment demonstrating a risk. The European Communities could not explain why any risks from its failure to adequately detect residues of hormones would be higher in the case that it permitted the importation of animals to which any of the six hormones had been administered for growth promotion purposes compared to its current ban. The United States stressed that presumably, under its current ban, the European Communities still ran the risk that it would not be able to detect all banned animals and meat. Furthermore, the European Communities had not explained why it was unable to implement MRLs for the six hormones when it was able to implement MRLs for other foods and substances.

4.183 The **European Communities** agreed that a potential for meat to slip past its detection systems existed, and that it could not expect to detect every instance of illegal use. But the European Communities stressed that it operated comprehensive and costly residue control programmes designed, and effectively applied, to detect, as far as technically possible and economically feasible, such residues from all sources.[122] The fact that there was a potential for prohibited residues to evade its control and detection was not in itself a reason for the European Communities to adopt the US approach on this issue. To the contrary, this risk of residues of potentially carcinogenic substances evading detection was an important factor in carrying out a proper risk assessment and seriously influenced, right from the beginning, the decision of cautious EC member States in setting the level of sanitary protection they deemed appropriate in their territory. The European Communities also did not dispute the fact that MRLs were useful tools in regulating drugs and food additives in appropriate cases. But it was obvious that in the case of mass medication of the food animal population, the amount of testing required to apply the EC level of protection would be very much higher than under the present EC legislation. It was equally obvious that the chance of detecting violations would be much lower. The European Communities argued that the difficulties arose because exporting countries (like the United States) were not willing and capable of ensuring, on a reasonable basis, that the ADI and MRLs recommended by Codex would not be exceeded in their exported meat. The technical and financial burden had to be shared mainly by the importing Members which wished to see the Codex's recommendations strictly observed.

[122] Directive 88/146/EEC explicitly required that undertakings in the EC member States producing the prohibited hormones, those companies authorized to market these hormones for whatever purposes and undertakings producing pharmaceutical and veterinary products based on those substances, must keep a detailed register recording (in chronological order) the quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary products. These requirements had now been tightened by requiring the names of the persons to whom such quantities had been sold or from whom they had been purchased to be made available to the competent authorities (Article 9 of Directive 96/22/EC). In addition, heavy fines and penal sanctions, including imprisonment, were imposed when violations were detected.

4.184 The European Communities argued that US authorities practically did not control the sale of these hormones either individually or as compounds, and noted that they were freely available on sale, even by mail. There was no testing and checking of residues for the natural hormones and for the synthetic hormones. The United States had even dropped the three natural hormones from their control programme, even though the United States applied MRLs on them, indicating that no testing had been performed because implant-associated residues could not be distinguished from normal background concentrations. The European Communities added that MGA had been tested for the last time in 1993, when only 22 samples had been checked of which one had tested positive. Zeranol had been last included in 1989 and trenbolone had never been included in the control programme. Moreover, the European Communities noted that the US FSIS had reported a number of cases of improper use of hormones in 1986. More recently, in 1993, the FSIS had stated that "one fourth of one per cent of animals tested showed positive for residue violation. In other words, almost 99.74 per cent of animals tested showed no residue violation". The European Communities argued that the FSIS 1993 data indicated that none or very few of approximately 130 million head of livestock slaughtered in the United States had been monitored for residues of natural or synthetic hormones.

4.185 The European Communities claimed that the situation on residue controls and checks in the United States was not clear and concluded that if it had followed the example of the United States in applying the Codex recommended MRLs in the way they were applied in the United States, it would have certainly failed to achieve its level of protection which was no residues of these hormones in meat for human consumption, and it would also have failed to protect animal health. The European Communities was correct in its analysis when performing its risk assessment in the sense of Article 5, that the use of these hormones for growth promotion purposes under the conditions identified by all scientific reports (i.e. in accordance with good veterinary practice) would not be technically or economically feasible. Therefore, the responsible EC institutions had rightly concluded that prohibition of use of these hormones was the only reasonably available least trade-restrictive measure.

4.186 The **United States** first noted that the EC claim that an MRL would not be feasible because of the associated amount of testing for residues was directly at odds with the EC claim that "at least in the European Communities there are comprehensive and costly residue control programmes designed and effectively applied to detect, as far as technically possible and economically feasible, such residues from all sources". Second, the United States noted that for purposes of the EC ban it did not matter how stringent an exporting country's requirements were or what type of programme was in place with respect to the use of these hormones. Animals and meat were banned, period. The issue in this dispute was not whether the United States subjected its exports of animals and meat to any

particular controls or whether the US sanitary measures were equivalent to the EC measures[123], but whether the EC ban was in accordance with the WTO Agreements.

4.187 The United States then noted that contrary to the EC allegations, it had an extensive system in place to ensure that growth promoting hormones were used domestically according to good animal husbandry practice. Sponsors were required to determine conditions for safe and efficacious use of their products and to supply that data to the government for review. Labels for products had to accurately describe these conditions for use and be written in a way likely to be followed in practice. All sponsors were required to manufacture their drug products according to specifications and Good Manufacturing Practices to ensure consistency of strength, purity and identity, and the United States inspected these manufacturing facilities periodically. The United States also required a manufacturer to keep records on the amount of product sold and to whom (the specific retailer); overselling in a particular area relative to need could trigger investigative action. The United States also had authority to investigate live animals on the farm or feedlot to ensure correct use of the products. The United States operated an adverse drug reporting system to ensure that products were being used in a safe manner. At the slaughterhouse, the United States inspected animals to ensure the proper use of the hormones.

4.188 These practices, along with directed monitoring ("for cause" inspections) and random sampling through the Residue Monitoring Programme, ensured that public safety was safeguarded. The United States operated a national residue programme (NRP) as part of its regulatory oversight of meat production. The NRP did not apply to the naturally occurring hormones because implant-associated residues could not be distinguished from normal background concentrations. Zeranol, trenbolone and MGA were among the compounds covered by the NRP. The compounds actually tested under the NRP varied from year to year, with emphasis given to those most susceptible to improper use. The most recent year in which hormone growth promoters had been tested was 1991, when 185 steers and 129 heifers were randomly selected nationwide at slaughter for DES/zeranol testing. All findings met FDA tolerances. The last year in which testing had been done for MGA was 1988. All of the 373 randomly selected heifers were in compliance with FDA requirements. Testing could be reinstituted if a problem were perceived. In addition, US slaughter establishments producing meat and offal products for export to EC member States were required to participate in an expanded residue testing programme conducted by private laboratories. Under this programme, the number of samples collected during the last five years, for the cattle, sheep, swine and equine species, had been approximately as follows: zeranol = 3500; MGA = 1300; trenbolone = 3500; and DES = 3500. To

[123] The United States noted that issues of equivalency were examined under Article 4 of the SPS Agreement.

the best of the knowledge of FSIS employees working closely with that programme, all of the findings met FDA tolerances.

4.189 The United States clarified the conditions of use for these hormones. In the case of cattle in the United States, hormones were not generally administered by individual farmers. Instead, the vast majority of the hormones were administered when the animal first entered the feedlot. At this time, a team under the supervision of a veterinarian assessed the overall health of the animal and provided veterinary treatment as required. An implant was usually inserted by team members at this time. As large commercial operations, the feedlots had great incentive to properly care for these animals, including proper placement of implants, in order to provide the consumer the highest quality product possible. Implants were developed for use with special delivery devices designed for ear implantation. The release rate of active ingredient from the implant was maximally effective for growth promotion purposes when implanted in the ear. Implantation at sites other than the ear was difficult in practice as the hide was very tough and not easy to penetrate. Other implantation was also not as effective as ear implantation, might damage the carcass with scar tissue thus decreasing its value, and would entail legal liability and a condemned product. Therefore it was in the feedlot's interests to use the implants under the conditions of use specified on the label.

4.190 The United States claimed that with respect to US imports from third countries, any exporting country was required to have a programme in place to ensure that food produced from animals treated with any drug was safe for consumers. This programme had to achieve a level of protection at least equal to the US appropriate level of sanitary protection. The exporting country's programme must include a systematic national residue testing programme. Exporting countries were required to report the results of their NRP to retain eligibility to export to the US market. To export meat to the United States, all foreign countries had to obtain an annual US residue certification stating that the country maintained, among other requirements, a control programme to ensure compliance with US standards for residues in meat destined for the United States. One element of the US audit of residue control programmes was the evaluation of annual testing results supplied by each country. The United States recommended that each country determine which compounds should be included in its annual residue sampling plan, and provide information with the plan that explained the decisions to include (or exclude) compounds. The selection of compounds to be included in the testing plan should be based on conditions present in the country, e.g., availability of specific compounds, conditions that warranted use, and the residue hazard when used. In determining whether a country maintained an acceptable residue control programme, the United States considered the following, in addition to the residue sampling plan and test results: (i) US port of entry testing results; (ii) the findings of on-site reviews of plants exporting product to the United States, and laboratories performing the analytical testing; (iii) compound selection, statistical design, and implementation of sampling plans; (iv) trace back and

enforcement procedures; and (v) timely receipt of investigative reports following a US port of entry violation.

4.191 The **European Communities** submitted that it did not argue that it was "unable" to implement MRLs for growth-promoting hormones, but that it was unwilling to do so. In this it was acting consistently, as it did not operate MRLs for other drugs which had powerful adverse physiological effects, including carcinogenicity, at low concentrations. Therefore, if after conducting a risk assessment a Member concluded that its level of sanitary protection could not be ensured by applying the MRLs recommended by Codex, this Member was allowed to depart from those MRLs. This was the principle on which both Codex and the SPS Agreement were based.

4.192 The European Communities referred to the reports of Dr. Pérez-Comas in relation to detection, control and administration of hormones. Dr. Pérez-Comas argued that:

> "... anomalous sexual development in Puerto Rico is a major and serious public health problem. (...) We have been detecting an increase of such cases since early in 1969 (...) Up to this date over 1,500 patients have been documented.
>
> "From our patients, we have deducted that environmental contaminants are a strong factor in etiology of the condition that affects children of both sexes, different races and nationalities residing in PR, and all ages in the form of Anomalous Sexual Development. (...) We have documented clinical evidence of increased serum total oestrogens in a significant number of patients, with over 60 per cent of the females with ovarian cysts, variable levels of FSH, LG & Prolactin, that recede or diminish in a significant number of patients after a meat and poultry depletion diet.
>
> "We have been informed that anomalous sexual development cases are increasing in Chile, Bolivia and Colombia. As to our knowledge no definite cause have been found, but poultry and meat contamination is being considered, for in Latinamerica multiple use of growth promoting hormones have been documented. We consider that in PR the Anomalous Sexual Development in children is complex with different etiological factors such as zeranol, other unknown oestrogenic substances, and pesticides. Serious emphasis must be done on the control of these substances and its avoidance in animal husbandry. (...)"[124]

4.193 Finally, the European Communities argued that the US unwillingness to comply with the EC measures was the only obstruction to its exports. But the

[124] A. Pérez-Comas and C.A. Saénz, "Anomalous Sexual Development in Puerto Rico: 28 Years of Experience", 28 February 1997.

experience of the "Interim Measure" showed that individual farmers in the United States had no difficulty in complying with the EC level of protection. The number of companies in the United States which promoted their meat to the consumer as having been produced without the use of hormones was significant and growing.

(v) Administration and Use of Hormones

4.194 The **European Communities** claimed that there were additional risks to human and animal health arising from the administration and potential misuse of hormones. At the 1995 EC Scientific Conference, it had been observed that a misuse could be hazardous to consumers, if instead of the authorized implant cheaper black-market products were administered to the animals via injections at undefined parts of the animals' bodies. Moreover, injection could be given in addition to an authorized implant. Such misuse would probably not be analytically detectable, and not only in the case of endogenous substances. If the use of hormonally active substances were authorized, this would probably also lead to a dramatic reduction of the possibilities to reveal such a misuse with the help of detected injection sites, because there would no longer be indications to select animals during the post-and ante-mortem examination that were considered to be suspicious. On the contrary, each animal would have to be controlled for injection sites. Since this was completely unrealistic, a randomised selection of the carcasses was the only control for injection sites. Consumers could thus be subject to the risk of eating undetected, maybe highly contaminated, injection sites. Irrespective of the assessment of a number of hormonally active substances by the Codex, the principle that the health hazard of a substance depended only on its dosage continued to be valid also for the risk of injection sites. Particularly in the case of illegally administered black-market products, the dosage was not predictable. In the context of preventive protection of consumers' health, it was necessary to take the misuse potential of a substance into consideration when assessing health risks. If health risks to consumers could not be excluded when a substance was misused, single substances with an extreme misuse potential should also be banned even if the substances were not hazardous when legally used. Risks to consumers' health could not be excluded if clenbuterol and hormonally active growth promoters were abusively administered. It was questionable if the authorization of these substances as growth promoters would end their extreme misuse potential; the authorization of a substance distinctly restricted its controllability. Thus the misuse of authorized substances was hardly controllable. Because of the effect on sampling and inspection, the authorization of a substance always went hand-in-hand with a facilitated use of the corresponding black-market product.[125]

[125] B. Jülicher, "Sampling Strategies", *1995 EC Scientific Conference Proceedings*, pp.537-539.

4.195 The **United States** rejected the EC attempt to justify its ban on the grounds that it could not be sure that the hormones would always be administered correctly. It was not clear to the United States how this differed from the purported "detection and control risks", since in both cases the European Communities claimed to be concerned that unauthorized meat would slip past its detection. In any event, the same problems applied to this category of purported risk as applied to the EC detection and control concerns. The European Communities did not identify any particular risk, nor did it produce any risk assessment or evidence of risk. Furthermore, the European Communities did not explain why there was not always a potential for meat containing prohibited residues to evade its detection, even under its current ban. The European Communities had permitted the sale and consumption of domestic meat even in the face of admitted and well-publicized illegal use of hormones in its territory. The European Communities also permitted the importation of meat, including meat from animals to which had been administered hormones for purposes other than growth promotion. There could never be an absolute guarantee that the European Communities could detect every instance of an incorrect administration of hormones. With regard to the potential misuse of these products, the United States claimed that experts had acknowledged that even if misused, the residues of the six hormones might well be below the Codex (or FDA) MRLs (in the case of the three synthetic hormones). Indeed, direct injection (rather than use of an implant) of doses 100 times higher than approved doses still resulted in residues well below the established ADI.

4.196 The **European Communities** responded that it had no difficulty in admitting that a potential for meat to slip past its detection always existed and did not expect to detect "every instance" of illegal use. But at least in the European Communities there were comprehensive and costly residue control programmes designed and effectively applied to detect, as far as technically possible and economically feasible, such residues from all sources, unlike the practice in the United States. The fact that there was a potential for prohibited residues to evade its control and detection was not in itself a reason for the European Communities to adopt the US approach on this issue. To the contrary, this risk of residues of potentially carcinogenic substances evading detection was an important factor in carrying out a proper risk assessment and seriously influenced, right from the beginning, the decision of cautious Members in setting the level of sanitary protection they deemed appropriate in their territory.

(vi) Risks Arising from Other Parameters

4.197 The **European Communities** argued that a potential source of risk frequently mentioned by scientists stemmed from uncertainty about the nature and reliability of the methods used to establish the relevant data. The procedure for characterising the risk from the use of hormones had remained largely unchanged for 30 to 40 years and scientists had argued that the process of the scientific assessment of the risk should draw on the science base to assess the risk, then ad-

dress uncertainties, rather than fuse these two elements. However, a much sounder scientific approach was to encourage strongly the investigation of the mechanism of toxicity of each new promoter. Unless more effort were directed to understanding why a particular adverse effect of concern occurred (i.e. assessment of the mechanism of toxicity), risk assessment would always be vulnerable to the criticism that its scientific basis was flawed. Science continued to make rapid advances and no risk assessment could be regarded as the definitive statement for all time. A regular review procedure was needed, the frequency of which should be determined by such factors as the availability of new toxicological data; the level of uncertainty identified in the products' risk assessment; and findings from exposure monitoring investigations. All too often, further investigations of the risk ceased at the point at which a particular promoter was either accepted for use or rejected. Means of progressing the knowledge base, in the areas where substantial uncertainties existed, had to be found.[126]

4.198 The European Communities also submitted that the JECFA 1988 report stated that "insufficient data were available on normal levels in some classes of animals likely to be treated with oestradiol-17ß would fall within the normal ranges for untreated animals in each class". The European Communities argued that this lack of data, however, was thought not to be important and JECFA had based its conclusions on extrapolations from other data. In the end, JECFA did not think it necessary to establish MRLs, because of the impossibility of detecting residues of natural hormones in treated meat.

4.199 Furthermore, the European Communities argued that scientists had raised concerns with regard to the confidentiality of data. It had been suggested that a separate risk assessment must be conducted on each growth promoting substance drawing on all the available data, not simply that provided by a company wishing to market a product. This required improved accessibility to information classified as confidential. For this purpose, it had been suggested that a time-limit should be set on the confidentiality of safety data.[127] The European Communities submitted that the rationale for maintaining confidentiality was to maintain commercial secrets. The normal procedure to obtain an authorization to market an animal drug (for instance as followed in the United States) was for the drug sponsor to demonstrate to the relevant authority that an animal drug was safe and effective in the target animals, safe for humans consuming edible products from treated animals, and safe for the environment.

4.200 Moreover, the European Communities observed that frequently the relevant authorities of some countries were said to operate under a "zero risk" concept, although zero risk could not be determined and zero residues were probably

[126] Dr. J. Bridges and Dr. O. Bridges, "Hazards of Growth Promoting Agents and Strategies of Risk Assessment", *1995 EC Scientific Conference Proceedings*, pp.258-259.
[127] *Ibid.*, p.262.

not achievable.[128] But for the general public, the idea that zero risk residues were not achievable was difficult to accept. Rightly or wrongly, public perception frequently was that relying solely on safety data provided by a company was unsound.

4.201 The **United States** claimed that the EC arguments on uncertainty about the nature and reliability of the methods used to establish the relevant data and their confidentiality was misplaced. The European Communities had once more identified no particular risk, offered no risk assessment showing any risk, and produced no evidence of a risk. Its reliance on general uncertainty was again a generalized concern that was no more than unfounded speculation rather than an actual risk. The fact that there were limits to science was not a basis under the SPS Agreement to maintain a measure. The United States and other Members agreed that there were limits to science, but the Uruguay Round participants had negotiated and agreed to the SPS Agreement with its reliance on science in full recognition of those limits. Moreover, to state that the "evidence" on which the European Communities relied to maintain its measure was "a lack of information on, for example, the mode of action, the effect of administering combinations and the effect of ingesting residues over a long period" and claim as its evidence only that hormones in general exerted powerful physiological effects and were associated, under certain ill-defined circumstances, with adverse effects on health amounted to no more than speculation and scare tactics. In the US view, the European Communities had put forth no scientific evidence to support the existence of these risks.

(vii) The Precautionary Principle

4.202 The **European Communities** argued that all countries, including the United States, regulated the use of hormones in farm animals. The difference between the European Communities and the United States in this respect was the extent to which their use was regulated. This difference in degree of regulation was a reflection of the different levels of consumer protection adopted by the European Communities and the United States. The European Communities took a precautionary approach, placing the attainment of a high level of consumer protection before the commercial interests of farmers and pharmaceutical companies. The United States took a different approach. Where there existed a doubt over the safety of a product, the European Communities gave the benefit of doubt to the consumer, especially in cases where the potential risks might affect very large parts of the population. The United States had, in the case of growth hormones, given it to the producer.

[128] The European Communities noted that the United States was supposed to apply a "zero" risk standard for carcinogenic substances under the so-called "Delaney Clause". Furthermore, when presenting the WTO Agreement to Congress for approval, the US Federal Drug Agency had argued that its "zero-risk" policy was not affected by the WTO Agreements.

4.203 The European Communities stressed that the difference in degree of regulation between the United States and the European Communities was due to the greater attachment of the European Communities to the precautionary principle.[129] Such an approach was required to avoid situations as those portrayed by many cases of health hazards which only became apparent long after substances or products had been assumed to be safe, such as Thalidomide and DES. Two cases of recent interest in the European Communities illustrated the desirability of taking a precautionary approach to consumer protection: E. Coli and BSE.[130]

4.204 The European Communities noted that Dr. S.S. Epstein of the School of Public Health, University of Illinois at Chicago, had explained the risks from the use of these hormones for animal growth promotion as follows:

> "Although the carcinogenicity of DES in test animals was known as early as 1938, its use as a feed additive was approved by the USDA and the US FDA, in 1947 .... However, misleading assurances of safety and stonewalling by the FDA and USDA, including

[129] D. Freestone & E. Hey (1995), "The Precautionary Principle and International Law".

[130] The European Communities explained that E. Coli was a bacterium which inhabited the intestines of all animals. In the early days of food bacteriology it had been assumed to be ubiquitous and harmless. In the first FAO monograph on meat hygiene, published in 1957, it was stated that: "There are not convincing reports which directly implicate E. Coli in outbreaks of food poisoning". The second report of the Joint FAO/WHO Expert Committee on Meat Hygiene (1962) had considered that knowledge of the importance of E. Coli in causing food-borne disease was lacking and should be investigated. Even in 1974, Thornton's Textbook of Meat Hygiene stated that animal strains of E.Coli were "unlikely to become established in the human bowel". When the European Communities, in 1964, had adopted its first rules on meat hygiene, it had taken a precautionary approach, requiring hygienic structures, equipment and handling procedures with a view to preventing all bacterial contamination of meat. This approach had been strongly criticised by the United States on the grounds that it was not necessary to lay down detailed production and processing methods, as consumer protection could be assured by end-product testing for dangerous pathogens, which did not include E. Coli. Subsequently, outbreaks of bacterial food poisoning, including several large E. Coli outbreaks in which children had died, had persuaded the United States to review and propose radical changes to its meat hygiene rules. Yet, only twenty years ago, E. Coli was not considered to be a significant danger to human health.

With regard to BSE, the European Communities noted that this was a new disease of cattle. It had been first recognised in the United Kingdom only 10 years ago. When it had been found to be a member of the group of transmissible spongiform encephalopathies, it had been widely assumed to be the bovine form of scrapie, a disease of sheep recognised for over 250 years. As there was no evidence of a danger to human health from eating meat from scrapie-affected sheep, it had been assumed in some quarters that there would similarly be no danger to humans from BSE. That assumption had recently been challenged by the appearance of a cluster of cases of a new form of Creutzfeldt-Jakob disease, a human spongiform encephalopathy, which experts considered was likely linked to BSE. In this case, it was fortunate that a precautionary approach was taken at an early stage, despite the generally held view that any risk to humans was uncertain or extremely small. The tissues known to contain the BSE agent, as well as some in which infectivity had not been demonstrated but which could possibly be affected, were removed from the human food chain. At the time, this action was criticised in some quarters as an over-reaction but it now appeared to have been farsighted.

the deliberate suppression of residue data, managed to delay a US ban on DES until 1979.

"The meat industry then promptly switched to other carcinogenic additives, particularly natural sex hormones, which are implanted in the ears of commercially raised feedlot cattle. Unlike the synthetic DES, whose residues can be monitored and whose use was conditional on a seven-day preslaughter withdrawal period, residues of natural hormones are not routinely detectable because they cannot be differentiated from the same hormones produced by the body. Since 1983, the FDA has allowed virtually unregulated use for these natural additives right up to the time of slaughter, subject only to the non-enforceable requirement that residue levels in meat must be less than 1 per cent of the daily hormonal production in children.

"A dramatic warning of the dangers of growth-promoting additives was triggered by an epidemic of premature sexual development and ovarian cysts involving about 3,000 Puerto Rican infants and children from 1979 to 1981. These toxic effects were traced to hormonal contamination of fresh meat products and were usually reversed by simple dietary changes. Using highly specialized research techniques, independent testing found that samples of the meat products were contaminated with oestrogen residues more than tenfold in excess of normal ranges. Additionally, elevated levels of oestrogen and the synthetic zeranol were found in the blood of affected children. Increased rates of uterine and ovarian cancers in adult women were also associated with the epidemic.

"More than a decade ago, Roy Hertz, then director of endocrinology of the National Cancer Institute and a world authority on hormonal cancer, warned of the carcinogenic risks of oestrogenic feed additives, particularly for hormonally sensitive tissues such as breast tissue, because they could increase normal body hormonal levels and disturb delicately poised hormonal balances. Hertz pointed to evidence from innumerable animal tests and human clinical experience that such imbalance can be carcinogenic. Hertz also warned of the essentially uncontrolled and unregulated use for these extremely potent biological agents, no dietary levels of which can be regarded as safe. Even a dime-sized piece of meat contains billions of trillions of molecules of these carcinogens.

"Virtually the entire US population of consumers, without any warning, labelling, or information, ingests unknown and unpredictable amounts of hormonal residues in meat products over a lifetime. In 1986, as many as half of all cattle sampled in feedlots as large as 600 animals were found to have hormones illegally implanted in muscle rather than the ear skin, to induce further in-

> creased growth. This practice results in very high residues in meat, which even the FDA has admitted could produce "adverse effects". Left unanswered is whether such chronic and uncontrolled oestrogen dosages are involved in increasing cancer rates (now striking one in three Americans), particularly the alarming 50 per cent increase in the incidence of breast cancer since 1965. These questions are of further concern in the light of recent evidence confirming the association between breast cancer and oral contraceptives, whose oestrogen dosage over a fraction of a lifetime is known and controlled, in contrast with that from residues of growth hormones in meat products."[131]

4.205 The **United States** responded that the article by Dr. Epstein cited reports over a decade old, inaccurate for several reasons, and did not constitute scientific evidence in support of the EC ban. First, Dr. Epstein had not cited any evidence with respect to the safety of residues of the six hormones for growth promotion purposes. Second, Dr. Epstein's facts were wrong. In the case of Puerto Rico, in contrast to Dr. Epstein's assertion, the cause of the premature development had never been identified and the initial reports of zeranol in samples of patients' blood could not be confirmed.[132] Third, the reference to the article by Dr. Hertz was not relevant. Dr. Epstein attributed conclusions to Dr. Hertz that he had never made. Also, the reference to feed additives was a reference to DES, not to the six hormones. The United States submitted that with almost 30 years experience with the use of zeranol, there had not been any adverse effects reported on human health resulting from the legal use of this product in cattle or sheep.

4.206 The United States concluded that the "evidence" put forward by the European Communities did not support the risks it alleged. It noted that the report of the 1995 EC Conference set forth on page 4 a list of the "Principles of risk-assessment" which illustrated that the European Communities had *stopped* its analysis at what was supposed to be the *starting point* for a risk assessment. Those Principles stated that *"the starting point in any risk-assessment is to identify all the potential (or even hypothetical) hazards (or untoward outcomes) that may be caused by eating meat containing residues of growth-promoting substances"*. In the US view, the European Communities had failed to move to the next step. As the report notes: *"Risk is a different concept; it is the chance, or the likelihood, that a particular hazard will occur as a result of eating meat containing residues of growth-promoting substances"*. The United States argued that by failing to consider whether there was a chance or likelihood of any of the hypothesized hazards, the EC ban was not based on an "assessment of the relevant risks", as required by Articles 5.1 and 5.2.

---

[131] S.S. Epstein (1990), "The Chemical Jungle: Today's Beef Industry", *International Journal of Health Services*, Vol. 20, pp.278-279.

[132] Hannon *et al*. (1987), *Archives of Environmental Contaminants Toxicology*, Vol. 16, pp.255-262.

4.207 Furthermore, the SPS Agreement required for any sanitary measure that there be "sufficient scientific evidence" and an "assessment of the risks" or, under Article 5.7, "available pertinent information". The United States claimed that the "precautionary principle", which the European Communities attempted to use to justify its ban, was not an approach unique to the European Communities. A wide number of the world's governments had subscribed to the precautionary approach in Principle 15 of Agenda 21 of the Rio Declaration on Environment and Development ("Rio Declaration"). Nonetheless, the United States argued that the European Communities had misunderstood the precautionary approach. The precautionary approach called for taking action based on preliminary or inconclusive scientific information where it might be important to act in the absence of conclusive scientific information. One example of the application of the precautionary approach was global climate change. In that instance, preliminary scientific information indicated the need to act as a precaution even though a full scientific understanding had not yet been achieved. The United States claimed that Article 5.7 reflected the precautionary approach, but the European Communities had admitted that its ban was not pursuant to Article 5.7.

(viii) Animal Health Protection

4.208 The **European Communities** argued that one of the aims of the measures at issue were to protect animals from the use of these hormones for growth promotion. In the preparatory discussions, the European Parliament had considered "the possible adverse effects of these substances on the immunity against various diseases of *animals* and that this in turn may lead to an increased use of antibiotics".[133] Furthermore, the preamble and text of Directive 88/146/EEC clearly established that concerns of potential risks to animal health were also taken into account. The strict conditions imposed by the Directive on the use of these hormones for therapeutic and zootechnical purposes had as one of its objectives the protection of animal health from improper administration. Article 5 provided that the EC member States must ensure that "*no animals* are dispatched from their territory to that of another member State which have had administered to them in any way whatsoever substances with a thyrostatic, oestrogenic, androgenic or gestagenic action...", except for therapeutic or zootechnical purposes. Article 6(1) provided that "member States shall prohibit importation from third countries of *animals* and of meat from animals to which have been administered in any way whatsoever substances with a thyrostatic, oestrogenic, androgenic or gestagenic action", except for therapeutic or zootechnical purposes and under conditions equivalent to those applied in the European Communities. One objective of this prohibition was to protect animal health, since the prohibition on trade in such animals clearly discouraged the administration of these hormones in the first place.

[133] European Parliament's Resolution, *EC Official Journal*, No. C288/158, 11 November 1985.

4.209 The European Communities claimed that scientists agreed that doses of these hormones at levels which produced a hormonal activity were carcinogenic to laboratory animals. The 1988 JECFA Report had documented these carcinogenic effects. It had reported that oral and parenteral administration of oestradiol-17β could increase the incidence of tumours in experimental animals. These tumours *largely* occurred in tissues with high levels of specific hormone receptors which were *normally* responsive to stimulation by oestradiol-17β. JECFA had also noted that the incidence of tumours of the mammary gland, ovary, uterus and vagina were higher in animals treated with progesterone alone than in control animals. The incidence of uterine tumours was "surprisingly high" and the incidence of prostatic tumours was higher in rodents treated with high doses of testosterone, than in control animals. JECFA concluded that the carcinogenic responses were related to the hormonal activities of each of these three hormones.

4.210 The European Communities noted that JECFA had also found liver hyperplasia and tumours in mice fed high doses of trenbolone acetate and slight increases in the incidence of islet-cell tumours of the pancreas of rats, which JECFA concluded arose as a consequence of the hormonal activity of the trenbolone metabolites. The JECFA review of zeranol noted oestrogenic but not carcinogenic effects in rats. In mice, however, higher incidence of anterior lobe tumours of the pituitary gland occurred than in mice in the negative control group. JECFA reported that such tumours rarely occurred spontaneously in mice but were known to result from administration of oestrogenic hormones. JECFA again concluded that the tumorigenic effect of zeranol was associated with its oestrogenic properties.

4.211 The various carcinogenic effects mentioned by the 1988 JECFA Report on laboratory animals were explained more fully in the reports of the International Agency for Research on Cancer (IARC). IARC Monograph, Supplement 7, 1987, reported sufficient evidence of carcinogenicity to animals from oestradiol-17β and progesterone. IARC noted that administration to mice of oestradiol-17β and its esters increased the incidence of mammary, pituitary, uterine, cervical, vaginal, testicular, lymphoid and bone tumours. In rats, there was an increased incidence of mammary and/or pituitary tumours. In hamsters, a high incidence of malignant kidney tumours occurred in intact and castrated males and in ovariectomized females, but not in intact females. In guinea-pigs, diffuse fibromyomatous uterine and abdominal lesions were observed. IARC reported that progesterone increased the incidence of ovarian, uterine and mammary tumours in mice. Dogs treated with progesterone for four years developed a dose-related incidence of mammary-gland nodules. Importantly, IARC indicated that there was evidence that *low* doses of progesterone administered over long periods acted in combination with carcinogenic agents, such as some viruses or chemicals, to enhance tumour developments. Therefore, *long-term administration* of synthetic progestins

could produce a comparable hazard by increasing the incidence of tumours due to other agents.[134]

4.212 The IARC had also found that zeralenone, a metabolite of zeranol, in the diet of laboratory animals had carcinogenic effects[135], and had caused other effects, including:

> "... atrophy of the seminal vesicles and testes, squamous metaplasia of the prostate gland, osteopetrosis, myelofibrosis of the bone marrow, cytoplasmic vacuolization of the adrenal glands, hyperkeratosis of the vagina and endometrial hyperplasia ... pseudopregnancy [and] infertility."[136]

In addition, consumption of zeralenone by pregnant animals caused a reduction in fetal weight and an increased prevalence of skeletal problems and incidence of stillbirths.[137] As regards the carcinogenic effects of the hormone MGA, published data documented the induction of a statistically significant incidence of mammary tumours in female mice.[138]

4.213 The European Communities added that the above carcinogenic effects were not the only negative effects which the administration of these hormones had on animals. The 1995 EC Scientific Conference had documented a number of other effects which resulted from these hormones.[139] Such negative effects included increases in liver abscesses, fertility problems, effects on male reproduction, alteration of gonadal function, decrease in pregnancy rates, increase of embryonic or fetal mortality rates, etc. The risks to animals of these negative effects were as high as (or even higher than) the risks these hormones posed to human beings, since they were administered directly to the animals and improper use could easily multiply the potential negative effects.

4.214 The **United States** noted that the protection of animal health was irrelevant to this case. The European Communities did not claim that its ban was designed to protect animal health in the territory of other Members, and imports of meat in this case were not relevant to the protection of the health of animals within the European Communities. In any case, data suggested that animals to which had been administered these hormones for growth promotion purposes were in fact healthier.

4.215 The **European Communities** stressed that it did not argue that the measures at issue were designed to protect animal health in the territory of other

---

134 *21 IARC Monographs*, p.132.
135 *56 IARC Monographs*, p.431; and *31 IARC Monographs*, p.287.
136 *Ibid.*, p.417.
137 *Ibid.*, pp.421-422.
138 J.W. Lauderdale *et al.* (1977), "Studies of a progesterone (MGA) as related to residues and human consumption", Vol. 3, pp.5-33.
139 R. Renaville, S. Massart, A. Prandi, U. Fazzini, M. Sindic, L. Nicolay, M. Falaki, A. Burny & D. Portetelle, "Aspects on the Use of Anablic Steroids in Animal Production", *1995 EC Scientific Conference Proceedings*, pp.75-77.

Members (regardless of how desirable that would have been). But the European Communities believed that it had the right under the WTO rules (and in particular the SPS Agreement) to prohibit imports from third countries of animals to which these hormones had been administered for the reasons explained above. This prohibition was not discriminatory, as it applied in exactly the same way to trade in such animals within the European Communities.

(f) Article 5.4 of the SPS Agreement

4.216 The **European Communities** claimed that Article 5.4 provided that Members *should (*not *shall)* take into account the objective of minimizing negative trade effects. This was complied with both in respect of intra-Community trade and trade with third countries. Only a high level of protection chosen by the European Communities would have ensured the flow of trade in the internal market. The imposition of veterinary controls on the use of hormones as growth promoters would have caused insuperable barriers to trade with third countries. Moreover, a government was not obliged to lower its level of protection below what it considered to be necessary. It should only keep in mind the objective of not going *beyond* what was necessary.

(g) Article 5.5 of the SPS Agreement

4.217 The **United States** further observed that the European Communities also claimed that its measures were consistent with Article 5.5. This was not accurate. The United States had shown that there was no scientific evidence that there was a risk to human health from the residues of the hormones when used for growth promotion. However, even if one were to disregard all of the scientific evidence and risk assessments that had been conducted and were to assume instead that these residues did pose a risk, the EC ban would still be inconsistent with Article 5.5. Article 5.5 provided in its relevant part that "each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade." Thus, Article 5.5 established a two-step test with respect to distinctions between a Member's appropriate level of protection in different situations: was the distinction in the levels of protection (i) either arbitrary *or* unjustifiable and (ii) did this distinction result in either discrimination *or* a disguised restriction on international trade.

4.218 The **European Communities** argued that Article 5.5 required consistency only in terms of avoiding arbitrary or unjustifiable distinctions in *applying* the chosen level of protection, and then only if such distinctions resulted in discrimination or a disguised restriction on trade. It could not be interpreted as requiring consistency in *setting* or *deciding* the level of protection, since the text would have specified it. This interpretation was consistent with the preamble, which stated that the harmonization of SPS measures did not require Members to change their appropriate level of protection. It followed from this that Article 5.5

did not require Members to achieve consistency between the level of protection which they chose against *different* hazards to human, animal and plant life and health. This would in any case be an illogical requirement; no Member protected individual plants to the same extent that it protected individual humans. Consistency of *application* meant that Members must in all circumstances apply *measures* which were capable of achieving the same level of protection against a given hazard unless there was justifiable reason in a particular situation to apply difference measures to achieve a different level of protection.

4.219 The European Communities had followed exactly the same principles for other drugs and food additives as it had for hormones. All such substances were evaluated on a case-by-case basis and where substances were deemed too dangerous, or potentially dangerous, to allow their residues in food, a zero tolerance was fixed. As an example, the use of antibiotics in livestock was regulated in the European Communities by forbidding the use as growth promoters of those antibiotics which were of therapeutic value in humans, in order to avoid problems of antibiotic resistance.

4.220 The **United States** argued that the EC claim that its measures were applied in exactly the same way to achieve the same level of protection in respect of all meat intended to be placed on the market in the European Communities, whatever its origin, was not accurate. The European Communities in fact applied different levels of protection to different meat. The European Communities had suggested that its appropriate level of protection with respect to the six hormones when used for growth promotion purposes was "zero risk". However, it had chosen a different, less stringent, level of protection with respect to carbadox. Carbadox was a substance that the European Communities permitted to be used for growth promotion purposes in the production of swine. It was a feed additive that was a known *genotoxic* carcinogen[140], unlike the six hormones. The experts advising the Panel all confirmed that carbadox was genotoxic. Genotoxic meant that scientists considered carbadox to induce cancer. By permitting its use and the sale and consumption of meat from animals to which carbadox had been administered, the European Communities had chosen an appropriate level of protection that was less stringent than for the six hormones involved in this dispute. There was no principle or criterion that accounted for the different treatment by the European Communities of harmless residues, in the case of the hormone ban, as compared to residues of carbadox. If the different treatment resulted from the EC selection of differing "appropriate" levels of sanitary protection, and in the absence of any principle or criterion that accounted for the distinction, then the distinction in the levels of protection was arbitrary and unjustifiable.

4.221 The United States noted that Article 5.5 required that if the challenged distinction in levels of protection were arbitrary or unjustifiable, consideration must be given to the second test, whether the distinction in levels of protection

[140] *36th report of JECFA* (1990), pp.45-50.

resulted in a disguised restriction on international trade. Carbadox was used in swine production. The six hormones were used mainly in cattle production. It was no coincidence that the European Communities had banned the use of the six hormones for growth promotion purposes while permitting the use of swine growth promotants. The EC swine industry was relatively more efficient and market-oriented than the beef sector. Efficiency in beef production was not as important in the European Communities, since that sector relied more heavily on EC domestic price support measures, import protection and export subsidies. Unlike beef, there was virtually no acquisition of pork under the EC intervention scheme. Also, in contrast to beef, EC pork could be exported to the United States without the use of export subsidies. As the United States had demonstrated, the European Communities clearly wanted to reduce beef supplies when it extended the hormone ban. The European Communities had no comparable concerns with respect to its pork sector. On the contrary, it needed to preserve competitiveness in order to maintain export markets. Therefore, it continued to permit the use of growth promotants for swine. As a result, the European Communities had set its appropriate level of protection for the six hormones at a more stringent level than that for carbadox because it needed to protect its beef industry from competition. The distinction in the EC levels of protection resulted in a disguised restriction on international trade.

4.222 The United States claimed that despite its arguments to the contrary, the European Communities must believe that there was a threshold of safety for synthetic hormones, since it permitted the use of synthetic hormones, for example allyl-trenbolone[141] (altrenogest), a feed additive for oestrus control in swine and horses. Allyl-trenbolone was a synthetic sex steroid with progestational activity[142], not approved for use in the United States. In addition, the European Communities allowed the use of medroxyprogesterone acetate, not a natural progesterone, as a vaginal implant for oestrus control in sheep. In all these instances the European Communities allowed meat from animals so treated to be sold and consumed. Furthermore, the European Communities accepted that there was a threshold for harm in the case of other compounds administered to farm animals. One such example was sulfamethazine, which caused thyroid cancer in laboratory animals, yet the effect was considered by JECFA to occur only above a threshold level. In that case the European Communities had no difficulty accepting the JECFA assessment and had set an MRL for this compound. Sulfamethazine was used in the European Communities for the treatment of respiratory ailments in chickens, cattle and swine. Apparently the European Communities only believed that there was no threshold for harm when such a position assisted it in discriminating against the banned meat and animals.

---

[141] EC Directive 96/22/EC, Art 4, 2(I).

[142] A.R. Peters (1992) "Endocrine Manipulation-Toxicological Frontiers", *J. Reprod Feter* Suppl 45, pp.193-201.

(h) Article 5.6 of the SPS Agreement

4.223 The **United States** recalled that Article 5.6 required Members, when establishing or maintaining a sanitary measure to achieve the appropriate level of sanitary or phytosanitary protection, to ensure that such a measure was not more trade-restrictive than required to achieve their appropriate level of sanitary protection, taking into account technical and economic feasibility.[143] The EC measures were "more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection"[144], contrary to Article 5.6. The EC ban was not intended to achieve any particular level of sanitary protection from any identified risk, and regulated meat based on the production method used rather than on any level of residues of hormones in the meat. For the United States, the level of any risk, if one could have been identified, would have presumably been related to the level of residues. Moreover, an "appropriate level of sanitary or phytosanitary protection" required that there be a particular risk to be protected against and the European Communities had failed to identify any particular risk from any of these hormones when used in accordance with good animal husbandry practice. The United States submitted that the EC ban stopped meat with one level of hormone residues from being imported and sold while permitting meat with higher levels of residues of the same hormone to be sold, because it continued to allow the human consumption of domestically-produced meat from animals administered hormones for therapeutic purposes, as well as meat with levels of endogenous hormones higher than those found in meat from animals administered the same hormones for growth promotion. Similarly, the European Communities permitted meat from pregnant dairy cows or from bulls and other food products (such as milk, butter and eggs) to be produced, marketed, consumed and used in food processing, although these products contained far higher levels of endogenous hormone residues than meat derived from steers and heifers treated with the six hormones. Consequently, the European Communities permitted the human consumption of endogenous hormone residues without any limitation while banning imported meat from animals administered safe hormones for growth promotion purposes. Furthermore, the EC ban was more trade restrictive than required because it severely restricted trade, although it was not designed to protect against any particular risk, nor to achieve a particular level of protection from that risk. The EC import ban applied regardless of whether the hormones were administered properly, regardless of any withdrawal period, and regardless of the levels of any residues of the hormones in the meat. Thus, the EC

[143] The footnote to Article 5.6 reads: "For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade."

[144] "Appropriate level of sanitary or phytosanitary protection" is defined in paragraph 5 of Annex A of the SPS Agreement as "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory".

measures were of the most extreme form possible short of a total ban on imports of meat.

4.224 The **European Communities** submitted that from the sequence of events which had led to the adoption of Directive 88/146/EC, it was clear that the European Communities had examined carefully the potential risks to human and animal health from the use of these hormones for animal growth promotion purposes. It had considered the scientific evidence which suggested that these substances, if used in accordance with good veterinary practice, did not seem to pose risks to human and animal health, but which did not exclude beyond doubt that they posed potential risks to human health. The European Communities had examined carefully all of the available options for ensuring the proper conditions of use and control of these substances before concluding that, at present, the ban on their use was the only scientifically, technically and economically feasible option.

4.225 The **United States** claimed that, even if (putting aside the lack of a scientific basis for the EC ban) one were to accept the EC "scientific evidence", the ban would be overbroad and thus was more trade-restrictive than required to achieve the EC appropriate level of sanitary protection. The European Communities did not contest that any human health risk from hormones in meat would be due to the *residues* of the hormones in the meat. Yet the European Communities had not regulated residue levels of these hormones. If the European Communities had serious concerns about health risks from hormones, then it would have regulated the *level* of residues of hormones. Instead, the European Communities banned selected uses of these hormones while ignoring the actual levels of residues to which consumers were naturally exposed from meat or other dietary sources. This was also true with respect to the three synthetic hormones. The European Communities did not regulate residue levels. According to the European Communities' own inaccurate claim, after a sufficient waiting time prior to slaughter, there would be no residues of the three synthetic hormones in meat from animals to which these hormones had been administered for growth promotion purposes. Yet the European Communities had still banned the meat. In other words, if it believed that hormones posed a health risk at exposures above a set level, the European Communities would have regulated the levels of hormones allowed in food in order to ensure that the set level was not exceeded, rather than imposing an absolute ban on the use of these hormones for growth promotion purposes with respect to animals, and meat thereof, exported to the European Communities. The European Communities had failed to do so, thus casting doubts on the credibility of its arguments.

4.226 The United States claimed that the obvious way to regulate the levels of residues in meat was through MRLs (bearing in mind that Codex had concluded that it was unnecessary to establish an MRL for residues of the three natural hormones administered for growth promotion purposes in accordance with good animal husbandry practice). To pretend that MRLs were not technically or economically feasible was directly at odds with the EC claim that "at least in the European Communities there were comprehensive and costly residue control

programmes designed and effectively applied to detect, as far as technically possible and economically feasible, such residues from all sources".

4.227 The **European Communities** argued that its appropriate level of protection was the assurance that meat would not contain residues of administered hormones and that this was achieved by requiring stringent veterinary controls on the use of hormones in food animals, including a restriction on such use to certain specified therapeutic or zootechnical applications. The European Communities considered that an examination of the possibility of extending this permission to the routine use as growth promoters revealed that the scale of meat production would render controls technically impossible, and that in any case the costs of control would be so high as to render such use uneconomic.

4.228 The European Communities indicated that the required control and monitoring system had been examined by the competent democratic institutions of the European Communities and rejected for a number of reasons. One concern was *costs*: it would be so expensive to restrict the supply and administration of hormone growth promoters by veterinarians that the costs would outweigh the benefits. Furthermore, *control* was a problem due to the scale of livestock production and the fact that implantation of growth promoters must be performed at certain restricted times of the growth period; it would be technically impossible to ensure at all times, and at reasonable administrative and economic costs, a proper administration of hormones. Another concern related to the *bureaucracy*; the recording of the treatment of individual animals and their checking at slaughter for the presence of implants (to ensure they had been correctly administered) would be a heavy and expensive bureaucratic burden and would further add to the cost of the process.

4.229 The European Communities argued that *inspection* raised other problems. The inevitable failure to find remnants of implants at slaughter in some animals (due to migration from the implant site, or mal-administration) would entail further expensive examination and residue testing, adding further to the cost. Residue testing would, of course, have to include the same testing and corresponding costs mentioned above in respect of third-country meat imported into the European Communities, as the European Communities would not be able, in the absence of internationally agreed rules on controls and testing, the widely diverging practices of Members, and the obvious and powerful economic incentives for meat producers to disregard the rules, to rely entirely on testing and controls carried out by third countries.

4.230 Furthermore, the European Communities argued that the installation and control of a *labelling* system to ensure integrity of identification from the live animal through slaughter and processing to a meat product would also be extremely expensive and laborious. The cost would have to be borne by the product, which again would render the whole process uneconomic. Retail premises, including restaurants, which supplied unwrapped meat directly to the consumer would have to carry a prominent warning that they used meat from animals treated with hormones. This would be a strong disincentive to using such meat

and would thus amount to a restriction on trade. In addition, consumers would not be able to make reliable authentic choices (e.g. of meat served in restaurants).

4.231 All of these considerations had led the European Communities to consider that the only technically and economically feasible measure to ensure that its appropriate level of protection was met was the ban. Any other requirements would have had the effect of stopping trade. The only alternative, a ban on the use of hormones for growth promotion purposes, however, had permitted trade in meat to continue.

4.232 The **United States** considered the EC arguments about technical feasibility and costs to be unfounded. With respect to *administration costs*, there was no justification for limiting the supply and administration of the hormones to veterinarians in all circumstances. Who administered the hormone had no connection to the residue level. The European Communities did not require administration by a veterinarian in all circumstances as could be seen for example from Directive 96/22/EC, Article 1.2(c)(I) and the second paragraph under Article 5. Furthermore, a concern that costs might outweigh the benefits was a consideration for the marketplace. It was not for the European Communities to prejudge the question by banning the importation of animals and meat. The WTO agreements provided for competitive *opportunities*, and the question here was why the European Communities would not provide the opportunity to supply animals and meat.

4.233 The United States argued that the European Communities had provided no reason to conclude that the *costs of inspection* under an MRL regime would be different from the costs under their current ban. One assumed that the European Communities were exercising oversight and enforcement with respect to imports of animals and meat now to ensure that no banned animals or meat were imported. It was difficult to understand why there would be less monitoring in the case of a ban than there would be in the case of MRLs. The European Communities was saying that it did not even have to *try* to identify programmes that would permit importation. This was contrary to the approach taken in the report of the Appellate Body on United States - Standards for Reformulated and Conventional Gasoline (AB-1996-1). The EC claims were also directly at odds with its statement that "at least in the European Communities there were comprehensive and costly residue control programmes designed and effectively applied to detect, as far as technically possible and economically feasible, such residues from all sources".

4.234 With regard to *control*, the United States noted that the European Communities had failed to make clear why the cost of control programmes undertaken in producing countries was relevant to the import ban. Countries had already undertaken expensive and extensive control programmes to comply with the current ban (for example, Australia had reported a cost in the order of $A10 million per year for its control programme to comply with the EC ban). These were not costs that would be borne by the European Communities. Why would these costs make an MRL regime not a technically or economically feasible alternative to the ab-

solute ban currently in place? Presumably a country exporting now to the European Communities could choose not to adopt any new measures to take advantage of any trade opportunities presented by an MRL regime, and that country would be no worse off than at present.

4.235 The United States dismissed the EC arguments on *bureaucracy*. Any bureaucratic burden in third countries that might result from an MRL regime did not constitute a reason for concluding that the MRL regime was not a technically or economically feasible alternative to the EC current ban. The same criticisms that applied to inspection and control also applied to this reasoning. The United States suggested that the European Communities could choose to maintain its ban with respect to domestically produced animals and meat if that was less costly for the European Communities, while applying an MRL regime to imports of meat.

4.236 The United States concluded that the European Communities had not explained, and could not explain, how it was unable to control the use of these hormones without a complete ban while other countries managed to effectively regulate the use of these hormones for growth promotion purposes without enormous costs. It was clear that the ban restricted trade. It had severely disrupted exports of meat and animals from the United States, and was not required for health protection. The risk assessments that had been performed had all concluded that these hormones could be safely used for growth promotion. The European Communities had presented no new scientific evidence to contradict those scientific conclusions or to demonstrate that the ban was required for protection from any identifiable risk. If there had been evidence of risks associated with certain levels of hormone residues in meat, then the European Communities should control the level of the residues rather than banning the use of the hormones altogether. Moreover, the European Communities had been unable to articulate any particular level of protection that the ban was required to achieve. As a result, in the absence of any clearly articulated level of protection, it could be presumed that the EC ban was more trade-restrictive than required, in contravention to Article 5.6.

4.237 The **European Communities** claimed that the United States had failed to discharge its burden of proof in this case. In particular, it had failed to establish that, on the face of the overwhelming scientific evidence that the use of hormones for animal growth promotion was potentially very dangerous to public and animal health, there were other type of *measures* which, whilst significantly less restrictive on trade, were capable of ensuring that the *level* of protection which the European Communities had chosen in this case (zero residue of hormones in animals and meat) was effectively achieved. Conversely, the European Communities had examined all of the alternatives in 1984 and again in April 1996, and had concluded that the prohibition on use of these hormones in animal growth promotion was the *only* reasonably available and less trade restrictive measure.

(i) Article 5.7 of the SPS Agreement

4.238 The **United States** argued that if the European Communities could not justify its ban as falling within the exception provided in Article 5.7, which dealt with "cases where relevant scientific evidence is insufficient" and permitted a Member to "provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information". These hormones had all been thoroughly tested, examined and reviewed. The scientific community had been able to conduct thorough risk assessments on the use of these hormones. The assessments had all concluded that these hormones did not pose any identified risk to human life or health when used in accordance with good animal husbandry practices. Both groups of scientists assigned by the European Communities to review the hormones had been able to reach a conclusion that the hormones were safe, based on the available scientific evidence. The United States concluded that the European Communities had never presented any "available pertinent information" on which it had based its ban, as required by Article 5.7. It would also be difficult, over 10 years after adoption and over seven years after they had gone into effect, to describe the EC measures as "provisional" as called for in Article 5.7.

4.239 The **European Communities** responded that the EC measures were not "provisional". They were definitive. Moreover, no risk assessment of hormones had been completely "thorough", due to lack of information. The European Communities stressed that the SPS Agreement required Members to carry out a risk assessment, not the scientific community. More importantly, the scientific evidence concerning the need to regulate the use of hormones was in itself sufficient to justify its legislation and the European Communities did not need to rely on the exception provided for in Article 5.7 concerning cases where relevant scientific evidence was insufficient. Nevertheless, the European Communities stressed that all expert opinion, including that of the 1988 JECFA Report on which Codex had based its decision, had concluded that scientific evidence did not exist concerning the mode of action, the effect of using mixtures of hormones and the long-term effects of exposure on consumers. The European Communities concluded that its measures were not "provisional" but, on the contrary, they were definitive.

3. Agreement on Technical Barriers to Trade

4.240 The **United States** submitted that the Agreement on Technical Barriers to Trade (TBT Agreement) was designed to ensure that a Member's technical regulations did not create unnecessary obstacles to trade. This was reflected both in Article 2.2 of the TBT Agreement and in clause 5 of the preamble.[145] The TBT

[145] Article 2.2 of the TBT Agreement provides: "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade." Clause 5 of the preamble expresses that the Members enter into the TBT

Agreement applied to "[a]ll products, including industrial and agricultural products"[146], and applied to "technical regulations" which were defined in the Agreement. The Agreement established a number of disciplines designed to ensure that a Member's technical regulations did not create unnecessary obstacles to trade, including the obligations contained in Articles 2.1 and 2.2 of the TBT Agreement. Although Article 1.5 of the TBT Agreement recognized that some sanitary and phytosanitary measures met the terms of the definitions of "technical regulation", "standard" and "conformity assessment procedure", the drafters of the TBT Agreement had made explicit that where a technical regulation, standard, or conformity assessment procedure was a sanitary or phytosanitary measure, the SPS Agreement, not the TBT Agreement, applied.[147] Whether a measure was a sanitary measure under the SPS Agreement depended on the *purpose* of the measure. The United States had shown that the EC measures were sanitary measures as defined in the SPS Agreement. Accordingly, they were not subject to the TBT Agreement by virtue of Article 1.5 of the TBT Agreement, but were subject to the SPS Agreement. However, the TBT Agreement's provisions demonstrated the full degree to which the EC ban was fundamentally incompatible with the EC WTO obligations. Even if the EC ban did not consist of sanitary measures, the European Communities still could not maintain the ban since it would be inconsistent with the TBT Agreement.

4.241 The United States submitted that the EC measures were technical regulations. They laid down mandatory process and production methods (PPMs) related to product characteristics for animals and meat. They prohibited the sale of animals to which had been administered any of the six hormones for growth promotion purposes, and meat from such animals. The European Communities did not contest that its measures were mandatory PPMs and during the debate on its measures in the Tokyo Round Committee on Technical Barriers to Trade, the European Communities had insisted that its measures were "requirements which had been drafted in the EEC Directive in terms of a PPM".[148] Similarly, the European Communities' own statements established that the PPMs were related to the characteristics of the product. For example, Directive 81/602/EEC cited the EC concern over "the residues [the substances] leave in meat".[149] The United States claimed that (as demonstrated by the discussion under Articles I

Agreement "*Desiring* ... to ensure that technical regulations ... do not create unnecessary obstacles to international trade."

[146] Article 1.3 of the TBT Agreement.

[147] The United States noted that a similar "carve-out" was provided for government purchasing specifications in Article 1.4 of the TBT Agreement.

[148] See, for example, TBT/M/Spec/5 (Minutes of Meeting held 22 May 1987), paragraph 9. See also the communication from the European Communities (TBT/Spec/21), of 23 July 1987, in which the European Communities states: *"The EC Directive constitutes a PPM.* The EC Directive establishes the principle of non-administration of hormonal substances for fattening purposes to animals of which the meat is exported to the EC. It thus constitutes a regulation in the form of a process or production method and not a standard expressed in terms of product characteristics."

[149] Clause 5 of the Preamble.

and III of GATT) the EC measures treated meat imported from the United States less favourably than like products produced within the European Communities and originating in the territory of other Members. The term "like product" was not defined in the TBT Agreement, but given the direct parallel between the language of Article 2.1 of the TBT Agreement and Article III:4 of GATT, the GATT approach to "like product" should apply. Similarly, given the direct parallels between Article 2.1 of the TBT Agreement and Articles I and III of GATT, a technical regulation that was inconsistent with Articles I or III of GATT should also be inconsistent with Article 2.1 of the TBT Agreement. Accordingly, for the same reasons that the EC ban was inconsistent with Articles I and III of GATT, it would be inconsistent with Article 2.1 of the TBT Agreement.

4.242 The United States claimed that inherent in Article 2.2 of the TBT Agreement was the requirement that a technical regulation fulfil a *legitimate* objective. Protection of domestic production was *not* a legitimate objective. The benefits of the WTO agreements would be nullified or impaired if Members were permitted to design their technical regulations in order to protect domestic production. This was reflected both in the prohibition in Article 2.2 on creating "unnecessary obstacles to trade" and in the statement in Article III:1 of GATT that internal measures should not be applied "so as to afford protection to domestic production". Yet, as shown in the discussion of Article III of GATT and the SPS Agreement, the EC measures were disguised protectionism, designed to restrict trade. Therefore, these measures were more trade-restrictive than necessary to fulfil a legitimate objective.

4.243 The United States stressed that the European Communities had required under paragraph 7 of Article 6 of Directive 88/146/EEC that conformity assessment procedures be established with respect to imports. However, this provision required that "[i]n accordance with the procedure laid down in Article 8, a control programme shall be drawn up regarding imports from third countries, to ensure that imports do not receive more favourable treatment than EC products."[150] In other words, the EC approach had reversed the general principle that imports were to be accorded no less favourable treatment than domestic production. Instead, treatment of imports was to be subverted to the objective of ensuring that imports received no more favourable treatment than domestic production. Not only was this contrary to Article 5.1.1 of the TBT Agreement, but it was an approach that clearly required that the EC conformity assessment procedures with respect to imports be prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade. Requiring that the conformity assessment procedures for imports be made more onerous wherever necessary to ensure that imports did not receive more favourable treatment than domestic production was not consistent with the requirement in Article 5.1.2 of

[150] The United States noted that similar language was found in Article 6 of Directive 81/602/EEC.

the TBT Agreement that "conformity assessment procedures shall not be more strict or be applied more strictly than is necessary".

4.244 The **European Communities** responded that in the present case, it agreed that the measures challenged were better defined as measures falling within the scope of the SPS Agreement rather than the TBT Agreement. The European Communities therefore did not respond to the arguments made by the United States as regards the TBT Agreement.

4. GATT 1994

(a) Article III:4 of GATT

4.245 The **United States** claimed that despite the requirements of Article III:4 of GATT, the EC ban prohibited the importation and sale of certain imported meat, while permitting the sale of like domestic products. The EC measures distinguished between:

(i) animals, and meat from animals, to which had been administered any of the hormones at issue for growth promotion purposes; and

(ii) animals, and meat from animals, to which any of the hormones had never been administered, or to which the three natural hormones had been administered for therapeutic purposes.

The United States maintained that there was no legitimate basis for the EC distinction. Not only was there no basis for distinguishing between these like products due to any risk to human health, because there was no basis for claiming a health risk from meat produced using the six hormones, but the European Communities' other basis for the measures stated a *proscribed* purpose, the protection of domestic production.[151]

4.246 Although the term "like product" had not been defined in GATT 1994, the United States observed that under GATT 1947 and GATT 1994 the approach had been to examine whether products were "like" on a case-by-case basis. In making a determination whether products were "like", panels had considered factors such as physical characteristics, end-uses, tariff classification and substitutability.[152] The United States argued that in this instance, animals, and meat

[151] Article III:1 of GATT provides that:

> "1. The contracting parties recognize that internal taxes and other internal charges, and laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products, and internal quantitative regulations requiring the mixture, processing or use of products in specified amounts or proportions, *should not be applied to imported or domestic products so as to afford protection to domestic production*" (emphasis added).

[152] The United States noted for example the panel reports on "United States - Measures Affecting Alcoholic and Malt Beverages", DS23/R, BISD 39S/209; "Japan - Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages", BISD 34S/83; and paragraph 6.9 of

from animals, to which had been administered any of the hormones for growth promotion purposes were clearly "like" other animals and meat from other animals. In fact, in the case of the three natural hormones, meat from an animal to which the hormone had been administered for growth promotion purposes could be physically identical to meat from an animal to which no hormone had been administered, or to which a hormone had been administered for therapeutic purposes. There was no difference at all between such physically identical products and thus no basis to distinguish between them for health or other legitimate purposes.

4.247 The United States claimed that as it had demonstrated in the discussion of the EC measures under the SPS Agreement, these hormones were naturally occurring in food animals, and their levels varied widely even among animals of the same species. Thus, for example, a heifer would naturally have higher levels of oestrogen than a steer to which oestradiol-17β had been administered. Whether there was a residue did not depend on whether the hormone was administered for growth promotion or for therapeutic purposes. Similarly, with respect to the synthetic hormones, there was nothing about these hormones that altered the physical characteristics, end-uses, tariff classification or substitutability in a way that would render animals, and meat from animals, to which these had been administered "unlike" animals, and meat from animals, to which they had not been administered. The synthetic hormones were rapidly metabolized by the animals and any remaining residues in the meat were safe.

4.248 The **European Communities** responded that because female animals are treated for growth promotion with male hormones, and vice-versa, the residues in an animal treated with a natural hormone are *different* from, as well as greater than, those which it would otherwise contain. The human diet normally contained a variety of meat; evidently if all the meat came from treated animals the amount of hormone residue ingested would be significantly increased. If a proper comparison were to be made involving male animals, it would have to be between treated and untreated males to see how far the levels of female hormones were increased in male animals. According to the US argument, heifer meat would be "within the normal range" if it contained as much testosterone as bull meat.

4.249 The **United States** argued that Article III of GATT had been interpreted to permit governments to distinguish between otherwise like products for legitimate regulatory purposes. As stated in the panel report on United States - Taxes on Automobiles: "Article III serves only to prohibit regulatory distinctions between products applied so as to afford protection to domestic production. Its purpose is not to prohibit fiscal and regulatory distinctions applied so as to achieve other policy goals. This view had been expressed in a recent panel report, which states:

---

the panel report on "United States - Standards for Reformulated and Conventional Gasoline", adopted on 19 June 1996, WT/DS2/R.

> "The purpose of Article III is ... not to prevent contracting parties from using their fiscal and regulatory powers for purposes other than to afford protection to domestic production. Specifically, the purpose of Article III is not to prevent contracting parties from differentiating between different product categories for policy purposes unrelated to the protection of domestic production. The Panel considered that the limited purpose of Article III has to be taken into account in interpreting the term "like products" in this Article. Consequently, in determining whether two products subject to different treatment are like products, it is necessary to consider whether such product differentiation is being made "so as to afford protection to domestic production".[153]

4.250 The United States did not contest the right of the European Communities to distinguish between products for legitimate policy purposes. Members' ability to so distinguish was confirmed by the text and history of Article III of GATT and the TBT Agreement. However, the United States did contest the legitimacy of the policy goal advanced by the European Communities for its discrimination. The European Communities had claimed health concerns as the basis for its ban, but all six of the hormones involved in this dispute had been determined to be safe by all the scientific experts that had reviewed them. Moreover, the European Communities had never put forward any basis to contest the safety of these hormones. The European Communities had also stated a competition rationale for its ban. However, in the US view, whatever the merits might be of harmonizing regulatory treatment within a Member's territory, such a policy was difficult to reconcile with GATT when the policy was applied to imports with no other health, environmental, or other legitimate policy purpose. It had been noted that "a primary purpose of the General Agreement was to lower barriers to trade between markets, and not to harmonize the regulatory treatment of products within them".[154] The United States further claimed that the EC measures had been motivated by a desire to reduce the supply of beef in the European Communities and they had worked to ease the European Communities' over-supply problems. By requiring that foreign producers adopt the same processes and production methods as EC producers, the EC measures had severely restricted imports, thus providing relief to domestic EC producers.

4.251 The United States claimed that it had been common, prior to the entry into force of the WTO Agreement, for governments to take action to restrict imports as part of an effort to control domestic supplies of agricultural products. Article XI:2(c) of GATT provided an exception for this purpose, subject to strict condi-

[153] Panel report on "US - Measures affecting Alcoholic and Malt Beverages", adopted 19 June 1992, DS23/R, BISD 39S/206.
[154] Paragraph 5.8 of the panel report on "US - Taxes on Automobiles", (DS31/R).

tions.[155] However, a primary component of the Agreement on Agriculture was to eliminate this practice.[156] The EC measures, as applied to imports, were yet another example of measures to restrict imports in order to control the total supply of an agricultural product. Finally, the United States argued that not only animals, and meat from animals, to which had been administered the hormones for growth promotion were "like" other animals and meat from other animals, but the EC measures resulted in less favourable treatment than that accorded to domestic sales and imports from other countries of other animals, and meat from other animals, in breach of Article III:4 of GATT.

4.252 The **European Communities** argued that the measures at issue had their domestic counterpart in the prohibition on the administration of the same types of hormones to animals reared in the European Communities and in the prohibition on the marketing of those animals and of meat from those animals. The measures applied to domestic products had identical scope and were subject to the same exceptions as the measures applied to the imported products. The only difference between the measures applied to domestic products and those applied to imported products was that while the former were applied at the stage of production and sale, the latter were enforced at the point of importation. Furthermore, the measures applied to both domestic and imported products as "products", even if their scope was defined in terms of processes and production methods ("PPM") rather than in terms of product characteristics. The present case was to be distinguished from the situation considered by the panel report on US - Restrictions on Imports of Tuna I, in which the panel had reasoned that the Note ad Article III covered only those measures that were "applied to products as such". Yet, according to the panel, the US internal regulations "could not possibly affect tuna *as a product*".[157] In contrast, in the present case the reason for prohibiting the importation of animals which had been treated with certain hormones, and of meat from those animals (as well as their domestic production and sale), was precisely that this treatment, unlike the PPMs for fishing tuna prescribed by the US regulations, modified the physical characteristics and biological composition of the products.

4.253 The European Communities disagreed with the US interpretation of "like products". In the EC view, a determination of "likeness" must be exclusively based on objective criteria related to the characteristics of the products themselves. The purpose of a regulatory distinction between "like products" might only become relevant in deciding whether a measure which was inconsistent with Article III:4 could be justified under any of the general exceptions provided for under Article XX of GATT. The European Communities contended that the pur-

[155] The United States noted that the panel report on "Japan - Restrictions on Imports of Certain Agricultural Products", adopted on 2 February 1988 (L/6253 - 35S/163), illustrated just how strict these conditions were.

[156] Article 4.2 of the Agreement on Agriculture.

[157] Panel report on "US - Restrictions on Imports of Tuna I", DS21/R (unadopted), dated 3 September 1991, 39S/155, pp.193-195, paras 5.8-5.14.

pose of the measures at issue was not to afford protection to domestic production but to protect human and animal health, as well as the interests of consumers and, therefore, would not, in conformity with the United States' own test, infringe Article III:4. Although two products need not be identical in order to be "like" for the purposes of Article III, previous panel reports had taken a consistently narrow approach when interpreting this term. In European Communities - Measures on Animal Feed Proteins, the panel had rejected a claim by the United States to the effect that all products used for the purpose of adding proteins to animal feeds were "like". The panel noted, *inter alia*, that the products concerned had different protein contents and different origins (vegetal, animal or synthetic).[158] More recently, the panel report on Japan - Taxes on Alcoholic Beverages, a case concerning the application of Article III:2 of GATT, had concluded that:

> "... only vodka could be considered as like product to shochu since, apart from commonality of end uses, it shared with shochu *most* physical characteristics. Definitionally, the only difference is in the media used for filtration. Substantial noticeable differences in physical characteristics exist between the rest of the alcoholic beverages at dispute and shochu that would disqualify them from being regarded as like products. More specifically, the use of *additives* would disqualify liqueurs, gin and genever; the use of *ingredients* would disqualify rum; lastly, *appearance* (arising from manufacturing processes) would disqualify whisky and brandy"[159] (emphasis added).

4.254 The European Communities reaffirmed its view that meat from animals to which had been administered any of the six hormones at issue for growth promotion had substantially different properties, composition and appearance than meat from animals to which those hormones had not been administered or to which they had been administered only for therapeutic purposes. Moreover, meat from treated animals was perceived by European consumers as a distinct product. For these reasons, animals treated with hormones for growth promotion, and meat from those animals, could not, in light of the criteria used by previous panel reports, be considered as "like" to other animals, and meat from those animals, for the purposes of Article III:4. The European Communities claimed that animals, and meat from animals, treated with any of the hormones at issue for growth promotion were different from animals and meat from untreated animals or from animals treated for therapeutic purposes, and referred to its arguments with re-

[158] Panel report on "EC - Animal Feed Proteins", at para. 4.2. The other panel report dealing with a regulatory measure discriminating between non-identical products is the panel report on US - Measures affecting Alcoholic and Malt Beverages. In this case, the panel found that low alcohol and high alcohol beer were "similar" in terms of physical characteristics but were not "like" for the purposes of Article III:4 because the distinction was not applied so as to afford protection to domestic production, BISD 39S/206, pp.93-295, paras 5.70-5.77.

[159] Panel report on "Japan - Taxes on Alcoholic Beverages", para. 6.23.

gard to the SPS Agreement. Taking into account the consumer's concerns as detailed with respect to the SPS Agreement, meat from animals treated with the hormones at issue for growth promotion and meat from untreated animals or from animals treated for therapeutic purposes were not substitutable for most European consumers and, accordingly, not "like" for the purposes of Article III:4.

4.255 The European Communities argued that even if animals treated with hormones for growth promotion, and meat thereof, and other animals, and meat thereof, were found to be "like products", its measures would still be consistent with Article III:4 because they afforded identical treatment to imported products and to domestic like products. The European Communities disagreed with the US interpretation of Article III:4. In the EC view, Article III:4 did not prevent Members from establishing regulatory distinctions *within* a given category of like products, provided that such distinctions did not, formally or in effect, give less favourable treatment to imported products than to domestic products. For this purpose, the comparison must be made between the treatment given to all imported goods as a whole and the treatment accorded to all like domestic products as a whole. Thus, in the present case the relevant comparison was not between imported products treated with hormones for growth promotion and domestic untreated products, but between imported meat and domestic meat.

4.256 The European Communities submitted that the wording of Article III:4 called for a comparison between the treatment given to "*the products* of the territory of any contracting party imported into the territory of any other contracting party ...." and the treatment accorded to "*like products* of national origin..." and not between the treatment given to "*any* imported product" and the treatment accorded to "any domestic like product". The ordinary meaning of Article III:4 did not require that a comparison be made on an import-by-import basis, but a comparison of the treatment given to all imported products as a whole vis-a-vis all domestic like products as a whole. In the EC view, the object and purpose of Article III had been made explicit in the general principle set forth in the first paragraph of that Article, which stated that internal taxes and regulations "should not be applied to imported or domestic products so as to afford protection to domestic production". Article III:4 gave effect to this principle with respect to internal regulations, other than tax regulations and mixing regulations, and should be interpreted in conformity with it. Where an internal regulation laid down different requirements for imported and domestic products, it might be assumed that domestic production was "protected" if any imported product received "less favourable treatment".[160] The situation was different where, as in the present case, the internal regulation did not distinguish between imported and domestic products but between different types of like products, irrespective of their origin. The

[160] Hence the "no-balancing" principle established by previous panel reports which have dealt with formally discriminatory internal regulations. See panel report on US - Section 337 of the Tariff Act of 1930, adopted on 7 November 1989, BISD 36S/345, 387, para 5.14; and panel report on "US-Standards for Reformulated Gasoline", WT/DS2/R, paras 6.14-6.15.

mere fact that an internal regulation accorded more favourable treatment to certain types of like products vis-a-vis other types of like products did not necessarily mean that domestic production of the like product as a whole was protected. For that, it would be necessary that those types of like product which were accorded more favourable treatment were inherently or at least predominantly domestic and/or that the types which received less favourable treatment were inherently or at least predominantly imported. The EC views found support in the panel report on US - Measures affecting Alcoholic and Malt Beverages, which stated that:

> "The panel recognized that on the basis of their physical characteristics, low alcohol beer and high alcohol beer were similar. It then proceeded to examine whether, in the context of Article III, this differentiation in treatment of low alcohol beer and high alcohol beer is such "as to afford protection to domestic production". *The panel first noted that both Canadian and United States beer manufacturers produce both high and low alcohol beer. It then noted that the laws and regulations in question in various states do not differentiate between imported and domestic beer as such*, so that where a state law limits the points of sale of high alcohol content beer or maintains different labelling requirements for such beer, that law applies to all high alcohol content, regardless of its origin. *The burdens resulting from these regulations thus do not fall more heavily on Canadian than on United States producers*"[161] (emphasis added).

4.257 Although in the EC view the panel report on US - Measures affecting Alcoholic and Malt Beverages erred by ascribing the analysis of the effects of a measure to the determination whether two products were "like" and not exclusively on the characteristics of the products, this panel report confirmed that Article III:4 was not infringed unless a regulatory distinction between like products had the *effect* of protecting domestic production.[162] The European Communities

---

[161] Panel report on "US - Measures affecting Alcoholic and Malt Beverages", BISD 39S/206, para. 5.73.

[162] The European Communities indicated that as noted above, the panel report on "EC - Measures on animal feed proteins" (the only other adopted panel report that has applied Article III:4 to an origin neutral internal regulation) found that the products concerned were not "like" by reason of their differences in physical characteristics and, therefore, did not have to rule on the relevance of the effects of the measure. Nevertheless, it is worth noting that the arguments made in that case by the US, acting as a complainant, were based on the premise that an internal regulation which is not applied to all like products does not infringe Article III:4, unless it is shown to have a protectionist effect:

> "The representative of the United States took the view that the measures focused the impact more directly on imported vegetable proteins, particularly soybeans, because they did not apply to animal, marine and synthetic proteins, even though such proteins were, with vegetable proteins, substitutable for use in feeds. *He maintained that animal, marine and synthetic proteins were excluded from the*

claimed that in case its measures were found to be contrary to Article III:4, they were justified by Article XX:(b) which did not affect the power of a Member to adopt a policy in order to protect human and animal health. Moreover, the European Communities submitted that in case the Panel were to find that its measures infringed Article III:4, for the reasons stated, they satisfied the requirements of the SPS Agreement and, consequently, must be presumed to be in accordance with the GATT, and in particular with the provisions of Article XX(b).

(b) Article I:1 of GATT

4.258 The **United States** noted that Article I:1 of GATT prohibited discrimination against products from one Member in favour of like products from other Members. However, the European Communities permitted the importation and sale from other Members of animals, and meat from animals, to which the three natural hormones had been administered for therapeutic purposes or to which hormones had not been administered. Noting that, as demonstrated, the banned beef was "like" beef from an animal to which hormones had been administered for therapeutic purposes and was like beef from an animal to which hormones had not been administered, the United States argued that the EC ban discriminated against the like US products. Consequently, similar to all the reasons described under Article III, the EC measures failed to accord immediately to imports from the United States the advantages, favours, privileges or immunities granted to like animals and meat originating in the territories of other countries.

4.259 The United States claimed that the EC discriminatory measures could not be justified by resort to Article XX of GATT, in particular Article XX(b). The European Communities had put forward no evidence to support its measures on health grounds, and as shown with respect to the SPS Agreement, these measures were "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade" within the meaning of the chapeau to Article XX. Furthermore, the SPS Agreement elaborated "rules for the application of the provisions of GATT which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)"[163] and sanitary measures that complied with the SPS Agreement were presumed to be in accordance with Article XX(b) of GATT.[164] It had been shown above that the EC measures were inconsistent with the EC obligations under the SPS Agreement. The European Communities had failed to establish that its ban was justified by invoking Article XX(b).

---

measures because there was substantial domestic production in the EEC and not because these products were not like products, taking account of their generally higher protein content and certain technical advantages".

(Panel report on "EC - Measures on animal feed proteins", para. 3.39).

[163] Clause 8 of the preamble to the SPS Agreement.

[164] Article 2.4 of the SPS Agreement.

4.260 For all these reasons, the United States claimed that the EC ban was inconsistent with the European Communities' obligations under the GATT, in particular Articles I and III.

4.261 The **European Communities** argued that the United States alleged violation of Article I was a claim which was outside the Panel's terms of reference. Consequently, the EC arguments were made only in the alternative, in case the Panel were not to uphold the EC argument. The European Communities stressed again that animals to which the hormones had been administered for growth promotion, and meat from those animals, had substantially different properties, composition and appearance than other animals, and meat from those other animals. Moreover they were perceived by consumers as a different product. For these reasons, they could not be considered as being "like" for the purposes of Article I:1 of GATT. In the European Communities' view, even if they were found to be "like", the measures would still not infringe Article I:1. The most favoured nation principle contained in that provision was concerned with discrimination between countries and not with discrimination between products. Article I:1 did not prevent Members from giving different treatment to goods falling within a single category of "like products", as long as the distinction did not discriminate, formally or in effect, according to the country of origin of the goods.

4.262 The European Communities maintained that this interpretation had been supported by a long series of previous panel reports, including the panel report on Belgian Family Allowances which had found that "the Belgian legislation would have to be amended in so far as *it introduced a discrimination between countries having a given legal system of family allowances and those which had a different system or no system at all*, and made the granting of the exemption dependent on certain conditions"[165] (emphasis added). According to Dr. Jackson, this panel report stood for the proposition that "permissible distinctions between the treatment of goods may be based only on characteristics of the goods and not on characteristics of their country of origin".[166] In European Communities - Measures on Animal Feed Proteins, the US claim that all feed proteins were like products and that by excluding some types of feed proteins from the scope of the contested measures the European Communities had discriminated between imports originating in the United States and imports of like products originating in third countries, thereby violating Article I:1, had been rejected by the panel which had noted that "a significant portion of EC imports of like products, including soybeans, subject to the measures originated from contracting parties other than the United States."[167]

---

[165] Panel report on "Belgian Family Allowances", adopted on 7 November 1952, BISD 1S/59, p.60, para. 3.
[166] J. Jackson, "World Trade and the Law of the GATT", pp.258-259.
[167] Panel report on "EC - Measures on Animal Feed Proteins", para. 4.20.

4.263 In addition, the European Communities noted that in Spain - Tariff Treatment of Unroasted Coffee, the panel had concluded that by applying different tariff rates to different varieties of coffee which had been previously found to be like products, Spain had infringed its obligation under Article I:1. In reaching this conclusion the panel had noted that the complainant, Brazil, exported to Spain mainly those varieties which were subject to the higher duty rates. Thus, imports from Brazil were discriminated *de facto* vis-a-vis imports from other countries that grew mainly the varieties subject to the lower duty rates.[168]

4.264 Finally, the European Communities pointed out that in United States - Restrictions on Imports of Tuna Fish I, Mexico had claimed that the labelling provisions of the Dolphin Protection Consumer Information Act violated Article I:1 because, in the case of tuna harvested in the Eastern Tropical Pacific Ocean ("ETP"), the right to use the label "dolphin safe" was accorded only if such tuna was accompanied by documentary evidence showing that it was not harvested with certain fishing techniques. Even though there was no question that tuna caught in the ETP by Mexico was "like" any other tuna, the panel rejected this claim by reasoning that:

> "According to the information presented to the panel, the harvesting of tuna by intentionally encircling dolphins with purse-seine nets was practised only in the ETP [....] By imposing the requirement to provide evidence that this fishing technique had not been used in respect of tuna caught in the ETP the United States *did not discriminate against countries fishing in this area*. The panel noted that, under United States customs law, the country of origin of fish was determined by the country of registry of the vessel that had caught the fish; the geographical area where the fish was caught was irrelevant for a determination of origin. *The labelling regulations governing tuna caught in the ETP thus applied to all countries whose vessels fished in this geographical area and thus did not distinguish between products originating in Mexico and products originating in other countries.*"[169] (emphasis added).

4.265 The European Communities argued that the measures at issue applied without distinction to all imports of meat irrespective of their country of origin and not only to imports originating in the United States. Furthermore, the measures did not discriminate *de facto* against US imports. Animals treated with hormones for growth promotion, and meat from those animals, were not an inherently US product or a product which was predominantly produced in the United States. In addition to the United States, there were other countries which authorized some or all of the prohibited hormones. On the other hand, untreated ani-

[168] Panel report on "Spain - Tariff Treatment of Unroasted Coffee", adopted on 11 June 1981, BISD 28S/102, pp.111-112, para. 4.10.
[169] Panel report on "US - Restrictions on Imports of Tuna I", para. 5.43.

mals, and meat from those animals were produced in virtually all countries of the world, including the United States. In fact, imports from the United States and from other countries which authorized the use of all or some of the prohibited hormones accounted for a major proportion of the EC imports.

4.266 The European Communities thus maintained that the measures at issue were also consistent with Article I:1 of GATT. In case the Panel were to find the contrary, the European Communities submitted that, for the reasons stated, they satisfied the requirements of the SPS Agreement and, consequently, must be presumed to in accordance with the GATT, and in particular with the provisions of Article XX(b).

4.267 The **United States** noted that the issue of the inconsistency of the EC ban with Article I:1 of GATT was within the terms of reference of this Panel, despite the EC argument to the contrary. The Panel had standard terms of reference established in accordance with DSU Article 7.1 and the United States request for the establishment of the Panel cited GATT, which included Article I:1. Furthermore, the United States had made explicit that its reference to Article III or Article XI was a non-exhaustive listing of the relevant GATT articles.[170] Moreover, the EC claim raised a general issue of interpretation: whether the phrase "cited by the parties to the dispute" in the standard terms of reference in the DSU modified the words "covered agreement(s)" or whether this phrase modified the words "relevant provisions". In the US view, "cited by the parties to the dispute" was clearly meant to modify "covered agreement(s)". This conclusion was clear from the text and the context of DSU Article 7.1.

4.268 The negotiating background of Article 7.1 confirmed this meaning. The provision on standard terms of reference in paragraph F(b)(1) of the Montreal Decision on "Improvements to the GATT Dispute Settlement Rules and Procedures" had provided that a panel would examine the matter referred to it by the complaining party "in the light of the relevant GATT provisions". This phrase had been modified to "in the light of the covered Agreements cited by the parties to the dispute" in the section on "Terms of Reference" at page T.3 of MTN.TNC/W/FA (the "Dunkel Draft" of 20 December 1991) in the text on "Elements of an Integrated Dispute Settlement System". The alteration was made in response to an initiative by the European Communities, inspired by its difficulties in the Airbus case. The objective was to make it possible for a defending party to "cite" agreements additional to those cited by the complaining party, and to have the panel apply all agreements cited by both sides.[171] Moreover, the European Communities' own arguments in this dispute contradicted its terms of

[170] See paras. 1.4 and 1.5.

[171] The United States noted texts dated 12 December and 17 December 1991, in which the same reference to “agreements cited” in terms of reference appeared under the descriptive subheading “Forum/Norm Shopping." This term had been used in earlier discussions in 1990, in the wake of the European Communities' inability to obtain terms of reference in the Tokyo Round Subsidies Code Airbus dispute which would permit application of the Agreement on Trade in Civil Aircraft as well.

reference claim. Even though the panel request did not refer to Article XX of GATT, and the European Communities did not "cite" this provision either in a dispute-related document or in DSB proceedings when the panel was established, the European Communities had sought to have the Panel examine the application of Article XX in this case. The European Communities could not have it both ways.

V. THIRD PARTIES SUBMISSION

1. Australia

5.1 **Australia** submitted that as a major exporter of meat and, in recent years, the world's largest beef exporter it had a major trade interest in this matter. Stressing its specific interest in the EC beef market, Australia noted that it had managed to continue its trade with the European Communities despite the implementation of Council Directive 88/146/EEC by the development of an Hormone Growth Promotion (HGP) control system. This system had allowed Australian cattle producers who wished to continue to trade with the European Communities to do so, but, at the same time, to be able to access and use hormones for growth promotion purposes for other markets that did not impose such restrictions. This had been at a cost to the Australian industry of about $A 10 million a year. However, Australia had never accepted the legitimacy of the EC measures. Noting that the purpose of the three Directives was the protection of human life or health and that the prohibition on the importation from third countries of meat from animals to which hormones had been administered was a sanitary measure as defined by the SPS Agreement, Australia claimed that the consistency of the EC measures with EC obligations should be considered against the provisions of the SPS Agreement which required that SPS measures "shall be developed and applied in accordance with the provisions of this Agreement" (Article 1.1).

5.2 Australia argued that the SPS Agreement established, *inter alia*, the basic rights and obligations of Members in respect of sanitary measures necessary for the protection of human life and health which may directly or indirectly affect international trade. Notwithstanding any other WTO rights and obligations, Australia considered that if a Member were acting inconsistently with its obligations under the SPS Agreement, it stood in breach of its WTO obligations. In addition, as the SPS Agreement represented an elaboration of the GATT in respect of SPS measures and as conformity with SPS obligations gave rise to a presumption of conformity with Article XX(b) of the GATT, Australia considered that the EC measures should be examined in the first instance against the rights and obligations of the SPS Agreement as it was this agreement which established the basic rights and obligations of Members in respect of SPS measures.

5.3 Australia placed particular stress on the fact that in observing that an international standard as provided for in Article 3.1 existed in relation to the EC hormone ban, the European Communities had failed to demonstrate its compli-

ance with Article 3.3. In particular, Australia argued that the European Communities had failed to demonstrate either that there was a scientific justification for its adoption of measures resulting in a higher level of protection or that it had carried out an examination and evaluation of available scientific evidence, including in accordance with the relevant provisions of Article 5 to show that the international standard was not sufficient to achieve its appropriate level of protection.

5.4 Referring to the conclusions of the 1995 EC Scientific Conference [paragraph ...], Australia argued that although these conclusions provided clear support to the view that the five substances considered at the Conference were safe to use within the conditions specified in Australia and within the Codex standards, the European Communities had confusingly claimed that "... [t]he scientific evidence for the necessity to maintain our measures is the evidence from the 1995 Scientific Conference ...". The European Communities had made no attempt to substantiate this assertion or to explain the contradiction between this statement and the Conference conclusions.

5.5 Although the European Communities had asserted that for the natural hormones it was known that they have adverse effects which, combined with a lack of knowledge of their action, lack of data on the effect of combinations and the lack of definition of "good veterinary practice", permit the European Communities to adopt a different level of protection, i.e. ensure the EC consumers that there are no residues left other than the naturally produced ones by the animals themselves, Australia argued that the European Communities had failed to establish that these statements reflected the findings of a risk assessment or an examination and evaluation of available scientific information in conformity with the provisions of the SPS Agreement. The European Communities had also not established the basis for its claim that there was a lack of definition of "good veterinary practice", which was generally taken to mean using veterinary chemicals in accordance with conditions of registration, including observing intended purpose, correct dose rates and withholding periods that were determined by the technical registration process.

5.6 With regard to the EC arguments that hormones had serious adverse effects on health, including cancer, Australia noted that such claims had also been made in respect of drugs containing hormonal substances which were directly administered to humans for medicinal purposes. The European Communities had not explained why it practised a zero risk policy in the issue under examination by the Panel but not in other comparable circumstances when it was known that the hormonal product would directly enter the human system. Good veterinary practice was the basis for use of the hormones at issue and to focus only on the worst case scenario as the European Communities had done could render the use of all veterinary chemicals illegal, just as the use of all chemicals used in human medicinal preparations might be banned. Furthermore, the statement that the intensive large-scale production of meat rendered effective control of hormone growth promoters technically and economically unfeasible, flew in the face of the fact that major meat exporting nations apart from the European Communities

were able to effectively control inappropriate hormone use without the imposition of a total ban on the use of these substances. All agricultural and veterinary chemicals used within Australia must undergo assessment and registration prior to distribution and use. This required a thorough assessment of detailed technical data packages by the National Registration Authority. The outcome of registration was to control the use, labelling, packaging and supply of the product. This was underpinned by legislation, with penalties where these conditions were not followed. Additionally, Australia backed up the system with individual property identification of cattle to the point of slaughter, a National Residue Survey to assess compliance with MRLs, and a National Vendor Declaration system for cattle through which vendors must declare the chemicals used on cattle offered for sale and the date of treatment.

5.7 Australia claimed that there was no evidence that the European Communities had undertaken a risk assessment on this matter in accordance with the provisions of Article 5. The European Communities had stated that "the European Communities has twice formed groups of scientists to examine the hormones at issue". However, they had stated themselves that "the purpose of the 1995 EC scientific Conference was not to perform for it a risk assessment, but to provide a public forum for discussion of the scientific aspects of the use of growth promoters". Therefore, the European Communities had explicitly accepted that this Conference was not part of a risk assessment process. At the Canada/EC consultations on 25 July 1996, at which Australia was present as a third party, the EC representative had said that there had been no risk assessment done since the Lamming Committee and that no work had been done in this area since 1988. However, nowhere within the EC first submission in this case, had it claimed that the Lamming Committee had undertaken a risk assessment process which could be considered to have met the requirements of Articles 5.1 and 5.2 of the SPS Agreement.

5.8 Emphasizing that Article 5.4 required Members, when determining the appropriate level of sanitary or phytosanitary protection, to take into account the objective of minimizing negative trade effects, Australia submitted that there was no evidence to suggest that the European Communities had taken into account negative trade effects when imposing the prohibition on imports of meat treated with hormones for growth promotion purposes. This prohibition had imposed significant compliance costs on the Australian meat industry.

5.9 With regard to Article 5.5, Australia argued that the European Communities had failed to demonstrate its compliance with this provision. "Consistency" did not demand a quantified level of risk, or that Members must have the same level of risk in respect of every measure. However, the European Communities must justify why it had adopted a lower level of risk in this case than in comparable circumstances. Australia agreed that in a general sense it was true that, through risk management, each country's acceptable level of risk might reflect societal values, but, as specifically stated by Article 5.5, the acceptable level of risk determined by a country through this process must be applied in a consistent manner, and could not be applied on an arbitrary or unjustifiable case-by-case

basis (for example, the European Communities choosing to accept zero risk in the case of meat from animals treated with growth promoting hormones).

5.10 Australia furthermore argued that the European Communities had failed to demonstrate its compliance with the obligation of Article 5.6. It observed that the European Communities had claimed that its "measures are not provisional: they are definitive"[172], and therefore submitted that Article 5.7 was not relevant in this case. Noting that as the European Communities had failed to comply with the provisions of Article 3.3, failing to demonstrate that there was a scientific justification for its level of sanitary or phytosanitary protection or that its maintenance of a level of protection higher than the relevant international standard was a consequence of the level it had determined in accordance with the provisions of Article 5, Australia concluded that there must be a presumption that the EC measures were not in conformity with the basic obligations of Articles 2.2 and 2.3 of the SPS Agreement.

2. Canada

5.11 **Canada** stated that it had not only a substantial trade interest in this matter, but a vital interest in novel questions of legal interpretation that arose in this case. This dispute was the first to examine the provisions of the SPS Agreement. Canada had also requested the establishment of a panel on the same EC measures, which the DSB had established on 16 October 1996, with similar terms of reference and the same composition as the present Panel (document WT/DS48/5 refers).

5.12 Canada indicated that all the six hormones at issue were authorized in Canada for cattle growth promotion. With respect to the 1995 EC Scientific Conference on growth promotion in meat production, Canadian scientists had expressed concern that the published report of the Conference proceedings did not reflect the most current scientific knowledge and that, therefore, caution should be exercised in making use of the proceedings in scientific evaluation.

5.13 Canada agreed with the US conclusion that the EC measures were inconsistent with the SPS Agreement. Canada disagreed with the EC presentation of the arguments in this case which, from a legal point of view, appeared to suggest that the SPS Agreement only became relevant after a contravention of GATT had been determined and questioned the relevance of the General Interpretative Note to Annex 1A of the WTO Agreement cited by the European Communities in support of its position. In Canada's view, GATT and the SPS Agreement were agreements of equal status contained in Annex 1A of the WTO Agreement (Article II of the WTO Agreement). Canada believed that one must first examine the SPS and TBT Agreements because these contained rules that were more detailed and more precise than those of GATT. Canada noted that the last preambular

[172] See para. 4.239.

paragraph of the SPS Agreement indicated that the Agreement was, in part, intended to be an elaboration of "rules for the application of the provisions of GATT which related to the use of sanitary and phytosanitary measures in particular the provisions of Article XX(b)". However, Articles 3 and 4, of the SPS Agreement on "Harmonization" and "Equivalence", did not correspond to any provision in GATT. The fourth and six preambular paragraphs, reflected the broad scope of the SPS Agreement. This reinforced the point that the SPS Agreement was an independent agreement.

5.14 Canada stressed that the "Basic Rights" of Members under the SPS Agreement were provided in Articles 2.1 and 2.4. Article 2.1 set out a limited right to take sanitary or phytosanitary measures and Article 2.4 confirmed one role of the SPS Agreement as an elaboration of the rules for the application of GATT which related to the use of sanitary or phytosanitary measures, and in particular the provisions of Article XX(b). The "Basic Obligations" of the SPS Agreement were found in Articles 2.2 and 2.3. Paragraph 2 expanded on the Article XX(b) requirement that the measure be "necessary", setting out three conditions: that any SPS measure be applied only to the extent necessary to protect human, animal or plant life or health, be based on scientific principles and not maintained without sufficient scientific evidence, except as provided for in Article 5.7. Article 2.3 was based on the requirements of the chapeau of Article XX, clarifying that the point of comparison for "where identical or similar conditions prevail" included the territory of the Member taking the measure.

5.15 Canada noted that Article 2 by its own terms was said to establish the "Basic Rights and Obligations" of Members. The other provisions of the Agreement set out more specific rights and obligations, illustrative of these fundamental rights and obligations. For example, the requirements set out in Article 5 that SPS measures must be based on a risk assessment and that the assessment must take into account available scientific evidence, were rational extensions of the basic obligations in Article 2.2 to ensure that SPS measures were based on scientific principles and not maintained without scientific evidence. Similarly, Article 5.6 gave precision to the obligation in Article 2.2 that a Member must ensure that any SPS measure was applied only to the extent necessary to protect human, animal or plant life or health. In effect, Article 5.6 set out how a Member was to meet this basic requirement of Article 2.2. Likewise, Article 3.2 provided a prescription for satisfying the presumption of consistency with GATT in Article 2:4.

5.16 Canada argued that in the panel report on United States - Standards for Reformulated and Conventional Gasoline ("Reformulated Gasoline") (WT/DS2/AB/R refers) the Appellate Body had reviewed the chapeau to Article XX of GATT. Given the close relationship between the text of the chapeau and the obligation in Article 2.3, Canada submitted that the Appellate Body's interpretation of the requirement that a measure shall "not be applied in a manner which would constitute a disguised restriction on international trade" was apposite to the present case. The Appellate Body found:

> "Arbitrary discrimination", "unjustifiable discrimination" and "disguised restriction" on international trade may, accordingly, be read side-by-side; they impart meaning to one another. It is clear to us that "disguised restriction" includes disguised discrimination in international trade. It is equally clear that concealed or unannounced restriction or discrimination in international trade does not exhaust the meaning of "disguised restriction". We consider that "disguised restriction", whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination", may also be taken into account in determining the presence of a "disguised restriction" on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX."[173]

In Canada's view, this reinforced the assertion in paragraph 140 of the US submission that a protectionist measure in the guise of a sanitary measure was the essence of a disguised restriction on international trade.

5.17 Canada agreed with the US conclusion that the EC measures contravened GATT and that Article XX could not justify these measures. Canada noted that the interpretation of GATT Article III was being considered by the WTO Appellate Body in "Japan - Taxes on Alcoholic Beverages" and that the report of the Appellate Body in that case might be relevant to the present case.

3. Norway

5.18 **Norway** argued that this case concerned the right of every state to make its own sovereign decision on the level of protection it afforded its citizens with respect to health hazards. This principle had always been part of GATT law and several panels, when deciding disputes related to Article XX(b), had reaffirmed such right.[174] The SPS Agreement, within its scope of application, might be con-

---

[173] WT/DS2/AB/R, DSR 1996:I, 3 at 23.

[174] Norway noted that, e.g. the panel report on "US - Restrictions on the Imports of Tuna" stated that:

> "The panel further noted that *Article XX(b) allows each contracting party to set its human, animal or plant life or health standard*. The conditions set out in Article XX(b) which limits the resort to this exception, namely that the measures taken must be "necessary" ... refer to the trade measure requiring justification ... not to the life or health standard chosen by the contracting party. (...)."

sidered an exemplification of Article XX(b). This was not a case of discrimination between like products, or discrimination between producers from different countries. The question was purely one of reaffirming the Member's right to decide, when a risk to its population was present, the limits to the risk to which it would expose its citizens, and its freedom to choose the measure to achieve this protection as long as the measure itself was consistent with WTO obligations. In an era of increasing consumer concern over the safety of food and the presence of potentially harmful residues from the use of veterinary drugs, pesticides etc., and at a time when old "scientific truths" had often been overturned by new evidence, it was of utmost importance that the WTO uphold this right of the Member to protect its citizens against the risks connected with the use of such substances.

5.19 Noting that the SPS Agreement restated the right of a Member to set its health standards in its preamble and in Article 3.3, Norway argued that it was clear that a Member had the right to determine the level of protection it considered appropriate for its population, subject to general WTO requirements with respect to the existence of a risk, and requirements with respect to justification of the measure the Member applied. In determining the appropriate level of protection, Norway argued the obligation upon the Member was only to show that a risk to its population was present. As long as the existence of such a risk had been established, the WTO was only concerned with the justification of the *measure* the Member choose to apply to achieve the level of protection it had deemed appropriate. According to Article XX(b), as well as Article 5.2 of the SPS Agreement, a Member did not have to scientifically prove the extent of the risk. The Member only had to show that such a risk existed (risk identification), and thereafter it was for the Member to define the level of probability of harm it wanted to assume - be it zero or greater (risk management).

5.20 Norway submitted that a Member must consider present day scientific evidence when making a risk assessment. Such evidence might ascertain or disprove the risk, and might be more or less complete, but this was only one of the elements to be taken into account in the risk assessment. Other relevant elements might be, for instance, the existence of adequate testing methods and internationally approved production methods or control requirements. Norway argued that the SPS Agreement did not require a Member to base its levels of protection solely on suggested maximum tolerances presented in current scientific evidence. The cases referred by the European Communities in its submissions clearly showed from history how often old scientific "truths" had been disproved by new

---

Furthermore, the Appellate Body in the case United States - Standards for Reformulated and Conventional Gasoline, in its concluding remarks stated:

> "Members have a large measure of autonomy to determine their own policies on the environment (including its relationships with trade), their environmental objectives and the environment legislation they enact and implement. So far as concerns the WTO, the autonomy is circumscribed only by the need to respect the requirements of the *General Agreement* and the other covered agreements."

scientific evidence. It had never been the intention of the GATT/WTO, nor should it be the task of this Panel, to infringe upon a Member's right to decide to be on the safe side where current evidence did not exclude beyond doubt a potential risk to human health.

5.21 Norway stressed that once the right of the Member to determine *its* appropriate level of protection was reaffirmed, it had to be ascertained that the chosen *measure* complied with the general obligations spelled out in GATT or the SPS Agreement. In Norway's view, the test to be applied according to Article XX of GATT and Article 5 of the SPS Agreement was the following:

(i) the measure was not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevailed;

(ii) the measure was not applied in a manner which was a disguised restriction on international trade; and

(iii) the measure was necessary, i.e. not more trade restrictive than required to achieve the appropriate level of protection, taking into account technical and economic feasibility.

Having applied this test to the measure, its consistency with the WTO obligations should be readily ascertained.

5.22 Norway submitted that the European Communities had the right to set its own level of protection in this case, and at the chosen level. It had clearly shown the uncertainties related to the possible harmful effect of long term exposure to the substances at issue and had clearly shown that its measure did not discriminate between countries, nor had there been any disguised restriction on international trade. The measure had been applied uniformly to all products containing the substances in question, be they domestic or foreign. In selecting the measure which was necessary to minimise the potential risk (risk management) so as to ensure the appropriate level of protection (zero or other acceptable level of risk), many factors had to be taken into consideration, of which maximum residue levels (MRL) was but one. The technical feasibility of ensuring adequate control of the use of the hormones, i.e. strict veterinary supervision of each implant, were of utmost importance, as well as the technical feasibility of control of the residue level in all the meat in question. Furthermore, the economic cost of the measure must be taken into account. An MRL system with extensive controls and verifications at the producer level and at point of importation might be so prohibitively expensive as to be ruled out. The European Communities had shown that other measures than the contested ban were not available to achieve the appropriate level of protection, which was consequently not more trade restrictive than necessary.

4. New Zealand

5.23 **New Zealand** indicated that its third party's substantial interest in this case was due to the fact that New Zealand was an agricultural exporting nation,

and meat exports formed a significant portion of its total exports. In the year ending December 1995, primary produce (e.g., meat and meat products, dairy, fish, fruit and vegetables, etc.) accounted for 72.1 per cent of New Zealand's total merchandise exports (NZ$ FOB). For the same period, meat and meat products accounted for 15.99 per cent of New Zealand's total merchandise exports (NZ$ FOB). Accordingly, the proper implementation of the SPS Agreement was a matter of fundamental importance to New Zealand, and the potential for sanitary or phytosanitary measures to be used as disguised restrictions on trade a major concern. New Zealand claimed that the SPS Agreement was an elaboration of relevant GATT provisions and Articles 2.1 and 2.4 established the primacy of that Agreement in determining the WTO legality of sanitary or phytosanitary measures. Accordingly, the legality of a measure falling within the definition of a "sanitary or phytosanitary measure" was to be determined in accordance with the provisions of the SPS Agreement.

5.24 Noting that the European Communities had justified the import ban on the basis that the importation of meat from animals treated with any of the substances might pose a risk to human health and safety[175], New Zealand concluded that the ban appeared to be a measure that fell within the definition of a "sanitary or phytosanitary measure" as defined in the SPS Agreement.[176] New Zealand noted that Article 1 of the SPS Agreement did not make provision for any Member to exclude specific sanitary or phytosanitary measures from the ambit of the Agreement. Moreover, the effect of Article XVI:4 of the WTO Agreement was to require Members to ensure the conformity of all their laws, regulations and administrative practices with the SPS Agreement. Accordingly, the import ban and all other sanitary or phytosanitary measures affecting international trade in place within the jurisdiction of any Member, were subject to the requirements of the SPS Agreement.

5.25 With regard to Article 2.2, New Zealand claimed that no evidence had been produced of an appreciable risk of an adverse health effect arising from the use of any of the substances. Even if it were to be shown that there was an appreciable risk, the European Communities would be required to demonstrate that the

[175] In this context, New Zealand noted that in the preamble of EC Council Directive 81/602/EEC of 31 July 1981 the banning of new licences for anabolic agents for growth promotion was characterised as being in the "interests of the consumer" and it discussed the potential "harmful effects" of the use of the substances in question. EC Council Directives 85/649/EEC of 31 December 1985 and 88/146/EEC of 7 March 1988 cited concerns relating to the effect on human health from the use of hormonal growth promotants. The preamble of the Proposal for a Council Regulation (93/C 302/06) on 14 October 1993 stated that the presence of such substances "may be dangerous for consumers and may also affect the quality of foodstuffs of animal origin". And finally, EC Council Directives 96/22/EC and 96/23/EC stated in their preambles that such substances may be dangerous for consumers.

[176] New Zealand argued that the import ban would also be inconsistent with Article 2.2 of the TBT Agreement were it not that Agreement explicitly noted (in Article 1.5) that it does not cover sanitary or phytosanitary measures. In the event that the import ban were determined to be neither a sanitary measure, nor a technical barrier to trade, the provisions of GATT would then need to be considered.

import ban was necessary to address it. In this regard, New Zealand noted that the European Communities had expressed particular concern about the perceived risks associated with the inappropriate or illegal use of hormonal growth promotants, particularly when used in "combinations" or "cocktails". However, even if it was demonstrated that an appreciable risk existed from such inappropriate or illegal use, the European Communities would need to demonstrate that a ban on imports was in fact "necessary" to address this specific concern. Finally, from the history of the scientific investigations into the five substances, under intense scrutiny by scientists in the last two decades, New Zealand did not consider that the importation ban could be presented as being "based on scientific principles" nor sustained by "sufficient scientific evidence". Moreover, in the case of the sixth substance, MGA, New Zealand was not aware of the existence of any scientific information which would warrant the import ban in its regard.[177]

5.26 New Zealand submitted that scientific evidence demonstrated that the level of hormones present in meat varied considerably. Meat from animals treated with the substances for growth promotion had a similar range or even lower hormonal residues than meat from some animals that had never been treated. Additionally, the European Communities allowed meat from animals that had been treated with the three naturally occurring substances for therapeutic purposes to be produced, imported and marketed within the European Communities.[178] New Zealand considered that for these reasons, the EC measures contravened Article 2.3 of the SPS Agreement.

5.27 New Zealand stressed that Codex had adopted international standards, satisfying itself that there was sufficient scientific basis. It was unclear what "available scientific information" the European Communities could rely on to provide "scientific justification" for the import ban and a selective examination and evaluation of available scientific information would not be sufficient to meet the requirements of Article 3.3. Moreover, there should be a scientifically established risk to human or animal life or health before any determination could be made as to a Member's appropriate level of protection. In this case, there did not appear to have been any scientifically defensible determination of an appreciable risk in the case of the import ban.

5.28 New Zealand claimed that the SPS Agreement did not allow for the adoption of a sanitary or phytosanitary measure that provided for a higher level of

[177] New Zealand indicated that because of differing use requirements and commercial factors, there were differences in the range of agricultural chemicals (such as MGA) registered around the world and hence differences in the standards contained in national laws. The absence of an international standard for a particular substance should not in itself be seen as justification for a particular import ban. In addition, it should be noted that Article 4 of the SPS Agreement encouraged Members to mutually recognise, for the purposes of trade, the equivalence of different sanitary or phytosanitary measures in jurisdictions other than their own.

[178] In New Zealand's indicated that it understood that the European Communities had not set any ADIs or MRLs for meat from animals treated for therapeutic purposes.

protection than an international standard in the absence of a scientific justification or a risk assessment process that had identified an appreciable risk. In the case of all six hormones, there would not appear to have been any EC assessment meeting the requirements of Article 5 which had identified any such risk. While it was evident that consumers in the European Communities might harbour concerns about the use of these substances, consumer perceptions as to risk did not provide a basis for the adoption of measures under Article 5. Furthermore, New Zealand submitted that the usual EC risk assessment and evaluation processes for veterinary medicinal products[179], which might otherwise have ensured a consistent approach as required by Article 5.5, did not form the basis for the EC measures.[180] Equally, given that many other products freely marketed within the European Communities contained much higher levels of the hormonal residues that the European Communities were seeking to avoid through the import ban, there would appear, in the absence of evidence to the contrary, to be arbitrary and anomalous levels of protection in place. Finally, Article 5.6 made it clear that even if it could be shown that there was an appreciable risk to health, given the significant trade implications of the import ban, the European Communities would have had to consider whether there were alternative, less trade-restrictive measures that could be applied to address such a risk. Noting that the European Communities did not seek to rely on Article 5.7, which was a manifestation of the "precautionary principle", as the basis for its import ban, New Zealand emphasized that the present situation appeared to be one in which the scientific evidence was neither insufficient nor inadequate.[181] Accordingly, this was clearly not an instance where the "sufficient evidence" standard could be substituted with the less rigorous standard of "available pertinent information". The fact that Codex had adopted an international standard would always create a strong presumption that sufficient scientific evidence existed.

[179] New Zealand clarified that the guidelines for assessments of veterinary medicinal products were contained, at that time, in EC Council Directives 81/851/EEC and 81/852/EEC. There were also guidelines presented in a proposed draft directive entitled "Testing of medicinal products for their mutagenic potential" which was published as Annex II in the *Official Journal of European Communities*, C 293/11, dated 5 November 1984.

[180] New Zealand added that, furthermore, since that time, the European Communities has not utilised the applicable assessment and evaluation processes to assess the use of these substances for growth promotion although it had assessed and approved their use for other therapeutic purposes without stipulating any MRLs for example in Commission Regulation (EC) 3059/94 of 15 December 1994).

[181] New Zealand noted that even the 1995 Scientific Conference sponsored by the European Communities, which was procedurally defective as a risk assessment process in that it excluded certain relevant participants and information, nonetheless, concluded that there was sufficient scientific information to determine that the five growth promotant substances could be used safely.

VI. PANEL'S CONSULTATION WITH SCIENTIFIC EXPERTS

6.1 The **United States** noted that Article 11.2 of the SPS Agreement referred to establishment of an "advisory technical experts group". In the view of the United States, this phrase referred to an expert review group established under Article 13.2 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU). Thus, the rules relevant to the establishment and procedures for such a group were those provided in Appendix 4 of the DSU. The Panel's conduct of the expert review process in the dispute should assure transparency, avoid conflicts of interest, affirm the integrity of the dispute settlement process, and aid public confidence in the outcome of the dispute. In this case, the Panel was to review the EC ban to determine if it was based on scientific principles and on a risk assessment, and if there was sufficient scientific evidence to support the ban. The scientific experts' role was a narrow one, they might help the Panel determine if there was a scientific basis for the EC ban.

6.2 As regarded the selection procedures and criteria, the **European Communities** considered that the use of experts by the Panel for the purposes of scientific and technical advice should respect general principles of law. In particular, it should be transparent, avoid conflicts of interest, affirm the integrity of the dispute settlement process and aid public confidence in the outcome of the dispute[182]. In addition, Appendix 4 of the DSU included general rules of law relating to the use of expert advice on the part of Panels. Even though the experts would not constitute an Expert Review Group but would be consulted individually and separately, such rules should be applied by analogy whenever relevant and appropriate[183]. In order to ensure that the principles outlined above were respected, the European Communities believed that a number of general criteria should be followed in the selection of the scientific experts by the Panel.

6.3 The European Communities indicated that, first, the experts nominated by the Panel should not be nationals of the parties to the dispute nor nationals of third parties in the same dispute. This principle aimed at ensuring a fair and impartial selection of experts and appeared all the more necessary in light of the possibility given by the Panel to the parties to nominate one expert each, without any limitation of nationality. Second, the Panel, in selecting experts with different fields of expertise, should ensure that all the areas which it had identified were covered, so that all the questions of the Panel received replies to the fullest extent possible. Third, given the very small number of experts that the Panel would consult, only scientists with proven expertise in the use of hormones in general and for animal growth promotion should be selected. Fourth, the experts should not have served as members of the Codex/JECFA group which produced the 1988

[182] The European Communities noted that in a letter addressed to the Panel on 21 October 1996, the United States had also agreed to these general principles.

[183] The European Communities noted that this had also been acknowledged in the Panel's letter of 30 October 1996.

JECFA report on the use of hormones for animal growth promotion. Fifth, past or present significant ties with the industry producing these hormones would not provide sufficient guarantees of lack of conflict of interest, of integrity and of aiding public confidence in the outcome of the dispute. The European Communities considered that the above comments constituted compelling reasons for the European Communities and underscored the limited pool proposed by the Codex secretariat from which the Panel would make its choice, despite the existence of a large number of scientific experts on these issues internationally. The European Communities indicated that Panel's favorable response to the EC request to add a fifth scientist with expertise in the area of carcinogenic effects of hormones in this case addressed one of the concerns of the European Communities.

6.4 As regarded the purpose of requesting information from, and the type and nature of the questions to be asked to, experts, the European Communities stated that this should be "to further the Panel's understanding of the scientific facts relevant to the dispute". In order to fulfil this objective and be in conformity with the provisions of the SPS Agreement and the DSU, the questions the Panel intended to ask must relate directly to the scientific issues of the case. These questions must be addressed to persons who on the basis of their recognized fields of expertise, could provide direct, reliable and verifiable information to the Panel. The questions should not concern legal issues or issues of interpretation of any of the WTO Agreements under consideration, because it was the sole responsibility of the Panel to interpret the legal provisions which had been invoked by the Parties and to apply them to the facts of the present case. The European Communities observed that the questions the Panel intended to ask should also not address nor request pure factual information, which was the responsibility of the parties to the dispute to provide, in accordance with the DSU rules and its provisions on burden of proof. They should not address issues of trade policy either, which were again the sole responsibility of the parties and on which scientists were not competent and could not be expected to pronounce themselves. The European Communities claimed that scientists must be asked only scientific questions directly relevant to this dispute and in the light of the scientific arguments made by the parties to this dispute. The European Communities recalled that it was the Panel's responsibility to interpret and apply the relevant legal provisions. Accordingly, the European Communities considered necessary to stress that it reserved all its rights with regard to the conformity of the Panel's approach on these issues with the relevant provisions of the SPS Agreement and the DSU.

Panel Procedures with Regard to Scientific Expertise

6.5 Following consultation with the parties, the Panel decided to seek scientific and technical advice as foreseen in paragraph 1 and 2, first sentence, of Article 13 of the DSU, and pursuant to paragraph 2, first sentence, of Article 11 of the SPS Agreement.

6.6 Names of individuals expert in the subject matter before the Panel were provided by the Codex Commission secretariat as well as by the International Agency for Research on Cancer ("IARC"). Brief curricula vitae were solicited from all experts who were prepared to assist the Panel.

6.7 The parties were provided the opportunity to comment on these potential experts on the basis of the curricula vitae, and in particular to state any compelling objections they might have with regard to any individual. The parties were invited to nominate one expert each, not necessarily from the list provided by the Panel. The Panel than selected two additional individuals from the list taking into account the comments of the Parties. At the request of the European Communities, the Panel decided to select an additional expert in the area of carcinogenic effects of hormones, on the understanding that the European Communities agreed that the Panel established at the request of Canada would seek advice from the same five experts. These experts were requested to serve, in their personal capacities, as individual advisers to the Panel. The Panel also sought information from the Codex Commission secretariat.

6.8 The Panel, in consultation with the parties, prepared specific questions which it submitted to each expert individually. The experts were requested to provide their responses, in writing, to those questions they felt qualified to address. The parties agreed that their written submissions to the Panel, including the written versions of their oral statements, be provided to each of the selected experts. Written questions were also submitted to the Codex Commission secretariat. The written responses of the experts and of the Codex Commission secretariat were provided to the parties.

6.9 The experts were invited to meet with the Panel and the parties to discuss their written responses to the questions and to provide further information. A summary of the responses provided by the experts is presented below.

6.10 The experts selected to advise the Panel were:

Dr. Francois André, Laboratoire des dosages hormonaux, France

Dr. Dieter Arnold, Deputy Director, Federal Institute for Health Protection of Consumers and Veterinary Medecine, Germany

Dr. George Lucier, Environmental Toxicology Programme, National Institute of Environmental Health Sciences, United States

Dr. Jock McLean, University of Swinburne, Pro Vice Chancellor, Division of Science, Engineering and Design, Swinburne University of Technology, Australia

Dr. Len Ritter, Executive Director, Canadian Network of Toxocilogy Centres, University of Guelph, Canada

Dr. Alan Randell of the Codex secretariat also advised the Panel.

Views of the Scientific Experts

Question 1:

> In various JECFA and Codex references the terms "good animal husbandry practice", "good veterinary practice" and "good veterinary and animal husbandry practice" are used. Can you define "good animal husbandry practice", "good veterinary practice" and "good veterinary and animal husbandry practice"? What are the implications, in terms of residue levels and potential hazards to human or animal health, of non-application of "good veterinary and animal husbandry practices" for five of the hormones in dispute?

6.11 **Dr. André** responded that these concepts related to quality assurance systems, however they were not precisely described or standardized, and the use of some of these concepts was not yet widespread. "Good animal husbandry practice" was described in various ways, such as "the stable to table approach" which took into account the use of veterinary drugs such as in a Herd Health Surveillance Programme (HHSP). In such a recording system, farmers, veterinarians and other people concerned with all aspects of primary production should cooperate to ensure good animal husbandry practice.

6.12 "Good veterinary practice" described each country's national or professional guidelines or rules which provided guarantees for professional activities. The use of veterinary drugs was controlled by means of an international code of practice of the Codex Alimentarius which described the use of veterinary drugs, from the necessity of a pertinent diagnosis to residue management (respect of withdrawal periods) in meat-producing animals. Dr. André noted that special attention should be paid to the prescription and to using the correct dosage, site and route of administration for medicines. Moreover, specific conditions for the use of particular drugs was regulated; ie., in Europe, EC Directive 96/22 described precisely the conditions of therapeutical or zootechnical use of the hormones in dispute.

6.13 Dr. André noted that "good veterinary and animal husbandry practice" did not appear to be well defined but could be considered as a combination of the two above-mentioned practices. The strict observance of "good veterinary and animal husbandry practice" was the only way to guarantee that each drug would be used according to the conditions for which it had been registered. Any disrespect of such practices, in term of dosage, injection route, withdrawal period or other conditions specified for use, would change the expected level of residues. Concerning the hormones in dispute, it could easily be demonstrated that overdosage, shorter withdrawal periods (when defined), or liquid solution injections instead of implants might lead to higher residue levels. Potential hazards to human and animal health might then appear.

6.14 Dr. André indicated that the real problem was one of control: how to ensure that these practices were really respected. There were official control services charged with this control. But now more and more veterinarians, farmers,

and farmer organizations were taking the control and were ensuring that they only used registered drugs as they were officially meant to be used.

6.15 **Dr. Arnold** observed that "good animal husbandry practice" was a broad term relating to the proper management and handling of animals. Particularly intensive production methods required good management. The terms management and husbandry included, for example, efforts toward improving rate of gain and feed efficiency and management of reproduction (e.g., hormonal control of oestrus, embryo transfer, treatment of infertility, prevention of pregnancy, termination of pregnancy, induction of parturition, etc.). Veterinarians were involved in the management of several of these conditions and were *inter alia* responsible that certain drugs were only administered after thorough diagnosis and in compliance with the approved label instructions. It was also a fundamental requirement that drugs (hormones, growth promoters, parasiticides and other substances) should not be used to replace good veterinary and animal husbandry practices.

6.16 Dr. Arnold indicated that the hormones under discussions were not *per se* hazardous or innocent substances. If ingested with food, their possible biological effects depended *inter alia* on the amounts ingested. Therefore, it was important that during the approval process conditions of use were established which guaranteed that even preferential consumption of food from treated animals would not lead to the ingestion of residues causing biological effects. The essential issue was compliance with the established conditions of use which were normally laid down in the label instructions. If "good veterinary and animal husbandry practices" were not applied, in particular if "good practices in the use of veterinary drugs" were not observed when using these substances, residue levels higher than those resulting from the authorized conditions of use may occur/were likely to occur in edible portions of the treated animals. These elevated levels did not always have biological effects - because the established margins of safety were usually high.

6.17 **Dr. Lucier** indicated that he had little expertise in this area, but it seemed reasonable to assume that non-application of such guidelines or inconsistent application of them would substantially increase the chance that acceptable residue levels could be exceeded, which would likely increase the potential risk to human health.

6.18 **Dr. McLean** responded that "good practice" was the operative part of these definitions. The word "veterinary" implied that a veterinarian was involved in the process as the prescriber, advisor or administrator. "Animal husbandry" was caring for animals and might involve a veterinarian in the process. "Good practice" in relation to the use of hormones involved the use of a registered product according to the prescribed instructions for its use and employing good farming practice. It might also include the use of approved administration apparatus and the identification of treated animals.

6.19 Dr. McLean indicated that departure from "good practice" was undesirable and a breach of the registration conditions. However, in practice, it was un-

likely that minor departures from good practice with registered products would cause significant increases in hormone levels in meat.

6.20 **Dr. Ritter** indicated that these terms had been elaborated in a recommended international code of practice (Codex Alimentarius, 1993) intended to foster the safe use of veterinary drugs in food producing animals and to ensure that, in accordance with the principles of this code, residues of veterinary drugs in food did not exceed permitted levels and residues did not pose a hazard to humans consuming food commodities produced with the aid of veterinary drugs. In practice, JECFA and Codex had not utilized these terms, but rather had employed the term "good practice in the use of veterinary drugs", which had been defined (Codex Alimentarius 1993) as "the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions. The maximum residue limit for veterinary drugs may be reduced to be consistent with good practice in the use of veterinary drugs". The maximum permitted residue was based on the type and amount of residue considered to be without toxicological hazard for human health while taking into account other relevant public health risks. When the hormones at issue were used in accordance with the prescribed use conditions, the levels that were present were in fact indistinguishable from those which would be present in an animal which had not been treated at all.

6.21 Dr. Ritter further noted that the principle or philosophy of good veterinary and good husbandry practice also implied that all veterinary products to be utilized in food producing animals should only be administered in strict compliance with relevant product information, approved by the appropriate regulatory authority, and in strict accordance with instructions issued by qualified veterinarians. Violations of any of these principles might result in higher than expected residues or residues of unexpected drugs. The implications of such violations were proportional to the frequency with which they occurred, the magnitude of the violation and the prevalence of such violations within the food production system. Notwithstanding, given the exaggerated estimates of safety inherent in the approach to the establishment of MRLs, it was unlikely that occasional violations could increase overall residue levels to those which, on an infrequent exposure basis, could pose a risk to consumers.

Question 2:

> Can meat produced with any of the six hormones in dispute for growth promotion purposes (natural and/or synthetic) be physically differentiated, by consumers or by any particular detection methods, from meat produced without them? Are residues of the three natural hormones administered for growth promotion purposes chemically different from residues of these hormones administered for purposes permitted by the EC?

6.22 **Dr. André** noted that no physical differences were observed between meat produced with or without the use of growth-promoting hormones, but questions of meat quality could be raised as far as physicochemical or organoleptic criteria were concerned. Significant alteration of eating quality and loss of ten-

derness of meat produced with various implants had been reported. These changes might also stem from differences in the chemical composition of meat. According to sex and/or implant type, differences of moisture and fat rates were observed.

6.23 Furthermore, sophisticated detection methods allowed differentiation of meat produced with or without synthetic hormones, even if a long withdrawal period was respected. For natural hormones, this differentiation was possible when esters of natural hormones were still present in the meat. In some cases it is possible to distinguish the two by physical means of isotope relations, but it would be very difficult to do at very low levels, Theoretically, *quantitative* differences might be expected between the legal use of natural hormones as growth promoters (i.e. as an implant) and their use as veterinary drugs (i.e. usually as injection); from the *qualitative* point of view, chemical differences could be expected in terms of metabolites and/or conjugates, owing to the dosage, the route of administration and the length of treatment.

6.24 **Dr. Arnold** responded that it was not possible to physically differentiate meat from treated animals from meat of untreated animals. However, many studies showed that the composition of the carcass was improved upon treatment in terms of more lean meat and less fat than in untreated control animals. Residues found in the meat from treated animals for growth promotion purposes would be qualitatively the same as residues found in meat from animals treated with the same substances for purposes permitted by the European Communities, but quantitatively could be slightly different depending on the compound administered, the dose, the route of administration, etc. If the substances were used according to good veterinary practices, there was initially a slight difference but at the time of slaughter there was no means to discriminate between treated and non-treated animals, irrespective of whether for growth promotion or for therapeutic and zootechnical purposes.

6.25 Of the categories of residues of biological concern, only the residues of the parent drug administered to the animals (e.g. the hormones itself or its esters) could be analytically differentiated with currently available analytical methods. Theoretically, hormones could be labelled with stable isotopes to permit discrimination between added hormones and endogenous hormones, but this had no relevance in practice. It was possible to discriminate whether or not animals had been treated with exogenous hormones. Despite their short half-lives in circulation, it was even possible, but not normally routinely feasible, to measure the concentrations of the esters at sites distant from the injection site.

6.26 It appeared that the substances used for growth promotion in the United States were (with the possible exception of testosterone-propionate) also used in the European Union for therapeutic or zootechnical purposes. Working-Group III of the 1995 EC Scientific Conference had concluded that: "While residue analyses for natural hormones on animals treated experimentally can show differences between them and untreated animals, *it is not possible in routine use to identify treated animals on the basis of assays of edible tissue samples* and it is difficult

in blood, urine or faeces. Successful identification of treated animals may be made by analysis of injection sites or detection of esters (e.g. oestradiol benzoate) in blood shortly after treatment. Identification of animals treated with natural hormones on the basis of a single time-point analysis is difficult. The situation is more complex for food-producing animals, where typically a mixture of androgen only is used. *Identification of meat from animals treated with natural hormones and imported from third countries is not at present possible"*[184]. (emphasis added)

6.27 **Dr. Lucier** indicated that the residues which occurred from the natural hormones were indistinguishable from those which occurred from the natural endogenous materials. This was not true, of course, for the synthetics. With appropriate analytical methods and appropriate residue levels one could detect residues of the synthetic materials here in question. The half life, the biological persistence, of the agents in question was for the most part rather short; they did not stick around the body very long. Half-life was the time it takes for half the material to disappear. If, for example, something had a half life of one day and, if you started out with 10 units of it, one day later you would have five, two days later you would have two and a half and so forth. So even though several months might elapse following an exposure to an agent even with a relatively short half life, a few molecules might remain. The number of molecules might be remarkably close to zero, probably not detectable by analytical methods, but a few molecules would likely remain. (See also response to question 5).

6.28 Dr. Lucier noted that it was likely that, on the average, meat from growth-promoted animals would be leaner (i.e. less fat) than meat produced without those agents. However, it was unlikely that, for a given piece of meat, one could physically differentiate whether or not it was from a growth-promoted animal. Residues arising from administration of the three natural hormones would not be chemically different from those in the body of non-treated animals although the residues were likely to be slightly higher in the growth-promoted animals.

6.29 **Dr. McLean** responded that for all practical nutritional and health purposes the meat was the same regardless of how it was produced, although there might be variations in the ratio of fat to lean meat. The residues of the natural hormones were generally similar when administered for growth promotion or for other purposes. Because the mode of administration used for growth promotion resulted in lower daily dosing, there might be quantitative and qualitative variations in the composition residues.

6.30 **Dr. Ritter** observed that it was generally known that when used as growth promoters, the naturally occurring gonadal steroid hormones - oestrogen, progesterone and testosterone and the related substances MGA, zeranol and trenbolone, could increase the growth rate, the proportion of lean meat to fat and food

[184] Working Group III, Detection and Surveillance, in *1995 EC Scientific Conference Proceedings*, p.31.

conversion efficiency in some species. Overall the response might vary between hormones, and might be maximized by the use of certain combinations of hormones. In general, the lean meat content of the carcass was improved and the fat content was decreased. Except in the case of some veal calves, effects on meat quality were generally not significant. Thus it was most unlikely that consumers could differentiate physically between meat produced with or without these hormones. JEFCA concluded that it would be very difficult to determine residue levels attributable to the exogenous use of the naturally occurring gonadal hormones.

6.31 While it was most unlikely that consumers could physically differentiate meat produced with synthetic hormones, residues could be reliably detected well below those levels regarded as safe. However, qualitatively the residue would be indistinguishable. Quantitatively, the amount that could be detected would be a function of the amount that would have been administered either for growth promotion or therapeutic uses.

Question 3:

> If any one of the six hormones or a combination thereof is administered to the animal, will there always be a residue of that hormone in the meat of that animal, even if it is so small that it cannot be detected? Question 32: Further to question 3, could the hormone load ingested by humans from other foodstuffs (including endogenous hormones) be greater than which occurs from the consumption of beef derived from hormone-treated cattle?

6.32 **Dr. André** indicated that a specific detection limit below which a residue could not be identified and/or quantified was defined for each method. It never meant that the residue was not still present in a given matrix. The lower the detection limit of the method, the lower the level of residue which could be revealed, but the longer the time of possible identification of the residue. For some growth promoters the time during which it was possible to find residues had changed from one week to one month after substantial improvement of the method (high resolution mass spectrometry instead of low resolution mass spectrometry for instance). With the development of sophisticated new methods, it was possible to observe residues remaining much longer than was commonly known.

6.33 Other foodstuffs than meat from hormone-treated cattle contained hormones, especially oestrogens. This was the case of offals, of certain plants, of meat from specific animals (such as pregnant cows); all contained high levels of hormones. However, the consumption of these foodstuffs was always occasional and would not enhance risks for human health. This was not comparable to the systematic enhancement of the hormonal content of meat.

6.34 **Dr. Arnold** stated that he was not considering the endogenously produced hormones as "residues" in his answer. Any exogenously administered hormones present in the body of treated animals should, however, be considered as "residues", even if there was no difference in structure and biological activity com-

pared with the endogenously produced hormones. The use of the term "residue" did not imply that these residues were potentially harmful to human health.

6.35 Whether animals were slaughtered without any withdrawal time or at the end of the legally established withdrawal time, there would always be a residue. The exogenous compound was not absent at the end of the withdrawal time; however, the sum of both the endogenous and exogenous molecules would be at or within physiological limits. If the presence of residues were to be regulated on the basis of "no-detectable-residues" (which was impossible because the endogenous hormones alone were already above the limit of detection), there would nonetheless be more than 1000 billions molecules of the administered exogenous hormone present in one kilogramme of meat at the limit of detection. In other words, the "no-detectable- residue" concept was a false-zero-residue“ concept. For any of the six hormones, it was impossible to estimate the withdrawal times required to reach true "zero-residue" levels even with the aid of the most sensitive analytical methods.

6.36 Many foods of both plant and animal origin contained natural hormonal substances in such amounts that, depending on the actual diet, the dietary intake could be lower, equal or higher than the amount ingested with beef from hormone-treated cattle. If the endogenous production was taken together with the dietary intake, it would always be much higher. Given their natural presence in food, he stated that one cannot escape eating these hormonally active substances, or similar substances with related biological potential.

6.37 **Dr. Lucier** responded that biological half-life data was available for each of these hormones, so residues could be reasonably predicted at various times after exposure had ceased. In the case of zeranol the half-life was approximately one day. Thus, if a sample contained 100 ppb when exposure ceased, 50 ppb would remain after one day, 12 ppb at three days, three ppb at five days and so on. Although the levels after several months would be extraordinarily small and very likely non-detectable, a few molecules would remain.

6.38 **Dr. McLean** indicated that a minute residue, well below any present method of detection, might remain. This could be postulated from a knowledge of pharmacokinetics. This minute residue would be of no significance when compared with endogenous production of natural hormones in the human body, or the dietary intake of natural oestrogenic substances in food or contaminants which were oestrogenic.

6.39 **Dr. Ritter** observed that in the case of the natural hormones, and in accordance with appropriate use procedures, hormone levels could be expected to decline to levels that would be associated with untreated control animals. Because these hormones were normally produced endogenously, it would be essentially impossible to distinguish these low levels as originating from an exogenous source, and in any case these levels fell well within the range normally present in untreated animals. In the case of the xenobiotic hormones, and in particular trenbolone acetate and zeranol, residue levels of these hormones would not normally be expected in untreated animals and hence could be detected in monitoring pro-

grammes. It was possible that, depending on the withdrawal period selected, some residues of the xenobiotic hormones might remain, even if below the limits detectable by routine methodology.

Question 4:

> How do the residues from the three synthetic hormones in dispute differ, in general, from those of the three natural hormones in dispute if administered in accordance with good husbandry practice and good veterinary practice? And, in particular, when used for animal growth promotion in accordance with good husbandry practice and/or good veterinary practice? How do residues of hormones naturally present in animals, meat, meat products or human beings, differ from those of additional hormones administered to animals? Do these differences, if any, result in different potential risks to human health?

6.40 **Dr. André** replied that because the compounds were not the same, they led to chemically different residues. The residues also differed quantitatively according to the dosage. Levels of oestradiol, testosterone and progesterone residues increased significantly in animal tissues after treatment, when compared with corresponding untreated animals. Usually, the increase of residue levels was more pronounced in fat than in muscle and other edible tissues. Concerning trenbolone and zeranol the approximate residue levels could be considered, for both compounds, to be close to the ppb level.

6.41 Differences between natural occurring hormones at a natural occurring level and the same hormones at a higher level or synthetic hormones (whatever their level of residue) resulted systematically in different potential risks to human health, due either to the level of residue or the nature of the residue (metabolites). According to the route of administration of additional hormones, some differences in metabolites patterns might appear. Metabolites could be species-specific: metabolites not formed in cows might form in humans and result in potential risks for human health. The potential induced risk could be due to the hormonal activity of residues. The potential adverse effect could also be a carcinogenic effect.

6.42 Within the physiological range these hormones had no different biological effects on human beings. But if one ate only meat from treated animals, there would be a very small enhancement of the mean of food hormonal intake and this would not be transformed in classical biological effects for human beings. The problem was that some other biological effects had needed to be studied over a long time. Such effects included, for example, changes in human fertility or change in the sex ratio, which was currently changing in some countries. But there was no currently known relationship between these developments and the fact whether these countries banned or not these hormones.

6.43 **Dr. Arnold** responded that in chemical terms, there was no difference between endogenously produced "natural hormones" and exogenously administered "nature-identical" hormones. There were, however, clear chemical differences between the "natural" and "nature-identical" hormones on the one side and

the xenobiotic hormones on the other side. The xenobiotic hormones do not naturally occur in animals, meat, meat products or human beings, so any reliably detected residue of the three synthetic (xenobiotic) hormones was indicative of a treatment of the animals. If the products were administered in accordance with the "good practices", such residues might frequently occur in concentrations too low to be detectable in meat.

6.44 In terms of biological activity, in principle, the potential biological effects of the "nature-identical" exogenous hormones were the same as for the "natural" endogenous hormones. While the concentrations of endogenous hormones were, however, regulated depending on e.g., sex, age, developmental stage etc., the exogenous hormones could, in principle, be added in such amounts as to either gradually disturb or - at high doses - even overwhelm the internal regulatory mechanism. Single high doses (e.g., resulting from the ingestion of a "full" injection site) would normally cause transient effects. Repeated high doses (not reached through ingestion of residues resulting from uses such as growth promotion, therapy, or zootechnical treatment) could significantly change the hormonal balance of the individual.

6.45 Dr. Arnold summarized that the potential risks to human health arising from the hormonal activity of the xenobiotic hormones was slightly different in quantitative terms. The potential risks arising from *other than* hormonal actions were qualitatively different. These risks were assessed during the review and approval process, and the approved conditions of use eliminated all unacceptable risks.

6.46 **Dr. Lucier** replied that the residues from the three synthetics differed in several ways from the naturally-occurring hormones. First, the chemical structure was different. Second, any metabolite or breakdown products would likely be different. Third, the synthetic hormone, although mimicking the natural hormone, might have additional biological properties not found in the natural hormone. These differences could possibly result in different potential risks to human health.

6.47 Some biological effect could occur. For example, a normal woman might have 30 per cent of her oestrogen receptors occupied at some given point in time. At that same point in time, if she was consuming meat that contained an additional burden of oestrogens because of the use of growth promoters, that receptor occupancy might be something like 30.01 or 30.001, a very very small increase. This increase would not be detectable, not even close to being detectable, by any experimental tools available today. Thus, a biological effect could be occurring; if it was occurring it would not be detectable; and finally the relationship between that biological effect (receptor occupancy) and a toxic effect, say cancer or birth defect or something like that, would be unknown. But if such an effect were occurring, it would be extraordinarily small, close to zero.

6.48 **Dr. McLean** indicated that the residues from the synthetic hormones differed from those of the natural hormones because they were chemically different compounds and therefore their metabolites would also be different. In the case of

the naturally occurring hormones, the residues in meat and humans would be very similar. Any difference would not pose a potential risk to health.

6.49 In relation to the naturally occurring hormones, Dr. McLean noted that it was not possible to differentiate between the effects of meat from treated animals against meat from untreated animals because essentially they were in the same biological range. In the case of the non-naturally occurring hormones, in establishing the ADI very sensitive end points were derived from studies in non-human primates, and then the situation of sensitive members of the population was taken into account when establishing safety factors. The levels in meat were substantially below those causing any effects in primates, and there was a reasonably good correlation in effects of hormonal levels in primates against humans. Therefore the levels present in meat from animals that were treated with the two non-natural growth promotants would not cause effects in humans consuming the meat.

6.50 **Dr. Ritter** observed that when introduced exogenously as subcutaneous implants, the natural hormones were absorbed and metabolized in an identical manner to the endogenous form thereby producing a spectrum, both qualitatively and quantitatively, of residues which were indistinguishable from the normal endogenous hormones. In the case of the synthetic hormones, trenbolone acetate, zeranol and MGA used as growth promoters, tissue residues were not normally present and hence detectable residues were attributable to their use. In this case, maximum residue levels were recommended only after careful and thorough evaluation of the safety file, food consumption factors, selection of appropriate withdrawal periods and, in consideration thereof, residues remaining were not considered to pose a risk to consumers of meat or meat products containing these residues at or below internationally recommended limits.

Question 5:

> The EC has identified certain potential health hazards of concern to it (ie., carcinogenicity, synergistic effects, genotoxic effects, long-term use and exposure to combination of the hormones in question). To what extent were these hazards taken into consideration in the context of the 1988 JECFA report or in the establishment of the Codex standards for the hormones in issue? To what extent do the risk assessments referred to by the EC assess these suggested hazards? Had the six hormones in dispute been used as animal growth-promoters over a sufficient number of years for an assessment of the long-term effects of such hormones on human or animal health to be made? Question 29: Further to question 5, to what extent do the ADIs and MRLs established by Codex for any food additive, pesticide, etc., take into account the effects on human health of exposures to mixtures of veterinary drugs, or exposure to the hormones in question originated by other sources? To what extent do the ADIs and MRLs established by Codex take into account the effects on human health of exposure to mixtures of veterinary drugs, or exposure to the hormones in question originated by other sources?

6.51 **Dr. André** indicated that the potential health hazards taken into account by JECFA were based on data available in 1988. Moreover only toxicological effects of these drugs were evaluated. Synergistic effects, long term use and combination of hormones were not fully evaluated. New results concerning toxicological effects of natural and synthetic hormones had been published since 1990, most of them in 1995 and 1996. Some of these new data were taken into consideration when preparing EC 96/22 and 96/23 Directives, however they were not taken into account by the 1995 EC Scientific Conference because the bibliography for the Conference had been prepared at the beginning of 1995. Many other hazards for human health could be either scientifically proven or excluded. Owing to the nature of these hormones, the residue levels, and the way they were ingested (assuming that good veterinary practice and good animal husbandry practice were respected), a 30 to 50 year period might be necessary to obtain substantial data (as for oral contraceptives or asbestos inhalation).

6.52 When individual drugs were used in common veterinary practice for therapeutic purposes, the probability of the simultaneous use of two drugs was low; the probability of an interference between them was lower, and lower still was the probability that one could influence the elimination rate of another. For the hormones used as growth promoters, the problem was different. They were used on a very large scale. Many animals were treated so that the probability to have simultaneous administration of other drugs and of these hormones became much higher. A good risk assessment should take this into account, but he was not aware of that having been done either in the countries where these hormones were in use or at the international level.

6.53 **Dr. Arnold** replied that synergistic (and antagonistic) interactions of these hormones at all levels - from the molecular to higher organisational levels - were key elements of their normal biological functions. It was difficult to identify what theoretical hazards might arise from theoretically possible maximal changes in the order of < 0.1 per cent of internal hormone pools due to the consumption of meat from animals treated with the approved hormonal growth promoters. Long-term exposure to hormones in laboratory animals and humans was fully covered by the JECFA evaluations (e.g. in the case of zeranol and trenbolone-acetate by the chronic/carcinogenicity studies reviewed). Data not available to the 32nd JECFA were completed at the 34th meeting of the Committee.

6.54 In the Community, the competent advisory body for the safety evaluation of oestradiol-17β, progesterone and testosterone was the Committee for Veterinary Medicinal Products (CVMP), a section of the European Medicines Evaluation Agency (EMEA). EMEA was also, in principle, the competent authority for the review of applications for marketing authorization of veterinary medicinal products used for growth promotion. A centralised review process would be mandatory under the provisions laid down in Regulation 2309/93. The use of any hormonal substance for growth promotion was, however, currently prohibited.

6.55 Under the provisions of Articles 7 and 14 of Council Regulation 2377/902[185], Maximum Residue Limits (MRLs) had to be established for the therapeutic and zootechnical uses of the three "nature-identical" substances before the end of 1996. The EMEA reviewed (in accordance with regulation 2377/90) the therapeutic uses of oestradiol-17β in cattle and horses. The public summary report states:

> "3. Toxicological effects found after oestradiol administration comprise hyperplasia of the endometrium, behavioural changes and effects of metabolic processes. Oestradiol does not induce gene mutations *in vitro*, but conflicting results are found in chromosomal aberration assays. Following long term exposure the incidence of tumours in tissues with a high level of hormone receptors is increased (e.g. mammary tumours). It is concluded that the toxic effects including carcinogenicity occur as an extension of the physiological effects of oestradiol ...
>
> 7. The conclusion of the FAO/WHO Expert Committee on Food Additives (JECFA) that no ADI and MRLs for oestradiol need to be established is adopted. Milk and plasma residue levels after treatment with oestradiol benzoate and oestradiol valerate have shown to be at or within physiological limits. Although it is likely that tissue residue levels will also be within physiological limits, this cannot be guaranteed, given the results with oestradiol hexahydrobenzoate. Still, compared to the lowest human daily production rate of oestradiol in prepubertal boys (6 (µg/d)) and compared to the amount of oestradiol in other food stuffs that are part of the human diet, the amount of exogenous oestradiol that humans will be exposed to through ingestion of tissue from treated animals is biologically insignificant, and will be incapable of exerting a hormonal effect in human beings".

6.56 EMEA also evaluated progesterone in accordance with regulation 2377/90. The public summary report consists of 17 paragraphs and shows that the following aspects had been considered by the Committee: natural occurrence, veterinary uses, target animal safety, biological effects, endogenous production in humans, normal levels in food animals and in food of animal origin, pharmacokinetics and metabolism, acute and short-term toxicity in laboratory animals, reproductive toxicity, teratogenicity/embryotoxicity, and long-term effects including carcinogenicity. The evaluation by JECFA of this substance was also considered.

With respect to carcinogenicity it was stated:

[185] Council Regulation (EEC) 2377/90, *EC Official Journal* L224/1 of 18 August 1990.

> "9. According to the International Agency for Research on Cancer (IARC), progesterone does not exhibit mutagenic activity in most *in vitro* and *in vivo* tests performed, but is known to increase the tumour incidence in endocrine target tissues (ovaries, uterus, mammae) after continuous (parenteral) doses clearly above the physiological levels. Progesterone is not carcinogenic per se, but acts via an epigenetic mechanism associated with its endocrine activity, i.e. its ability to cause a hyperproliferative effect at cellular levels mediated by steroid-hormone receptor interaction. Hence, tumours will not result from ingestion of progesterone at levels that do not produce any hormonal effects".

The evaluation process of testosterone in accordance with regulation 2377/90 was still ongoing.

6.57 So far no complete risk assessment had been conducted in the Community; the most competent assessment was made by the Scientific Working Group on Anabolic Agents in Animal Production chaired by Professor Lamming. This Committee comprehensively reviewed the available scientific evidence, including industry data, concerning five of the substances under dispute. Its recommendations were endorsed by the Scientific Committee on Animal Nutrition, the Scientific Committee on Food and the Scientific Veterinary Committee of the EC. However, when the interim report was published, long-term toxicity data on the xenobiotic substances was available only for trenbolone acetate. The report also does not mention that "synergistic effects" and exposure to combinations had been considered. The "Pimenta Committee" did not itself perform a scientific risk assessment but rather expressed views on public perception of scientific opinion, the role of science in society, consumer preference, other socio-economic factors and various aspects of implementation and control of a ban.

6.58 The 1995 EC Scientific Conference had no legal mandate and the Steering Committee was entirely free to design the programme and to nominate invited participants. A legal notice in the report clarified that neither the European Commission nor any person acting on behalf of the Commission was responsible for the use which might be made of the information. The Conference did not assess the hazards referred to by the EC in this dispute. With regard to the Codex process, Dr. Arnold noted that it was true that the EC had objected to move these MRLs to the next step in the procedure, but without raising any health issues. The EC had opposed because it had specific legislation prohibiting the use of, and consumers did not wish to eat meat from, treated animals.

6.59 Sufficient time had elapsed to allow an assessment of the long-term potential effects on the health of the target animals. If long-term effects of these substances were to be studied, the effects of the endogenously produced amounts of these substances and of the exogenously administered human doses in therapy etc. were most relevant. Lifestyle and ingestion as normal food constituents could also be important. In the unlikely event that the minute amounts added from resi-

dues would have any effect on human health, it would not be possible to discover this effect against this background.

6.60 In response to the follow-up questions (in particular, question 29), Dr. Arnold noted that the primary mode of exposure to food additives was through ingestion of the substance in the food supply. JECFA considered, where applicable, the occurrence of the substances as normal body constituents; the natural occurrence in foods; exposure from other uses; and interactions with other food additives. For example, when canthaxanthin was evaluated, the Committee considered also the uses of this substance as feed additive in animal nutrition and as an orally administered pigmenting agent for human skin in both pharmaceutical and cosmetic applications. Early in its deliberations about safety margins the Committee had concluded that the margin of safety should allow for, *inter alia*, the possibility of synergistic action among food additives. The ADI for food additives generally included the natural occurrence and the deliberate addition to food of the substance. Testing of "mixtures" was not normally required. However, some food additives were by their very nature mixtures.

6.61 With regard to pesticides, testing of "mixtures" was also not required, neither in the framework of the activities of the FAO/WHO Joint Meeting on Pesticide Residues nor in the legislation of the European Communities as laid down in Directive 91/414/EEC Annex II, Part A (O.J. L 230 pp.15-18).

6.62 For veterinary drugs, testing of "mixtures" was not required. However, the comprehensive basic pharmacological screening required for all drugs could provide information requiring further follow-up in specifically designed tests. JECFA had evaluated a number of substances where the ADI was based on a pharmacological No Observed Effect Level. The legislation of the European Union also did not require testing of "mixtures" (see Directive 92/18/EEC amending the Annex to Directive 81/852/EEC, O.J. L 97 of 10 April 1992, pp.1-23). However, there was a difference between "mixtures" and fixed combinations. Such combinations required justification on the basis of adequate testing. Repeated dose toxicity testing could be modified (i.e. reduced) in certain instances, for example, if new combinations of known substances were proposed and no potentiating effects had been observed during initial screening.

6.63 Dr. Arnold noted that testing of "mixtures" of hormones was not normally required, unless an unknown fixed combination was administered. He noted that the experimental animals in toxicity testing (or humans, if there were uses in human therapy) were typically exposed to all hormones existing in the body. Virtually all cells were targets of one or several of the approximately 50 known hormones and their metabolites. The same hormone could have several targets; the same cell might have several responses to a single hormone. The battery of tests included exposure at all stages of development from embryonic to fetal to neonate to reproductive state until the end of the whole lifespan, and this way all situations of hormonal control were covered. This meant also that all xenobiotic hormonally active substances had been tested with respect to possible interac-

tions with the hormone system. No specific toxicity testing had been performed with the fixed combinations authorized in the European Communities.

6.64 JECFA developed its strategies concerning the evaluation of anabolic hormones in its 25th and 26th Report. These indicated that the toxicological evaluation of residues of anabolic agents that are present in human food obtained from animals treated with these agents must take into account whether the residue was identical to a human endocrine hormone. In the latter case, the possible endocrinological effects and carcinogenic potential of the residue must be closely examined. In addition, it was noted that chemically modified hormones, hormonally active agents from plants, and synthetic anabolic agents presented the following specific problems:

(i) extreme potency and consequently the need to ensure minimal residues;

(ii) potential tumorigenic activity; and

(iii) the presence of their metabolites in animal products that might be of endocrinological or toxicological consequence.

The evaluation for acceptance of the use of xenobiotic anabolic agents in animal food production resembled in many respects the evaluation of pesticides, since the two essential elements required were:

(i) adequate, relevant toxicological data; and

(ii) comprehensive data about the kinds and levels of residues when the substances are used in accordance with good animal husbandry practice, which required evidence as to the efficacy of the anabolic agent, the amounts used to produce the effect, the residue levels based on field trials, and information about methods of analysis of residue levels that could be used for control or monitoring purposes.[186]

6.65 **Dr. Lucier** responded that the issues of carcinogenicity, synergistic effects, genotoxic effects and chronic exposure appeared to be considered in the JECFA report, although the basis for the evaluation (ADI recommendation) was based primarily on hormonal effects in monkeys because the other effects or issues were considered of less relevance to human health risks. The hormones in question had been used long enough to get information on whether or not they posed animal health risks, provided that good records were available. However, there was no tractable approach for detecting human health risks from long-term use as the health risks, if any, would be quite small.

6.66 The number of molecules that remain following appropriate use of these agents was very small, particularly in relation to the amount of naturally occurring oestrogens or androgens. So the accompanying risk that would be associated

[186] Environmental Health Criteria 70, WHO, Geneva, 1987.

by consuming meat containing residues would be extraordinarily small. It would be very hard on scientific grounds to say that the risk was zero, but it was likely to be very, very small. It could be zero.

6.67 In terms of the carcinogenic activity of the hormones in question, it was already known that naturally occurring physiological levels of androgens and oestrogens were carcinogenic. Therefore, the issue of threshold was irrelevant to the toxicological evaluation of these agents. If a hundred thousand molecules of something already exist in the body and some of those molecules were producing a DNA damage event, there was some possibility that the same damage event would occur if another molecule was added to it because it was the same molecule. It would not be possible to distinguish that additional event from the ones that occurred from the thousand molecules. But it would not be possible to say that none of those events were related to that additional one molecule. This would not be detectable. The chances were very very small, but it would be impossible to say that the event could not occur.

6.68 With regard to the increased incidence of some tumours occurring in various countries in the world referred to by Dr. Epstein, it was probably true that there was a real increase in testicular cancer and this increase appeared to be predominant in young men which was especially disturbing. Why this was occurring, no one really knew its cause. There was no reason to think, however, that it was associated with oestrogen. There were many other factors that could be causing that. Breast cancer was also on the rise. However, one could not necessarily attribute that increase to exposure to exogenous external oestrogens. There were many reasons why exposure to genotoxic agents could be accounting for the rise in breast cancer rates; one needed to be cognisant of other factors and not just blame the exogenous oestrogens for everything. Regarding the oral contraceptive issue, Dr. Lucier indicated that Dr. Epstein was probably right that there would be an increase in breast cancer risk for women who started taking the pill very young because that extended the period of time in which they were exposed to high levels of oestrogen and this was a known risk factor for breast cancer. The same exposures a little bit later probably would not have an increase, so when averaged out, there was no statistically significant increase in breast cancer from oral contraceptives. No one challenged the fact that oestrogens were carcinogenic.

6.69 With regard to Dr. Metzler comments, Dr. Lucier noted that the adducts that may arise from synthetic materials were likely different and of more concern, in terms of a risk assessment, than the ones that arise from the naturally occurring ones, because there already was a given body burden of the naturally occurring oestrogens. The question of genotoxic or non-genotoxic was essentially irrelevant here since the dose response relationships for oestrogen increases in cell division (one possible mechanism of carcinogenesis) was likely to be linear because normal levels of oestrogen were causing cell replication.

6.70 **Dr. McLean** replied that the 1988 and 1989 JECFA reports addressed the issues of carcinogenicity and genotoxicity and their findings were accepted by

Codex. The compounds were not genotoxic carcinogens and the responses seen were related to their hormonal effects. These hormonal effects were evaluated using sensitive end-points in non-human primates. In the case of synergistic effects, it was recognized that the levels resulting from treatment with the naturally occurring hormones were significantly less than the natural levels already present in the treated animals. In addition, it must be recognized that all three hormones occurred in male and female animals and humans. With regard to mutagenicity, data for the naturally occurring substances was reviewed and referenced in the JECFA 1988 Report. The report was not silent on the matter but it referred to mutagenicity data that was in the published literature. In the case of progesterone, testosterone and oestradiol-17β, there were a number of published documents that JECFA did look at, and they are referenced in its report.

6.71 There was also human data available from therapy with various natural and synthetic hormones. This therapy was continued in humans for many years and the risks have been evaluated. The levels found in meat after treatment are many orders of magnitude lower than therapeutic levels, are poorly absorbed orally and so do not represent a hazard. The compounds had been used in many countries for long periods of time and there was no human epidemiological data which suggests any hazard. With regard to Dr. Epstein's observations related to increasing numbers of tumours, Dr. McLean observed that the increase in tumours occurred also in those countries where the use of growth promotants was not widespread and the increase began before the hormonal growth promotants received widespread use.

6.72 **Dr. Ritter** noted that data relating to carcinogenicity and genotoxicity were indeed available to the Joint FAO/WHO Expert Committee on at least five of the six hormones under discussion (all but MGA). In all of these cases, the relevant data formed the basis of: (i) the safety evaluation, (ii) the decision by the Committee that an ADI need not be allocated for the natural hormones, and (iii) the establishment of both an ADI and MRL's for trenbolone acetate and zeranol.

6.73 With relation to oestradiol, progesterone and testosterone, JECFA concluded that the increased tumour incidence was attributed to the hormonal activity of these hormones associated with the very high doses utilized in the experiment. These effects were not considered relevant to an evaluation of the safety of food residues. The Report was silent on the results of mutagenicity studies, which were available to the Committee for review. With relation to trenbolone acetate, JECFA similarly concluded that the carcinogenic effects detected were a direct consequence of the hormonal effect associated with the high doses utilized in the study and not of direst relevance to the interpretation of the safety of the food residues. JECFA also concluded that the tumorigenic effect of zeranol was associated with its oestrogenic properties at the high doses utilized in the cancer study, and therefore a safe exposure level to humans could be determined.

6.74 The issue of potential synergy was addressed, at least in part, by JECFA through the conduct of biochemical studies directed at the effect of excretion of

hormone combinations when compared to single hormones alone. Although these studies did not specifically address issues related to altered toxicity due to synergy, these limited data did provide evidence that while administration of hormone combinations could be expected to alter excretion kinetics quantitatively, there was no evidence of important qualitative changes. It was, however, clear that definitive studies relating to genotoxicity or carcinogenicity of hormone combinations had not been carried out, even though this was frequently the preferred method of use.

6.75 Dr. Ritter observed that the use of gonadal type hormones as anabolic agents had been in agricultural practice for approximately 40 years through many parts of the world. Regarding the synthetic hormones, both zeranol and MGA had been used as anabolic drugs, at least in the United States, for approximately thirty years while trenbolone acetate had been in use for approximately ten years. At least in the case of the natural hormones and both zeranol and MGA, broad scale use had now been in place for more than a generation with only few and isolated reports of potential adverse effects. The primary potential concern with regards to human health effects had been that of carcinogenicity. While the use of the growth promoting hormones for periods as long as 40 years should have been sufficient to result in an increased cancer risk in the human population, an increase which could be attributable to the use of these hormones had not become apparent. Noting that both breast cancer, particularly in post-menopausal people, and prostatic cancer had increased sharply in affluent countries. Dr. Ritter pointed out that this increase was thought to be primarily associated with genetic predisposition and significant alterations in lifestyle (Houghton and Ritter, 1995).

6.76 **Dr. A. Randell** commented on the relationship between the Acceptable Daily Intake (ADI) and the Maximum Residue Limit (MRL) and whether or not these were measures of acceptable risk. The maximum residue limit was definitely not a health-based limit. It was a limit established for the control of veterinary drugs in actual practice. The establishment of a maximum residue limit was such that the maximum residue would never lead to residues which would, in a normal ingestion of the product, cause any consumer to exceed the acceptable daily intake. Therefore there was an upper boundary to the maximum residue limit imposed by toxicology considerations. The lower limit was normally derived from residue trials in practice according to the proposed good veterinary practices in the use of these drugs. However, in the case of zeranol, this limit fell so far below not only the toxicologically derived limit but also the limit that one could determine with normal methods of analytical chemistry, that it was increased to take into account the fact that if a decent control programme were not going to be overly expensive, than the limit must be controllable by analytical procedures rather than by residue trials. The acceptable daily intake itself also was not a direct risk assessment in the sense that it provided a statement of quantitative risk. The ADI concept stated that there would be *no appreciable risk* as a result of exposure to the chemicals concerned. This was true within the JECFA and JMPR framework, for food additives, residues of veterinary drugs and pesticide residues. (Dr. Lucier's comment that the risk was probably somewhere be-

tween zero and one in a million, provided some sort of quantitative framework, but JECFA had never established a quantitative evaluation of risk in the application of the ADI.)

Question 6:

> Is there any more recent scientific evidence available with respect to the effects on human or animal health of the use of any of the six hormones in dispute especially when used for growth promotion purposes, other than the evidence already taken into account by Codex? How reliable are extrapolations from animal studies to possible adverse effects in humans? Further to questions 6 and 8, are you aware of new scientific evidence showing that the carcinogenicity, synergistic effects, genotoxic effects, long-term use and/or exposure to combinations of the hormones in question and their metabolites, if any do not only depend on the hormonal activity of the dose administered? Would such evidence invalidate the ADIs and MRLs established by JECFA/Codex?

6.77 **Dr. André** noted that recent reports of the effects on *animal health* from the use of the six hormones in dispute as growth promoters confirmed and finalized previous results.[187] Based on anatomical or histopathological observations, these results demonstrated the effects of commercially available implants on animal behaviour, development and reproduction. Young bull behavioural modifications had been confirmed: young bulls treated with zeranol "spent more time idling, eating and ruminating than controls".[188] Animal libido was systematically altered. The changes in the behaviour of bulls were usually correlated with histopathological modifications, well described in the 1980s as a tool for treatment diagnosis and more recently confirmed in bulls.[189] Similar phenomenon had been recently studied in other species, as the effect of trenbolone in male pigs.[190] The influence of these hormones used as growth promoters on reproductive tract development and reproduction had been confirmed in beef heifers: "The lower pregnancy rate in zeranol implanted heifers 100 days after exposure to bulls was caused by failure to cycle early in life and, in those that were cycling, failure to conceive and abortions between 25 and 45 days of gestation".[191]

6.78 First results of recent research work with mice on the effects of hormones on animal sexual development and reproduction were published in 1995. They concluded that "DES and Zeranol administered during mid pregnancy leads to decrease fetal weight and size and lower numbers of male offspring at birth".[192]

---

[187] Renaville *et al*. (1987), Dehaan *et al*. (1990), Moran *et al*. (1988), (1990), Herenda (1987), Beal *et al.* (1988).
[188] Legoshin *et al*. (1994).
[189] Tipirdamaz 1991, Ciftci (1990).
[190] Lopez-Bote *et al*. (1994).
[191] King *et al.* (1995).
[192] Perez-Martinez *et al*.

In 1996, the same authors demonstrated "that prenatal exposure to zeranol or DES induced abnormal testicular differentiation in the mouse".

6.79 Concerning *human health*, there was a discussion on the decrease of human sperm counts[193], an apparent increase of the incidence of hormonally-mediated diseases like breast cancer and endometriosis, and a decrease in the male/female ratio, which were thought to be due to oestrogens in the environment. Whether the use of hormones for growth promotion was contributing to this could not be scientifically proven at the present time.

6.80 Extrapolations from animal to human was an official tool for toxicological and efficiency evaluation of drugs under development. In general, they were regarded as conservative even if they did always contain a certain level of uncertainty. Moreover, these tests on animal models did not take into account the multiple exposure to many different compounds (characteristic for human diet). Humans were sometimes more sensitive for a certain effect than animals, and they were not always in as good health as laboratory animals. The action of food processing on residues was not checked in animal experiments. For some effects of chemicals on humans, such as long term effects over generations, no animal models existed. In other cases, results on animal models have sometimes been considered as not representative. For these reasons, many drugs which had been fully validated in animal models had been banned after several years of use in humans and the discovery of an unknown hazard.

6.81 **Dr. Arnold** indicated that since the last (JECFA) evaluation, science had made further progress in several areas, including the molecular mechanisms of action and the epidemiology of cancer. The newly available information did not, however, substantially change the basis for the evaluation of the five substances by the Codex/ JECFA system. Although animal studies, in general, could provide useful information on possible adverse effects on human health resulting from exposure to chemical substances, the possible health effects resulting from the oral ingestion of trace amounts of residues of the three nature-identical hormones, (oestradiol-17β progesterone and testosterone) could not be reliably and *quantitatively* predicted from the information contained in available studies.

6.82 Early studies in mice, which were conducted between 1940 and 1973, and which were referenced in the IARC Monographs, were in no way designed to assess the human cancer risk resulting from oral ingestion of low doses of oestradiol-17β. None of these studies used the oral route of exposure in any animal species. None of them was conducted under GLP-like conditions or according to contemporary test guidelines. Many of them were poorly documented. The principal aim of these studies was *to experimentally produce tumours* under a variety of condition. The test substance was usually subcutaneously administered (frequently as implant). The doses were often extremely high and not infrequently caused a high number of early deaths. Such dosing was inadequate for carcinogen

[193] Nimrod and Benson (1996).

testing in relation to the safety evaluation of residues. The studies demonstrated that subcutaneous injection or implantation of high doses of oestradiol-17β or of its esters alone or in the presence of other carcinogenic factors resulted in increased incidence of mammary, pituitary, uterine, cervical, vaginal, lymphoid and interstitial-cell tumours in mice. The IARC working group concluded on the basis of all animal data that there was *sufficient evidence* for the carcinogenicity of oestradiol-17β in experimental animals.

6.83 Similarly the animal studies with progesterone which were reviewed by IARC were also limited to subcutaneous and intramuscular injections and subcutaneous implantations of high doses; in rats and rabbits it was always given in combination with other sex hormones. Progesterone was administered together with carcinogenic substances such as dimethylbenzanthracene, methylcholanthrene, diethylstilboestrol or N-2-fluorenyl-diacetamide in the majority of the studies reviewed. From these studies IARC concluded: "There is *limited evidence* for the carcinogenicity of progesterone in experimental animals. In the absence of epidemiological data, no evaluation of the carcinogenicity of progesterone to humans can be made."

6.84 Similarly to the other two nature-identical steroid hormones, testosterone and its esters were tested in experimental animals by subcutaneous injection and/or implantation, and in rabbits by intramuscular injection. In this case IARC concluded: "There is *sufficient evidence* for the carcinogenicity of testosterone in experimental animals. In the absence of adequate data in humans, it is reasonable, for practical purposes, to regard testosterone as if it presented a carcinogenic risk to humans. The only related data in humans, although insufficient for an evaluation, concern the possible long-term effects of androgenic anabolic-steroids."

6.85 The contribution of information obtained from these animal studies was of little relevance for the *quantitative* assessment of the potential effects on human health of orally ingested, very low residual amounts of these substances having no effects on the physiological hormonal balance. In particular no additional human cancer risk could be deduced from these animal studies in the absence of other relevant information. With reference to studies conducted by other scientists, namely Dr. Liehr and Dr. Cavalieri regarding different types of DNA damage or genotoxicity established for oestrogen, Dr. Arnold agreed that with chemical methods all these things could be produced. The question was whether it occurred in living cells, at what concentrations, what enzymes were involved, what was the compartmentalization of these enzymes, etc. In his view, there were many gaps in the evidence. A scientist could not exclude that at the end somebody might show that oestrogens acted directly on the gene. For the moment, the evidence was not convincing and did not invalidate the basic conclusions of JECFA 1988.

6.86 In response to the follow-up questions, Dr. Arnold indicated that hormonal activity was a necessary requirement of hormonal carcinogenesis caused by the substances in dispute. He was not aware of any evidence which would invalidate the ADIs and MRLs established by JECFA/Codex.

6.87 **Dr. Lucier** indicated that animal data were usually relevant for estimating human health risks, particularly for hazard identification, and there was a substantial body of knowledge and past record to substantiate this conclusion. However, it should be kept in mind that there is considerable uncertainty in extrapolating high dose animal data to low dose human risks. Over the last 5-10 years much had been learned about (i) the mechanisms whereby hormones triggered responses in target cells including the interplay or cross talk between receptor systems, (ii) the development of credible approaches for dose-response evaluation, (iii) the spectrum of toxic effects produced by hormonally-active agents, and (iv) the role of metabolic activation of hormones. There was a growing body of knowledge that some hormones could be converted to genotoxic metabolites. However, it was not clear whether these metabolites are involved in the carcinogenic process.

6.88 **Dr. McLean** responded that he did not believe that data developed after 1989 would justify a revision of the present use of hormones for growth promotion. For example, studies of *in vitro* receptor binding assays in the presence of pesticides had not produced evidence of concern. The extrapolation in the case of the hormones was arguably more reliable than with any other class of compounds because their mode of action and their metabolism was similar in both animals and humans. Non-human primate and human data was also available in many cases. In the case of trenbolone and zeranol, the usual safety factors for inter- and intra-species variation were still applied. The extrapolations from animal studies to humans was reliable in this case. The current ADI and MRL would only be invalidated if new data established a lower NOEL. In the case of trenbolone and zeranol, the NOEL used was conservative and therefore low. In any event, if any national body or group believed that it was time for re-evaluation of some of the hormones previously evaluated by JECFA it should approach the JECFA as had been done on a number of occasions with the number of compound of varying chemical classes.

6.89 **Dr. Ritter** observed that the JECFA review, and the subsequent decisions by Codex, were based largely on reviews conducted approximately a decade ago. In respect of the three natural hormones (oestradiol, progesterone and testosterone), the 1995 EC Scientific Conference generally recognized that these substances could increase the growth rate, the properties of lean meat to fat and the feed conversion efficiency of some species of animals. The Conference reaffirmed that the resulting residues in meat were within the normal physiological range and concluded that the conditions of use of the natural growth promoting hormones provided a reasonable safeguard of public health. In respect of the synthetic hormones utilized for growth promotion (trenbolone and zeranol), the 1995 EC Conference advanced the view that at doses required for growth promotion, residue levels of these xenobiotic hormones were well below the levels regarded as safe. The Conference also noted the availability of only limited data on possible adverse effects in target animals and emphasized the need for further study of the effects of growth promoters administered in combination, as the presence of one might alter the metabolism of the other.

6.90 The validity of extrapolations from animal studies to humans was the pre-eminent issue in contemporary toxicological hazard and risk assessment and was the basis of the hazard evaluation for drugs, pesticides, food additives and other contaminants worldwide. Given the reliance by both national regulatory authorities and international agencies on animal studies for predicting possible adverse effects in humans, it would seem *de facto* that the international scientific community had placed a great deal of faith in the validity of these extrapolations. At the same time, however, it was also clear that the validity of animal models in predicting adverse human effects was influenced by many factors including selection of the appropriate animal model, dose selection, duration and route of exposure and selection of appropriate risk models designed to estimate human risks resulting from the use of a substance under realistic and practical use conditions.

6.91 Recognizing the inherent limitations of any predictive model, Dr. Ritter indicated that the scientific community had elaborated a hazard and risk assessment paradigm that involved evaluation of a broad range of toxicological endpoints, selection of the most sensitive for determination of a NOEL, application of an additional uncertainty factor for derivation of an ADI and models for estimation of dietary exposure which invariably substantially exaggerated intake levels. The net effect of this series of overly conservative calculations was most likely very conservative estimates of risk, intended to compensate at least in part, for the limitations inherent in the reliability of animal to human extrapolations. Indeed, in its concluding commentary, the Steering Committee of the 1995 EC Scientific Conference noted that the nature of the calculations described above was such that adherence to the ADI provided a high degree of confidence that adverse effects would not become apparent in people. In other words the European Conference essentially reaffirmed and strengthened the earlier conclusions reached by JECFA that in accordance with operating procedures that were provided for the use of these substances, their use did not constitute a risk to consumers of food commodities produced with the hormones at question, at least for five of the six substances.

6.92 Dr. Ritter noted that Dr. Liehr's work and the work of many investigators was to produce an effect. This was to the most fundamental issue in pharmacology and in toxicology, the concept of dose response. Dr. Liehr was very interested in understanding the induction of cancer as a result of exposure to these hormones. Therefore, his protocol would necessarily be designed in such a way so as to produce the desired effect, in his case the tumour. The intent in the case of food residues, was obviously to avoid a dose level which might constitute a human risk. Therefore, the levels that were present as residues in food were thousands or hundreds of thousands or millions of times lower than they would be in an experiment which was specifically designed to induce a tumour. These two experiments were completely at cross purposes with each other; they were from their very initiation intended to produce entirely different results. To compare a protocol which had been designed to produce a tumour to a food residue the use practice of which was set up in such a way so as to minimize the presence of the residue, was a relatively meaningless comparison. Moreover, no one could rea-

sonably assure that the presence of these residues albeit at low levels constitutes zero risk; in fact scientifically it would be impossible to ever test to a certainty. But the point was that if these low levels did constitute a risk, they constituted a risk of a magnitude which approached zero.

Question 7:

> Is there any scientific evidence available which demonstrates that a potential for adverse effects on human or animal health arises from the administration of any of the six hormones in dispute, in general, and in particular for animal growth-promotion purposes, if administered in accordance with good animal husbandry practice and/or good veterinary practice?

6.93 **Dr. André** replied that there was no published scientific evidence that the administration, in accordance with good animal husbandry practice and/or good veterinary practice, of any of the six hormones in dispute in general (i.e. for therapeutical and zootechnical purposes) and in particular for animal growth promotion purposes, induced adverse effects on human health. This only meant that during the last decades, in countries where they are in use either for growth promotion purposes or for therapeutical and zootechnical purposes, none of the heath problems which could be due to their use (such as cancers, reproduction problems ...) had been scientifically related to their use. However the questions remained whether this had been studied and whether the period of use was long enough (see response to question 5 above). Concerning animal health, see response to question 6 above.

6.94 **Dr. Arnold** indicated that he was not aware of the existence of such evidence.

6.95 **Dr. Lucier** responded that, to his knowledge, there was no piece of scientific evidence to indicate that any of the six hormones in question had unequivocally caused adverse effects in humans when administered and used properly. However, there was some information available which raised concern for a slight effect on incidence of human disease (see response to question 8).

6.96 **Dr. McLean** stated that there did not appear to be any evidence which unequivocally established that adverse effects had been caused in animals treated with hormonal growth promotants or in humans consuming meat from treated animals.

6.97 **Dr. Ritter** observed that as early as 1982, a WHO appointed Working Group concluded that when the natural sex hormones were used in accordance with instructions for their use in growth promotion, such use would not present any harmful effects to consumers of products which had been produced with the aid of these promoters. This Working Group also concluded that the levels of zeranol and trenbolone, and their major metabolites, found in edible tissue following appropriate use as growth promoters, were substantially below the hormonally effective doses in animal test systems and did not present a risk of harm to humans. Overall, the Working Group concluded that the five compounds were safe for use in target animals and in subsequent consumers when they were used as prescribed for growth promotion in meat production.

6.98 The EC 1995 Scientific Conference concluded that the effects on *animals* in terms of disease incidence, performance, general mobility and meat producing efficiency were either unchanged or improved. The effects on animal welfare were negligible in terms of health, performance and effects on behaviour, although it was noted that there might be a transient increase in sexual activity for 2-10 days in some adult steers receiving oestradiol.

Question 8:

> Is there any scientific evidence available that residues of any of the six hormones in dispute could have carcinogenic effects, even though in the case of the two synthetic hormones these residues fall within the MRL levels established by the Codex? Is there any scientific evidence concerning the biochemical and physiological mechanisms by which the hormones subject to this dispute exert their carcinogenic effects? Please describe the relationship between the hormonal effect and the toxic effect of the six hormones. Is there a threshold level below which there is no scientific evidence that residues of the hormones would have adverse health effects on humans? Are the concepts of "Acceptable Daily Intake" and "Maximum Residue Level" valid for, or applicable to, genotoxic carcinogens?

6.99 **Dr. André** indicated that previous results on the carcinogenesis of hormones had recently been confirmed. This was true for single hormones as well as for mixtures of hormones, administered *in vivo* and *in vitro*. Concerning the mechanism by which the hormones exerted their carcinogenic effects, the most important model was oestradiol-17β itself. It had been proven that oestradiol-17β, which was involved in the development of breast cancer, stimulated the development of malignant cells. Recent results showed that oestradiol-17β enhanced genomic instability in malignant cells, inducing deletions or additions in DNA. It was reported that natural oestrogens (mainly oestradiol) induced cell transformation via over expression and synthesis of oncoproteins. Some new information about the potential role and mechanism of action of progesterone in breast cancer induction and about the biochemical aspects of pituitary oestrogen induced carcinogenesis were published; however, they did not demonstrate achieved molecular induction process.

6.100 Recent data on the mechanism of the carcinogenic effects of hormones led to the conclusion that hormones or their metabolites exerted a direct effect on tumour initiation by DNA damage; for oestrogen-dependent tumours, catechol oestrogens and their quinone forms would appear to be involved. Further, hormones stimulated the growth of tumours in tissues in which they had specific receptors. They had a complex carcinogenic and genotoxic effect. The hormonal effect stemmed from receptor binding, translocation to the nucleus and gene activation. Powerful oestrogens were strongly bounded and concentrated in the nucleus. If their hydroxylation and oxidation induced potential genotoxicity and carcinogenicity, it was not surprising that the more hormonally efficient they were, the more genetoxic and carcinogen they could be.

6.101 Dr. André concluded that hormones had to be considered as genotoxic compounds and for such carcinogens, no threshold level could be defined; no ADI and consequently no MRL could be established. This was the general opinion of toxicologists (Kuiper, EC 1995 Scientific Conference). This opinion had also been adopted by the United States Environment Protection Agency (EPA) for a carcinogenic non genotoxic dioxin, TCDD.

6.102 **Dr. Arnold** responded that there was no evidence available showing that residues of any of the six hormones in dispute could have carcinogenic effects, even though in the case of the two synthetic hormones these residues fell within the MRL levels established by the Codex. It was not possible to summarise briefly all the known facts published in thousands of papers in the last decades and in particular in the past 5-20 years.

6.103 Steroid hormones primarily influence the expression of genetic information at the level of transcription by binding to, and activating, transcription factors. The activated transcription factors interact with the regulatory or promoter region of the genes. The hormone receptors are these transcription factors in the case of e.g., steroid and thyroid hormones. The complete DNA sequence of the human oestrogen receptor was cloned for the first time in 1986 using the breast cancer cell line MCF-7. In the mean time, the genomic genes for all three receptors (oestrogens (ER), progestins (PR) and androgens (AR)) had been cloned. Dr. Arnold characterized the biochemical hormone-receptor-interactions as follows: receptors were present in low concentrations; their binding sites were saturable at physiological concentrations. The binding sites exhibited high specificity and high binding affinity; binding was reversible. Specific receptor binding was the initial and necessary step in the sequence of events leading to a hormonal effect although it was not the only reaction the hormones could undergo. The effects terminated upon dissociation of the hormone-receptor complex.

6.104 The involvement of receptors in hormonal signal transduction was thus explained by the fact that in addition to the recognition domain for the hormone they possessed a second functional domain (about 70 amino acids long) through which they could bind to DNA. Steroid-hormone-regulated genes had at least two different regulatory elements, a "generic" promoter element and (a) hormone response element(s) (it was not clear how many response elements actually existed in naturally occurring genes). It bound the hormone-receptor complex more avidly than the surrounding DNA did. The hormone-receptor might also regulate several genes in the same cell and different genes in different target cells. Metabolites and related exogenous synthetic hormones might work on a different set of response elements. The details of how the interaction with DNA promoted transcription was still an area of investigation. However, the basic principle was well established.

6.105 Carcinogenesis could be operationally described as a multistage process involving at least three stages: initiation, promotion and progression. The intermediate stage of promotion did not appear to involve structural alteration of the genome of the cell but rather depended on altered gene expression. Both oestro-

gens and androgens had been shown to be effective promoters in their target cells as well as in liver. In contrast to initiation, promotion was a reversible stage depending on continued administration of the promoting agent. Besides tissue specificity, the general characteristics of hormonal carcinogenicity were: long induction periods and prolonged exposure at high levels with concomitant severe derangements in homeostasis. The dose-response relationship of promoting agents (as well as the receptor-hormone binding) exhibited sigmoidal curves with an observable threshold and a maximal effect.

6.106 Hormonal carcinogenesis in experimental animals had mainly been studied in rats, mice and hamsters. The promotor model of hormonal carcinogenesis had been developed through studies of a variety of tissues of these animals. The question under dispute was not whether these models were still valid but rather whether genotoxic mechanisms could additionally exist or would need to be considered in order to fully explain the carcinogenic potential of hormones. In a recent review ("Molecular Mechanisms of Oestrogen Carcinogenesis", J.D. Yager and J.G. Liehr, Annual Review of Pharmacology and Toxicology 1996, Vol. 36, pp. 203-32) it was confirmed that the hormonal effects of oestrogens were necessary but not sufficient to induce tumours. One metabolite of oestradiol (16-Hydroxyoestrone) was claimed to be capable of binding to DNA *in vitro* but this could not be confirmed *in vivo* (unpublished observations by one of the authors). It was furthermore postulated that the catechol-oestrogen formed by hydroxylation in position 4 of the A-ring of the molecule could be involved in the generation of reactive oxygen species through redox cycling. Catecholoestrogens were also able to bind to DNA *in vitro*, a finding which was not confirmed in vivo.

6.107 Dr. Arnold further responded that according to current scientific knowledge, threshold levels below which residues of the hormones had no adverse health effects did exist for a given individual. The individual threshold levels varied and this has to be considered when setting exposure limits for the entire population.

6.108 Dr. Arnold indicated that the ADI was derived from a "No Observed Effect Level" (NOEL) using appropriate safety factors. While it did not itself represent a threshold dose, it was indirectly related to a not precisely known threshold dose. Therefore, the ADI concept as defined by JECFA could not be applied in order to establish an exposure limit for direct-acting genotoxic carcinogens for which, at least theoretically, no threshold dose could exist. MRLs could be established, in principle, to regulate genotoxic carcinogens. Basically there existed two possibilities: if the residues were genotoxic carcinogens, alternative models, e.g., risk extrapolation, could be used to find an MRL; in the case of carbadox, JECFA was unable to allocate an ADI because the parent drug was considered to be a genotoxic carcinogen. In this case, however, the residues were demonstrably not carcinogenic under approved conditions of use. Thus, an MRL could be established on the basis of regulating an innocuous metabolite.

6.109 Dr. Arnold noted that MRLs primarily facilitated fair international trade and were not directly related to health effects. Only the total dietary intake of the residues of concern, taking into account all MRLs established for the same substance and all relevant commodities and their consumption by the population, could be compared with an exposure limit.

6.110 **Dr. Lucier** responded that in the case of the naturally occurring hormones, particularly oestradiol-17β and testosterone, there was very good evidence that physiological levels were carcinogenic. For example, breast cancer would strike one in nine women in the United States over their lifetime and there was compelling evidence that physiological levels of oestradiol-17β were necessary for this effect. The evidence came from both animal experiments and human studies and was derived from a large base of peer-reviewed published information. In the case of oestrogen, early menarche and late menopause increased risk whereas ovariectomy was protective. Also, endometrial cancer was dramatically increased by oestrogen replacement therapy if unopposed by progesterone. In the case of breast cancer, consumption of beef with elevated levels of oestradiol-17β could increase risk slightly if the carcinogenic risk was not already saturated by physiological levels of oestrogen. The question of threshold was irrelevant. It was known that existing levels were already carcinogenic.

6.111 However, Dr. Lucier noted that evaluation of carcinogenic risk in people consuming meat from growth-promoted animals was complex. For example, progesterone might protect against endometrial cancer. From a different perspective, one knew that diet was a critical determinant of breast cancer risk and that fat in the diet was a risk factor. Therefore, consumption of meat containing residues of growth-promoting agents might actually decrease risk because that meat contained less fat than meat from non-growth promoted animals. On balance, breast cancer and prostate cancer risk could possibly be decreased by eating meat from growth-promoted animals. Moreover, exogenous oestrogens protected against osteoporosis and cardiovascular disease.

6.112 Dr. Lucier indicated that simple categorization of agents as genotoxic or non-genotoxic, alone, had little value in determining if an ADI approach or a linear approach was more valid for risk assessment. This opinion was supported by analysis of 500 cancer bioassays conducted by the National Toxicology Programme (NTP).

6.113 **Dr. McLean** replied there was no evidence that the residues had any carcinogenic effect. In the case of the two synthetic hormones which had a MRL, this was based on a NOEL derived from a hormonal end-point in non-human primates. There was data available which gave information on the mechanism by which hormones influence the occurrence of tumours in animals and humans. This was a very active field of research because of the importance of tumours of various organs, such as the breast or the prostate. Natural and synthetic hormones exerted their effects by binding to cell receptors and causing a series of biochemical events which influenced the metabolism of the target tissues. In addition, cell proliferation and/or turnover might be influenced. If the level of hor-

mone was below that required to cause these events, there would be no adverse effects. However, in the case of the natural hormonal growth promoters, the normal levels of hormones in the human body were already many times greater than those from residues in food. The small amount in meat would not influence the course of events and therefore would not affect human health. Indeed it was very difficult to determine exactly where our hormone burden came from. But the fact of the matter was that humans were constantly being exposed to very significant levels of hormones and that the incidence of tumours which were associated with hormones in humans such as, for example, the breast or the prostate, had not significantly increased since the surveying had been carried out.

6.114 **Dr. Ritter** noted that carcinogenicity data had been available and reviewed for the three natural hormones and for both trenbolone and zeranol (see response to question 5). The issue of increased tumour production with all five hormones was therefore more a matter of theoretical consideration than one of practical risk. As was the case with oestradiol, and indeed with the other hormones under consideration, tumour induction associated with high exposure to these substances was a manifestation of tissues with high levels of specific hormone receptors that were normally responsive to stimulation by the particular hormone (JECFA, 1988). These effects, when they occurred, were generally considered to be the expression of very high dose receptor stimulation and were not believed to have any particular relevance for the evaluation of risks associated with dietary exposure to residues at much lower levels.

6.115 It was also widely recognized that toxic effects which might typically manifest at considerably lower levels then those required for receptor stimulation and attendant tumorigenic effects were a more appropriate basis for evaluation of potential adverse effects in humans following exposure to dietary residues. Notwithstanding, some authors (Liehr, 1996, unpublished; Adlercreutz, unpublished; Arnold, et al., 1996) had recently advanced alternative hypotheses regarding metabolism and mechanism of action of the gonadal hormones.

6.116 Historically, for chemicals which displayed carcinogenic properties in laboratory animals, it was assumed that a threshold dose did not exist. This view was due, in large part, to the fact that early studies focused on very potent carcinogens which manifested their effect by direct covalent binding to DNA; agents of this type which acted through direct covalent binding to DNA had also referred to as genotoxic. The subsequent hypothesis argued that even a single molecule of a substance might cause a heritable change in the DNA structure which would ultimately lead to tumour formation. In practice, it was now recognized that such a scenario was not likely, and that in any case many carcinogens acted through a non-genotoxic mechanism and hence did not target cellular macromolecules such as DNA. This particular point had been extensively elaborated with trenbolone, which was the subject of elaborate studies which demonstrated the absence of covalent binding potential associated with this hormone (JECFA, 1988). It was now apparent that NOELs could be determined for many chemicals that may show some evidence of carcinogenicity under experimental conditions. Under conditions where the effect was clearly non-genotoxic it might be possible

to derive NOELs, establish an ADI and propose an MRL. Chemicals which produced carcinogenicity through a clear genotoxic mechanism should be regulated as if a threshold dose could not be derived and hence a NOEL, ADI and MRL could not be proposed. In the case of non-genotoxic carcinogens, there was little scientific validity to the belief that these chemicals should be treated or regulated differently than chemicals which produced other adverse effects through non-genotoxic pathways.

6.117 Dr. Ritter concluded that there was no compelling evidence to suggest that these compounds should be immediately re-evaluated, on the basis not only of the historical reviews which had been carried out by JECFA and other organizations, but also on much more recent reviews, including those published as a result of the European Conference on Growth Promotion in late 1995, early 1996, and indeed on the basis of the statements presented by Dr. Liehr, Dr. Metzler and others. Dr. Liehr's recent work and the work which others recently cited suggested that there were circumstances under which adverse effects could be demonstrated in association with a multitude of these compounds. However, scientists were compelled to look at the totality of the evidence as it was available. In Dr. Ritter's view, the totality of evidence, recognizing the information presented by Dr. Liehr and other scientists, as well as the historical information, suggested that the assessments that were provided in JECFA 1988 continued to assure a reasonable degree of safety to consumers of these commodities. This was not only his opinion, he stressed, but indeed also the consensus conclusion of the 1995 EC Scientific Conference.

Question 9:

> Is there scientific evidence of particular human health effects in countries where meat produced with the use of any of the six hormones in dispute for growth promotion purposes is allowed for consumption as compared to health effects in countries where the use of such hormones is forbidden?

6.118 **Dr. André** indicated that there was no known scientific evidence of such particular health problems. Only serious, long term epidemiological studies could give informative data (see also response to question 5). Furthermore, the causal relation could be difficult to identify, i.e. if comparisons between human health disorders was between the United States population and the Community population, there were so many differences in life style between the two continents, that the probability to prove the responsibility of one causal factor (like hormones) would be very low. However, a correlation between breast cancer incidence and blood oestrogen levels in the North American and Japanese populations was demonstrated. Other markers of particular human health effects could be prostatic cancer, human fecondity or sex ratios.

6.119 **Dr. Arnold** replied that no such evidence existed. Such comparisons could probably not be made because other factors, such as genetic differences of populations, lifestyle differences, differences in therapeutic uses of some of the

substances and numerous other factors, would have much greater influence on the incidence of possible health problems.

6.120 **Dr. Lucier** stated that he did not believe that geographical patterns of human disease offered an approach for determining if residues of growth-promoting agents in meat increased risk of those diseases.

6.121 **Dr. McLean** noted that he was not aware of any evidence that there was any difference between the health of humans in countries where hormonal growth promoters were used and in those countries where they were not used. The life-span of humans in countries where hormonal growth promotants were used had steadily increased for a number of years. However, the reported incidence of cancer had increased because the population was older, diagnostic capacity had improved and better nutritional status increased cancer rates.

6.122 **Dr. Ritter** indicated that he was unaware of any data or other evidence of adverse human health effects in countries where meat was produced with the aid of the hormones in question, when compared to countries where the hormones were not utilized for meat production.

Question 10:

> How do the potential adverse effects on human health from residues in food in general, and meat in particular, from pesticides administered in accordance with good agricultural practice compare with potential adverse effects from residues of the six hormones in question, when the meat is from animals to which have been administered these hormones for growth-promotion in accordance with good animal husbandry practice and/or good veterinary practice?

6.123 **Dr. André** noted that these parameters were not developed with the aim of comparing the potential health risk of compounds. Each compound with potential adverse effects on human health was submitted to individual evaluations, so as to determine specific ADIs and MRLs (in food of concern). With regards to pesticides, Dr. André pointed out that some of the pesticides might facilitate adverse effects of oestrogens on human health.

6.124 **Dr. Arnold** responded that pesticides had biocidal properties and were frequently also otherwise very potent chemicals. Certain groups of pesticides were also used as veterinary drugs, e.g. as ectoparasiticides. These substances might have a significant potential to harm human health if not used according to good agricultural practices. The MRLs established in the EU and elsewhere provided sufficient consumer protection. It appeared that the margin of safety applied when establishing Codex MRLs for residues of veterinary drugs might be somewhat higher if the food baskets used and the calculated Theoretical Maximum Daily Intakes (TMDIs) were compared. JECFA/JMPR and CRVDF/CCPR had started harmonising MRLs for substances which were used in both agriculture and animal production.

6.125 **Dr. Lucier** replied that the tools of risk assessment were not sufficiently accurate to determine if pesticide residues or residues of anti-microbial agents

posed a greater risk than residues of growth promoting agents. In each case, the risk was somewhere between zero and a small number.

6.126 **Dr. McLean** observed that there have been very few documented cases of adverse effects caused by pesticide residues in food, when they were administered in accordance with "good practice". There did not appear to be any proven cases linked to hormonal growth promotants. The use of the word "potential" implied hypothetical cases. Given that hormones had effects on sexual characteristics and metabolic processes, then potentially these would change, if the changes could be perceived or detected.

6.127 **Dr. Ritter** indicated that MRLs need not be established for the natural hormones, when used in accordance with good veterinary and/or agricultural practice (see response to question 5). In the case of the synthetic hormones, the nature of the studies used to establish their safety, and the methodological approach for the establishment of MRLs, including determination of a NOEL, calculation of an ADI, establishing a withdrawal period and proposing MRLs, was virtually identical for both pesticide residues and hormone residues. As a result, one would not expect that potential adverse effects on human health would be lesser or greater for hormone residues than might be the case for pesticide residues.

Question 11:

> How do the potential adverse effects on human health from residues of carbadox (used in swine production) differ from the potential adverse effects arising from residues of the six hormones in question when used for growth-promotion in accordance with good animal husbandry practice and/or good veterinary practice? Question 30: Further to question 11 and 26, would you consider that the potential adverse effects on human health and/ or animal health from residues of carbadox, monensin, olaquindox, avoparcin, benzylpenicillin, carazolol, ivermectin and organophosphorous compounds are comparable to the potential adverse effects arising from residues of the six hormones at issue when used for growth-promotion in accordance with good animal husbandry practice and/ or good veterinary practice? Are any of the above mentioned substances carcinogenic? If any one of these substances or a combination thereof is administered to the animal, would there always be a residue of that substance in the meat of that animal, even if it is so small that it cannot be detected?

6.128 **Dr. André** indicated that carbadox proved to be a genotoxic compound, and consequently no ADI value had been proposed by JECFA (see also response to question 10). Olaquindox was known to be carcinogenic. Dr. André was not familiar with the others.

6.129 **Dr. Arnold** noted that as long as the "good practices" were observed, there was no relevant difference. If the lengthy withdrawal time was not observed in the case of carbadox, potentially genotoxic carcinogenic residues of the parent drug and another carcinogenic metabolite were likely to be present in meat of

treated animals. In the case of the hormones, only the frequent consumption of injection sites or implants would potentially cause effects on human health.

6.130 Olaquindox was genotoxic in a number of tests. However the parent drug was extensively metabolised and was not present as a residue if "good practices" were applied. Ivermectin was extremely potent against parasites, but it was safely used in humans for the treatment of e.g. "river blindness" at much higher than residue levels. Carazolol was a hazardous substance for humans with chronic bronchitis which was a substantial part of the general population. In addition, carazolol was administered to the target animals by injection. Benzylpenicillin was absolutely harmless for the general population but could provoke allergic reactions in some sensitized people even at the level of the MRL. Avoparcin was not registered as feed additive on the American continent; its use in the EU had recently been withdrawn. Strict adherence to the identified "good practices" was an absolute requirement for the use of some of these substances. Nearly all of these substances left detectable residues in meat of treated animals under conditions of "good practice in the use of veterinary drugs". At the oral hearing Dr. Arnold added that there is a commercially available alternative for carbadox mainly oxytetracycline.

6.131 **Dr. Lucier** indicated that it was difficult to accurately compare risks from carbadox residues to risks from residues of growth-promoting substances (see also response to question 10). However, he expressed concerns about carbadox residues and that the risks from these residues were likely greater than the risks associated with the use of growth promoters.

6.132 **Dr. McLean** replied that carbadox and its metabolite desoxycarbadox were not permitted in meat, because the latter compound was carcinogenic. In the case of carbadox, a withholding period was set to achieve the situation where there were no detectable residues in food. The three naturally occurring hormones were normally found in animals and humans. The data supporting the use of trenbolone and zeranol was extensive, with toxicological end-points related to their hormonal effects. Finite residues were permitted for trenbolone and zeranol. In this way any risk of adverse effects was managed through the MRL and safety to consumers was assured.

6.133 Dr. McLean further noted that olaquindox was considered to be genotoxic and no toxicity studies were available on its metabolites, therefore JECFA was unable to determine an ADI or MRL. Benzylpenicillin was widely used as an antimicrobial agent in animals and humans. Allergenic potential was the major toxic effect and it was recommended that the total intake be kept below 30 micrograms per day for a human. Benzylpenicillin showed no carcinogenic potential. While carazolol showed no genotoxic or carcinogenic potential, it was a potent beta-adrenoceptor blocking agent. MRLs had been established for pig tissues. However, if carazolol was used in pigs to prevent stress during transport to slaughter, there was concern that residues at the site of injection could result in consumers receiving a pharmacologically active dose of the drug. The toxicity and residue data base for ivermectin and related compounds was extensive and

the drug was also used in humans. The compound did not show genotoxic or carcinogenic potential and an ADI and an MRL had been established.

6.134 The organophosphorus compounds (OP) were described by Dr. McLean as powerful neurotoxins, and most of the untoward effects were related to the direct exposure of operators and others. There was a new syndrome of organophosphate - induced delayed polyneuropathy - which was of concern when there was acute exposure.[194] The OP had been associated with carcinogenicity and there were reports of acute poisoning associated with the consumption of treated food. Very low levels of the parent compound and/or metabolites might remain, although they could not be detected by sensitive analytical techniques. Dr. McLean did not comment on monensin or avoparcin because of the limited amount of registration data available which was in public domain.

6.135 **Dr. Ritter** observed that carbadox was reviewed by the JECFA in 1990. In its review, the JECFA considered data from short-term and long-term carcinogenicity, mutagenicity and reproduction studies with carbadox, and data from mutagenicity and long term studies of its metabolites. JECFA noted that results from several long term feeding studies in rats demonstrated dose-related increases in both benign and malignant tumours at doses above 1.0 mg/kg BW/day. Positive findings were also noted in 14 of the 15 mutagenicity studies reported. JECFA concluded that carbadox appeared to be both genotoxic and carcinogenic. Results from additional studies carried out with quinoxaline-∝-carboxylic acid, an important metabolite of carbadox, indicated that there were no effects on incidence of tumours, even at doses of 100 mg/kg BW/day. In view of the carcinogenic and genotoxic nature of carbadox and desoxycarbadox, a metabolite of carbadox, JECFA was not able to establish an ADI. Notwithstanding, the JECFA recommended MRLs of 0.03 mg/kg in liver and 0.005 mg/kg in muscle of pigs, based on and expressed as quinoxaline-∝-carboxylic acid.

6.136 The establishment of an ADI and recommendation of an MRL reflected scientific confidence in the expressed residue levels being essentially devoid of risk to humans exposed to dietary residues on a lifetime basis. Therefore, neither carbadox nor the growth promoting hormones should pose potential adverse human health effects as a result of exposure to dietary residues at or below the MRLs specified by JECFA. Notwithstanding, it was noteworthy that carbadox and at least one of its metabolites was both carcinogenic and mutagenic, while the hormones were not considered carcinogenic or mutagenic at biologically relevant doses. In addition, reliable residue monitoring and risk estimation of carbadox residues was somewhat complicated by the presence of bound residues, while residues of the hormones either fell within normal physiological range or could be reliably and easily measured.

[194] M. Lotti, *Toxicology 21*, (1992) p.465.

Question 12:

> Are residues of the six hormones in question found in milk or milk products? If yes, how do the levels of these residues compare to those found in meat from animals to which hormones have not been administered? How do the residue levels in milk compare to those found in meat from animals which have been administered these hormones for growth-promoting purposes? For therapeutic or zootechnical purposes?

6.137 **Dr. André** replied that residues of hormones in general are found in milk. However, the comparison with meat levels was not relevant. Moreover, hormones were not supposed to be used for growth promotion purposes in lactating cows, only in culled cows. For specific therapeutic or zootechnical purposes, only individual animals were allowed to be treated with hormones. In this case, the milk was not to be delivered for human consumption, as was the case for many other drugs.

6.138 **Dr. Arnold** noted that after injection of approved products (nature-identical molecules) permitted for use in the EU to lactating cows, residues would be found in milk. Depending on the product it could take several milkings before the residue levels would have returned to physiological values. Residues found in milk could be higher, equal or lower, depending on which tissues were compared and depending on many other factors (dose, route, age, sex, withdrawal time etc.)

6.139 **Dr. Lucier** indicated that if residues of the hormones in question existed in the human body, then residues would also be present in human milk.

6.140 **Dr. McLean** replied that hormones are lipid soluble and therefore pass into the fat portion of milk. More polar metabolites would also pass into milk, but it must be stressed that the hormones should not be used for growth promotion in lactating animals. When the various hormones were used for therapeutic or zootechnical purposes, the doses were much higher, therefore the levels in the tissues were higher. It had to be expected that the levels in milk would also be higher.

6.141 **Dr. Ritter** observed that growth promoting hormones were generally only permitted for use in beef cattle and veal calves, and not in lactating dairy cattle. Foxcroft and Hess (1986) reported that, at least in the case of the natural hormones, the residue levels of the administered compound or it metabolites in animal products were insignificant in comparison to the levels of the same steroids to which human subjects might normally be exposed. This could occur either (i) as a consequence of the endogenous production rate of sex steroids in human subjects or (ii) as a consequence of the steroids in meat and/or milk products derived from untreated animals.

Question 13:

> What factors and procedures should scientists consider in establishing an appropriate assessment of the potential adverse effects on human health from the use of the hormones in question?

6.142 **Dr. André** responded that an appropriate assessment of the potential adverse effects on human health stemming from the use of the hormones in dispute "should be more rigorous than common veterinary drugs because of the duration of their use and the very limited, if any, health benefits to the target species".[195] Scientists should consider all data available at the present time in dealing with the adverse effects of each compound (see response to question 8), their metabolites and their mechanisms of action, including their action at the level of exposure. Species-specific metabolite patterns should be compared, using (as far as possible) a combination of *in vivo* and *in vitro* experiments. Studies should include long-term feeding trials to address life time exposure. All studies should be performed with combinations of the hormones in dispute prior to registration, to obtain valuable data. The effects of the treatment on the kinetics of other common drugs had to be assayed. Epidemiological studies in humans concerning cancer incidence and other hormone related diseases had to be initiated.

6.143 **Dr. Arnold** indicated the following should be considered: pharmacokinetic data including metabolism in test animals and target animals, where available in humans; data (preferably quantitative data) from adequately designed toxicity studies in suitable animal species, including information on genotoxicity/carcinogenicity, and no hormonal effect levels; target animal safety studies; efficacy trials; epidemiological studies and other relevant observations in humans; kinetic residue studies; natural occurrence and human exposure from all sources, including endogenous production of the same or similarly acting substances; experience from the history of use in human and veterinary medicine (if applicable); and known or proposed conditions of use. A marketing authorization should only be given to strictly formulated products (not to the active substances). Conditions of use should be fixed in a binding manner in the approval process.

6.144 **Dr. Lucier** replied that there were several factors that should be systematically studied or evaluated if information was not available for assessment of risks from the hormones in question. Of special concern were potential risks for cancer and non-cancer effects (reproduction, development, cardiovascular disease, etc.). Additionally, information on effects in sensitive sub-population should be considered. Sensitivity could be conferred by genetic predisposition (presence or absence of cancer susceptibility genes), age (fetus, children or the aged), gender, existing disease status, nutrition, and co-exposure to other chemicals. These factors needed to be considered, although it was unlikely that information on them would ever be complete for any given substance.

6.145 **Dr. McLean** noted that the testing protocols used in countries such as the United States, Canada, the United Kingdom, Australia and by JECFA were adequate to assess the effects of the use of hormones on human health. In addition,

[195] Bridges, *1995 EC Scientific Conference Proceedings*, p.250.

there was a need for residue monitoring programmes to ensure that residues in meat were less than any MRL which had been established.

6.146 **Dr. Ritter** observed that scientists considered a wide array of toxicological endpoints and risk assessment procedures in estimating potential adverse effects on human health from residues of all chemicals, including anabolic hormones, other veterinary drugs and pesticides. The issue of factors and procedures which were appropriate to the assessment of the potential adverse effects on human health included toxicity studies which established the following: which organs and/or systems were most vulnerable to the toxic effects and under what exposure conditions; the nature of any damage and/or disease produced, and the dose response relationship; the time course for the onset and any progression of the adverse effect; the mechanism responsible for the adverse effect; the relevance of the adverse effect observed in experimental animals to humans; the potential impact of biological mechanisms which led to the adverse effect but which, by virtue of the dose utilized, were not relevant to the assessment of the biological effect in humans (this was particularly important for the hormones in question which were only associated with adverse effects at doses which were not considered to be of relevance to the assessment of human health effects arising from food residues); whether it was appropriate to consider the adverse effects observed as a function of a threshold mechanism, or rather if a genotoxic mechanism was more likely and hence a threshold mechanism would be an inappropriate risk model.

6.147 In addition, Dr. Ritter noted that it might also be relevant to establish if the nature of the residue was distinguishable from normal endogenous levels - this was particularly relevant for the use of the natural gonadal hormones which resulted in residue levels typically in the range of untreated animals; whether appropriate and reliable methods existed for the estimation and monitoring of residues of the hormones following their use as growth promoting substances; and knowledge of the uncertainty inherent in the hazard and risk assessment paradigm.

Question 14:

> What are the potential hazards, if any, to human or animal health of the use of large quantities, or doses higher than those recommended, of any of the six hormones in dispute? And from the administration of these hormones contrary to good animal husbandry practice and/or veterinary practice? Can you think of any incentives or disincentives for farmers to use quantities larger than those specified in the label of the manufacturers or to administer these hormones contrary to good animal husbandry practice and/or veterinary practice? Are you aware of any evidence of such use by farmers?

6.148 **Dr. André** indicated that a higher dosage, another route of administration than those recommended for delivery (other location for implants, injectable solutions of hormones, etc.), shorter withdrawal periods, etc., in short, any disrespect of good animal husbandry and/or good veterinary practices, might induce

higher levels of residues or changes in metabolite patterns. The first consequence would probably be a modification in animal behaviour and/or health. It was reasonable to think that a higher residue content in meat would enhance the risk of hazards to human health.

6.149 The anabolic effect of the hormones in question was proportional to the dosage, with a maximum effect. Farmers tried to obtain larger effects through administration of more implants than recommended, although it was not evident that a double dose, even at one time, gave a better response. In some cases, a parenteral administration (e.g. intramuscular injection) produced a more rapid effect than implants, and farmers tried by this mean to obtain faster effects. Disincentives for farmers to use larger quantities would be a decrease of the benefit/cost ratio, but implants were usually cheap. In countries where they were in use for growth promotion purposes, penalties due to higher residue levels detected in meat products compared to the MRLs might also have dissuasive effects on farmers. When five out of the six hormones in dispute were allowed in France, the experience was that farmers tried to give a second dose later. They did not respect the withdrawal period and they injected another dose at half way through the theoretical withdrawal period. Clearly they saw benefit to do this because the effect was longer at the time. Dr. André further reported that during the four to five years when these hormones were allowed as growth promotants in France, the misuse of other hormones continued and the black market was also present.

6.150 **Dr. Arnold** noted that there were considerable safety margins built into the established MRLs for the synthetic residues. As long as "good practices" were observed, the calculated theoretical maximum daily intakes of residues would range around 5 per cent of the ADI for both zeranol and trenbolone acetate. It had been shown that the implantation of approximately five times the recommended dose of zeranol would have almost no effect on maximum residue levels in the muscle and liver of steers slaughtered only five days after implantation. When a total dose more than 100-times higher than the recommended dose was intravenously administered as 6 split doses over three days to steers and the animals were slaughtered on the third day after the last dose, consumption of the meat of these animals would still not have caused an above-ADI intake of residues of zeranol.[196] The studies available to the 32nd and 34th JECFA showed that residues of trenbolone were highest if heifers were implanted shortly (15 days) before slaughter. With respect to the calculated theoretical maximum intakes, there was no difference whether this implant was the first or the second which the animal had received. From these data, it seemed unlikely that even the frequent use of higher doses, or repeat doses or slaughtering the animals at earlier than recommended times after implantation, could result in residue intakes in excess of the ADI by the consumer. For the three nature-identical hormones, the safety margins (theoretical residue intakes compared with endogenous production

[196] *Food and Nutrition Paper 41*, pp.44-45, FAO (1988).

rates of the most sensitive sub-population) were much higher than for the synthetic substances.

6.151 Dr. Arnold had no information with regard to melengestrol acetate, nor regarding incentives or disincentives for farmers to use combinations or illegal "cocktails" of these hormones. Although these pellets and another devices had been developed to give optimum results when the dose was respected, this did not necessarily prevent some farmers using more implants. But this did not necessarily cause higher residue levels in the carcass. On the other side, it was clear that if twice the amount was injected directly, all levels increased in plasma and in tissues, not necessarily in a linear way, but significantly. That was the difference between a slow release device (like ear implant) and a direct injection. On the other hand, the long term release of high doses might influence the pattern of hormone excretion in the animal's body and this was the intention of using such compounds.

6.152 **Dr. Lucier** indicated that any increase in the magnitude of exposure would likely increase any potential risks, but he did not consider himself qualified to answer the rest of this question.

6.153 **Dr. McLean** responded that the hormones in question, with the exception of MGA, were not well absorbed when administered orally. Grossly excessive doses might have an effect on consumers of meat, but these effects were likely to be mild and transient and could pass without being noticed. The dose prescribed under "good practice" was sufficient to exert a commercially satisfactory response, and there was no advantage in exceeding this dose. The dose suggested by the sponsor gave the optimum response and therefore, within limits, there was no need or benefit in administering more than was suggested. The regulatory authorities also examined the effects of overdosing during the registration process. Most regulatory authorities, including JECFA, required that data for residues setting did take into account dose rates that were in excess of what was normally used (generally at least twice and sometimes more) so that the effect of overdosing or variations in uptake could be seen. In countries where the use of these compounds was permitted, there were good educational campaigns for farmers as to the correct use and the reasons why the prescribed dose should not be exceeded, and the penalties that existed if one did. The results from residues surveys showed that, by and large, there was no exceeding of the MRL. In Australia, trenbolone and zeranol had been targeted in residue surveys very specifically looking for violations, and to all intents and purposes violations did not occur. Even if there was misuse, and that was difficult to prove, there were still no residues that exceeded the MRL. A similar situation existed with the naturally occurring hormones, where it was not possible to determine whether or not a violation had occurred because the levels that were found in the carcass fall within the normal range.

6.154 Dr. McLean observed, however, that in countries where the use was not controlled and there was no farmer education campaign and where it was difficult to apply a penalty, then the MRL was significantly exceeded. One of the impor-

tant factors of legalizing these compounds was to conduct an education campaign and to put in place monitoring procedures to ensure that the MRL is not exceeded. What was important with the maximum residue limit is to understand that it was a legal limit and not a health limit. In other words, exceeding of the MRL did not represent a hazard to health but rather a limit at which the authorities took action. However, to exceed the MRL would not be considered to be good practice.

6.155 **Dr. Ritter** noted that it was very difficult, if not impossible, to estimate potential hazards which might be associated with the administration of the hormones contrary to good practice, as the magnitude of the potential hazard would be related to the nature, extent, frequency and magnitude of the inappropriate administration. It had been reported that in the case of the anabolic hormones and using commercially available implants, repetitive implantation had only little influence on the residue profile.[197] Similarly, full and half-dosages led to similar hormone levels in edible tissues which, in the case of the endogenous hormones, were within the physiological range. Further, unlawful and improper use of oestradiol might result in residue levels some 300-fold in excess of established tolerance limits, and yet it was virtually impossible to visualize any hazard to humans ingesting meat from animals treated with zeranol.[198] Similarly, when steer calves were implanted with zeranol in accordance with recommended procedures, the margin of safety for consumption of edible products was greater than 25,000 and 150,000 for liver and muscle, respectively. While this work did not specifically address the issue of potential abuse, the large margins of safety postulated by the authors suggested that even under limited circumstances of abuse, it was unlikely that consumers would be exposed to unacceptable risks.[199] In countries where use of these hormones, the six hormones in particular, had been permitted for a very extended period of time, most notably Canada and the United States, monitoring and compliance programmes which had been conducted for many years consistently demonstrated that residue levels were entirely within recommended limits and that instances of violative residues, that was residues which would indicate abuses taking place, had almost never been reported. It seemed that at least in those jurisdictions where use was lawful, the practicality of abuse had never become a reality. There were few and isolated examples of violative residues in those countries where use had been permitted.

Question 15:

> What are the consequences in terms of potential hazards to human or animal health from the use of legally marketed combinations, if they exist, or illegal "cocktails" of the six hormones in dispute for animal growth promotion? Have legally marketed combinations been subject to the same

[197] Hoffman and Evers (1986).
[198] Truhaut *et al*. (1985).
[199] Sundlof and Stickland (1986).

testing regime as each of their individual components? Is there any evidence of synergistic effects of combinations of hormones? Can you think of any incentives or disincentives for farmers to use combinations or illegal "cocktails" of these hormones?

6.156 **Dr. André** replied that specific consequences stemming from the use of legally marketed combinations were not known. If they existed potential hazards could be due to synergistic and/or additive effects of the residues. This answer was also valid for illegal "cocktails" of the six hormones in which more than two components could be present. However there was another important potential hazard from the systematic use of these combinations: their use could result in modifications of kinetic parameters of other drugs. For example, trenbolone and testosterone were shown to dramatically decrease the elimination rate of sulfamethazine, trimethoprim and antipyrine in goats, with opposite experimental results in rats. As a consequence, residue levels could be higher than the MRLs at slaughter, even when legal withdrawal periods were respected.[200] Recently, the increase of the level of beta agonist residues in liver owing to concomitant oestradiol treatment had been demonstrated in calves.[201]

6.157 Dr. André was aware of only one combination (TBA + oestradiol) having been assayed by the JECFA in the context of residue determination in steers. No other combinations had been tested whereas individual components had been tested for toxicological effects. Evidence of synergistic effects of combinations of hormones existed and were well studied mechanisms. For example, concerning endocrinological therapy in humans, combinations of oestrogen and progestin hormones were used; oestrogens induced the synthesis of specific receptors for progestins, which could then exert their specific action. Legally marketed combinations had been developed on the basis of synergistic effects of their components on growth promotion.

6.158 Incentives for farmers to use combinations (legally marketed) or illegal "cocktails" of these hormones were frequently reported by official control bodies, since farmers tended to think that the more hormones used, the better the anabolic effect. Moreover, interactions between these hormones and other endogenous biochemical parameters (e.g. corticoids, IGF, etc.) were of great importance for human health and could be documented.

6.159 **Dr. Arnold** noted that fixed combinations were registered in the form of strictly formulated veterinary medicinal products and were different from illegal mixtures for which the term "cocktail" had been coined in Europe. Fixed combinations were not only used for growth promotion but also for the purposes permitted in the European Union. These combinations were approved and registered by the competent authorities under the respective rules governing veterinary medicinal products. The applicant had to justify the combination and had to demon-

[200] Van Miert (1988).
[201] Kuiper, *1995 EC Scientific Conference proceedings*, p.377.

strate the quality, efficacy, target animal safety and consumer safety of these products before they could be marketed. For these types of registered products, there was no evidence of a hazard to human health.

6.160 Dr. Arnold reported that the pharmacodynamic and toxic effects of practically all possible combinations of oestrogens, progestins and androgens had been studied in whole animals, organs, tissue and cell cultures, and other *in vitro* systems under a great variety of conditions. There was ample evidence of both synergistic and antagonistic effects. Such effects physiologically played important roles in endocrinology and metabolism. The current understanding of these phenomena clearly indicated that concerns over human health hazards arising from combinations of minute amounts of residues in meat were not justified.

6.161 The flourishing grey market in other veterinary medicines within, for example, Germany showed that farmers tried bypassing official distribution channels when purchasing otherwise licensed high quality products, mainly in order to save costs and prevent having to pay the veterinarian. To what extent "good practices" in the use were otherwise followed remained subject to speculation. It seemed, however, that not all rules were violated at one time. The situation with prohibited substances (e.g. hormones, chloramphenicol) and with abused substances (e.g., clenbuterol) was completely different. There was clearly a black-market where the "dirty products" prevailed. The availability of reasonably priced legal alternative products could be an incentive for many farmers to legalise their practices. Whether this would eliminate illegal cocktails now that the black-market has been well established, remained entirely speculative.

6.162 **Dr. Lucier** indicated that there was a definite research need in area of synergistic and/or antagonistic responses to combinations of endogenous or exogenous hormones. Based on current knowledge, it was likely that interactions existed but it was impossible to say with any degree of confidence for a given combination whether the interaction would be synergistic, additive or antagonistic. There was limited evidence to suggest that synergistic responses were occurring although the relevance of these findings to human risks had not been shown. Dr. Lucier noted that the same combinations of hormones, at certain levels, could have both some adverse health effects and some positive ones.

6.163 **Dr. McLean** replied that the legally marketed combinations had been examined by regulatory authorities to ensure that residues did not exceed levels seen in normal animals or the prescribed MRL. There were synergistic growth promoting effects seen in treated animals. Illegal "cocktails" were mostly found in countries where the use of hormones was prohibited, resulting in the establishment of an illegal market. They were not normally used where the full range of drugs was available because there was no advantage in the use of illegal drugs, and registered products were usually cheaper and of consistent quality.

6.164 **Dr. Ritter** noted that when growth promoting hormones were used as combinations, this use did not alter existing MRLs which had been either recommended internationally or established by national regulatory authorities, and hence the use of hormone combinations was not likely to have any direct adverse

consequences in terms of human health. In the case of "illegal" cocktails, it was impossible to speculate on the potential for adverse effects in either humans or animals, as this potential would be a function of the nature of the cocktail, the species of use, the dose, frequency and duration of use, and a range of other factors which could not be assumed.

6.165 In general, safety (toxicology) evaluations of drugs, pesticides and other food contaminants were carried out on single compounds only, rather than as combinations. There were several reasons for this approach which included prior pharmacological and biochemical knowledge that toxicity associated with combinations was not likely to produce effects greater than the sum of the individual components. On a more practical level, it was difficult to contemplate the broad range of possible combinations which would be the subject of testing. Finally, as different commercial interests might be involved in the production and sale of various growth promoting hormones, proprietary interests would make it unlikely that combinations could be evaluated toxicologically. In some cases, the efficacy of hormone combinations had been evaluated. In the case of combinations of trenbolone with zeranol or oestradiol, for example, it was found that (i) the combinations were equivalent in young bulls and steers, (ii) anabolics containing oestradiol were more effective in veal calves, and (iii) the composition and quality of the meat was not modified by the use of combinations when compared to single use.[202] As with any drug or unlawful drug combination, farmers sometimes were under the incorrect impression that combinations which had not been evaluated might provide significantly enhanced efficacy over those which had been approved for use. Such improper use of illegal cocktails could affect withdrawal times and residue limits and might, in some jurisdictions, result in compliance and enforcement as disincentives to the unlawful use of non-approved cocktails. Dr. Ritter noted that it must also be recognized that the quest for ever improved yield could lead some producers to the use of unapproved drug combinations.

6.166 **Dr. Randell** indicated that the monographs which were prepared by JECFA at the 32nd session clearly indicated that trials were done on mixed implants as well as on single substance implants. JECFA had considered such mixtures as oestradiol together with testosterone, oestradiol together with progesterone, oestradiol benzoate together with testosterone propionate and also oestradiol with trenbolone acetate under the oestradiol evaluations. These were known to JECFA at the time, and the pharma-kcenetics of these substances as they were gradually metabolized and excreted by the animals were studied by the experts at that time. Moreover, the information which was available to JECFA included carcinogenicity studies for all of the substances concerned.

Question 16:

> Which substances in addition to the hormone compounds at issue are present in the commercially available products marketed for animal growth

[202] Bouffault and Willemart (1983).

> promotion? Are there any potential adverse effects on human or animal health? Question 33: Further to question 16, are there other substances in human implants potentially dangerous to human health?

6.167 **Dr. André** noted that if the question referred to the excipient or to potential sub-products of synthesis, these data, as property of manufacturers, remained confidential. Concerning the simultaneous use of other drugs marketed for growth promotion (e.g. antibiotics), their residue levels could be modified by the use of the hormones (see response to question 15), so that a potential adverse effect on human health could appear.

6.168 **Dr. Arnold** indicated that other growth promoters (antibacterials) were used under the feed additives legislation of the European Communities (e.g., flavomycin, virginiamycin, zinc bacitracin, salinomycin, monensin, lasalocid). The review process was centralised. There were no known potential adverse effects on human or animal health if these additives are properly used. The use of glycopeptide avoparcin was recently withdrawn as a precautionary measure because of some suspicion that glycopeptid-resistance selected by the use in animal production could be transferred to human-pathogenic enterococci.

6.169 **Dr. Lucier** responded that there are many known cases of the presence of oestrogenic substances arising from plant products, pesticides and industrial contaminants. It was likely that the oestrogenic potency of these substances, taken together, exceeded that from meat residues of the six hormones in question.

6.170 **Dr. McLean** stated that there were a number of non-active components used in the implants to ensure that the drug was delivered over the life of the implant. These included a carrier for the drug and an inert matrix which made up the implant. The formulation was approved by the regulatory authorities in each country. The components were often used in human and other animal drug formulations and their safety had been established.

6.171 **Dr. Ritter** replied that the composition of commercially available products was generally regarded as proprietary information. Consequently, he had no direct knowledge of the identity of the substances other than the hormones which might be present in commercially available hormone preparations.

Question 17:

> What are the implications for human or animal health of residues from misplaced implants or improper administration, i.e. when administered differently than indicated in the label of the manufacturer, of any of the six hormones in dispute ?

6.172 **Dr. André** indicated that the consumption of meat (or of any meat-containing food preparation) containing a misplaced implant could be a hazard for human health, in particular for children, fetuses, pregnant women or immunodeficient people. Misadministration of any of the six hormones in dispute could change the kinetics of elimination of these hormones and induce a subsequent higher level of residues. This could become a real health hazard if there was systematical misuse.

6.173 **Dr. Arnold** observed that there might be a concern only where misplacement (growth promotion) or improper administration (therapy, zootechnical treatment) lead to consumption of a whole implant or injection site. Otherwise, residues remaining in the carcass of the respective animal would have no effects, even if they were higher than would be expected if "good practices" had been applied. The worst case assumption was that a whole fresh implant containing oestradiol or an ester of this hormone is consumed, because the implanted dose was higher than the doses injected for the other purposes and orally active oestradiol-doses were lower than the required doses of the other hormones. If this entire dose was ingested at once, only transient effects on hormonal feedback mechanisms would be expected. Clear hormonal effects would occur if an entire injection site was processed, e.g., into a meat containing product and the same person would eat the whole product in divided portions over a couple of days.

6.174 **Dr. Lucier** stated that improper or misplaced implants could very well increase residues, thereby increasing the potential risk of the hormones in question. Preventive strategies for misuse needed to involve veterinary supervision, educational programmes, monitoring and stiff penalties for abuse.

6.175 **Dr. McLean** replied that the implants would likely be detected if they were eaten because the matrix could not be chewed. If swallowed, they would not be digested but would pass through the human gastrointestinal tract largely unchanged. The implications of misplaced implants may not be of great concern because they were often placed under the skin and removed at slaughter or during processing. In order to facilitate correct and easy administration, applicators were generally available from the pharmaceutical companies. One of the features of injections subcutaneously in the ear was that there was no massive reaction at the site. It was specifically designed, and all the residue studies were carried out, with the implant injected in the ear. The aim of injecting it there was to get prolonged and slow release at low levels over a period of time. It was specifically designed to be that way. Moreover, the injections were usually implanted in the ear because it was very easy to palpate a pellet or an implant under the skin of the ear which was a second way of identifying treated animals.

6.176 **Dr. Ritter** responded that the growth promoting hormones were generally administered as feed additives or as implants. In the event that implants were implanted at sites other than those recommended, it was possible that these sites contain unacceptably high residue levels if utilized as a source of human food. The selection of the ear as a site of implantation rather than other sites was because it was a tissue which normally did not enter the food chain and it made identification of the source of the material very easy. Injection site residues, which could be much higher than normal tissue residue levels, were thus extremely unlikely to enter the food supply. The extent to which acceptable residue levels might be exceeded would depend on the exact site of implantation and the withdrawal period involved. The implication for human health would in turn be related to these two variables.

6.177 Dr. Ritter indicated that illegal injection of oestradiol preparation could produce injection site residues which largely exceeded tolerances. In the case of feed additives, improper use might imply use of approved drugs in non-approved species, improper dose, improper combinations, improper duration of use and improper withdrawal periods. However, the provision of human safety was assured through the establishment of maximum residue levels, levels considered to be safe if consumed by humans in the diet for an entire lifespan. In the event that any of the improper use conditions noted above occurred, and to the extent that such improper use would impact on final residue levels, human safety was assured through appropriate monitoring of the food supply for compliance with approved MRLs.

Question 18:

> What are the effects on growth promotion of the use of female hormones on male animals and vice-versa? Are there any potential adverse effects on human or animal health from such use?

6.178 **Dr. André** said that the effects of hormones on growth promotion was sex-dependent. The use of male hormones associated with female hormones (ratio 10:1) in heifers had the best anabolic effect without sexual behaviour problems and vice-versa. Concerning the human health, the level of residues had to be taken into account, whatever the gender of the meat producing animals. Concerning animal health, the use of oestrogenic compounds in male animals was shown to result in squamous metaplasia, hyperplasia of the collecting ducts and fibromuscular hypertrophy in the prostate and bulbo-urethral gland, fibromuscular hypertrophy and hypoplasia of the epithelium in the seminal vesicles and epididymis and impaired testicular development. In female animals, oestrogen treatment resulted in squamous metaplasia and fibromuscular hypertrophy in the Bartholin's gland, hyperplasia and secretory activity in the vagina and cervix, and impaired follicular developments in the ovaries. The latter could also be observed when females were treated with androgens, impaired follicular developments in the ovaries sometimes resulted in cystic ovaries.

6.179 **Dr. Arnold** indicated that supplemental oestrogens in castrated males increased growth rate, presumably through an increase of endogenous levels of growth hormone, improved feed efficiency and reduced aggressive behaviour. Testosterone was mainly used to slow down the release rate of oestradiol because blood levels required for anabolic effects could not be reached with implants. No adverse effects were known on humans. The use in animals of hormonally active growth promoters might have behavioural side-effects in individual animals.

6.180 **Dr. Lucier** observed that some effects, possibly adverse, could occur in the animals receiving the growth-promoted substances. These effects could include feminization of male animals and masculinization of female animals based on both molecular and biological endpoints. These effects should not occur in people eating meat containing residues at the MRL of the hormones in question.

6.181 **Dr. McLean** commented that there was a wide range of combinations and doses available for a range of types of cattle. The combinations were designed to

ensure maximum dose response in the target animals. These combinations had been subjected to studies to ensure that the residue levels did not exceed prescribed values.

6.182 **Dr. Ritter** indicated he had no expertise in this area.

Question 19:

> What differences exist between the therapeutic or zootechnical use of hormones permitted by the EC and the use of hormones for growth promotion purposes, as permitted in the US and in accordance with good animal husbandry practice and/or good veterinary practice, in terms of administered quantities, residue levels and potential adverse effects on human or animal health? Do common therapeutic or zootechnical uses of the hormones in question in the EC involve large scale (ie.,whole herd) or repetitive treatments?

6.183 **Dr. André** observed that the use of the hormones for therapeutic or zootechnical purposes and for growth promotion purposes was not comparable for many reasons. The number of animals treated was different, as for therapeutic use very few animals were treated. For zootechnical purposes, the number was higher but remained limited. There were no systematic, repetitive treatments. For growth promotion purposes, the number of animals seemed to be large.

6.184 In addition, Dr. André stressed that the future of the animals treated either for therapeutic or zootechnical purposes or for growth promotion purposes was very different. In the first case the animals usually remained on the farm for months or years after treatment and the problem of residues was not of concern. The only comparable situation was for oestradiol benzoate, for which, in case of unsuccessful treatment in a cow, a withdrawal period of two months had to be observed. In the second case, the animals were slaughtered weeks or months after the treatment. Furthermore, the delivery conditions differed. In the EC, the therapeutic use of these hormones was particularly regulated. Finally, Dr. André noted that none of these therapeutic/zootechnical uses would change the level of residues of hormones in meat on large scale as occurred from growth promotion use. No scientist had said that it was a bad thing to use these hormones for therapeutical use; their use on a large scale for growth promotion was not the same thing.

6.185 **Dr. Arnold** replied that the total dose contained in an implant of oestradiol-17β was much higher than the dose injected for therapeutic purposes because the implant contained the quantity needed over a long time (e.g., 200 days). On a daily basis, however, the dose injected was much higher, and therefore, tissue residues (excluding the injection site) after treatment were much higher if compared with the residues measured at any time after implantation. No representative data were available for progesterone or testosterone that would permit comparisons. With the exception of oestrus synchronisation, individual identified animals were treated.

6.186 **Dr. Lucier** indicated that it was possible that extraordinarily low residues (likely non-detectable) of the hormones could be present at slaughter if the animals had received the hormones for therapeutic use (see response to question 3).

6.187 **Dr. McLean** replied that the therapeutic use of hormones generally required the administration of a larger dose, which in turn resulted in greater levels of residues. The persistence of these residues depended on the dose, formulation and site of administration. Individual animals or groups of animals were often treated at one time, but rarely the whole herd. Treatments may be repeated. Treated animals should be identified so that they were not slaughtered for human food until a suitable withdrawal period had elapsed. It was often necessary to withhold milk. When hormones were used for growth promotion, the implants slowly released the active ingredients and there was never a high peak of hormones in the tissues. In the case of therapeutic use, there often was a significant peak.

6.188 **Dr. Ritter** responded that the primary difference between the therapeutic and/or zootechnical uses of the hormones permitted by the Community when compared to growth promoting uses related primarily to the frequency of use, dose, and the potential number of animals to be treated. In all cases, therapeutic and/or zootechnical uses would generally involve lower doses at less frequent intervals in fewer animals, and, in the case of the Community, was restricted to administration by a licensed veterinarian. Notwithstanding, at least in the case of the natural hormones, the approach adopted by the Community for therapeutic/zootechnical uses provided for residue levels which fell within the range of levels normally found in untreated animals. While the basis for use of these hormones for growth promotion purposes was fundamentally different, the resulting residues appeared, nevertheless, to also fall well within the normal physiological range.

Question 20:

> Do you consider that the conditions imposed by the EC for the therapeutic or zootechnical use of these hormones can achieve its aim of avoiding any potential adverse effects on human health resulting from residues in meat from animals treated for such purposes?

6.189 **Dr. André** commented that this question was not related to a scientific expertise, and as a consequence, he could only give a personal opinion. When used for therapeutic or zootechnical purposes, these hormones were used by (or under the control of) veterinarians. This guaranteed that they were used according to the indications for which they had been registered (i.e. dosage, route of administration, withdrawal period). Moreover these hormones were used either on individual animals or in well defined herds, usually in order to synchronize oestrus. In this case, the animals were reproducting animals, they had a high value and would be slaughtered only several years after the treatment. The problem of residues was not of concern for these animals. It could not be compared with the use of these hormones for growth promotion. When used for therapeutic purposes, these drugs were needed to restore health and the benefit/cost ratio was

very high. When used for zootechnical purposes, the consequence for a great majority of the animals was to become pregnant and, exceptionally, to be slaughtered.

6.190 **Dr. Arnold** indicated that the products which could be used were reviewed according to the criteria established for the approval process of veterinary medicinal products, including established withdrawal times. If the approved conditions of use were observed, any potential adverse effects on human health resulting from residues in animals treated for such purposes could be avoided.

6.191 **Dr. Lucier** replied that the EC measures for the therapeutic or zootechnical use of these hormones could not guarantee "zero risk", although the potential risks were likely lower than risks from their use as growth promoter.

6.192 **Dr. McLean** responded that he was not fully familiar with practices in the Community. However, studies on antibiotic residues have shown that the involvement of veterinarians in the control and prescribing of antibiotics on farms did not always guarantee that residues would be controlled. The same situation would probably exist with hormones.

6.193 **Dr. Ritter** recalled that the Community allowed the administration of oestradiol, testosterone and progesterone to animals for therapeutic and zootechnical purposes only under conditions which restricted administration to a veterinarian, required registration of treatments and a sufficient withdrawal period. Given the nature of conditions imposed for such use, it was unlikely that residues resulting from exogenous application of the gonadol hormones would be present as residues. Notwithstanding, growth promotion uses of the natural hormones similarly would not result in residue levels in excess of those expected in untreated animals.

Question 21:

> Is there a difference in terms of potential adverse effects on human or animal health between residues of these hormones administered as feed additives, compared to residues of these hormones which are implanted or injected?

6.194 **Dr. André** indicated that as far as he knew, the metabolism of these hormones administered as feed additives had not been studied. To produce residues meant that they were absorbed, and that they are efficient and metabolised. Nevertheless, their use as feed additives could induce a risk for people potentially in contact with these hormones (factories, farmers, children etc.), and a risk for the environment.

6.195 **Dr. Arnold** responded that melengestrol acetate was only used as a feed additive. Zeranol and trenbolone acetate were used as implants only. Oestradiol-17β, progesterone and testosterone were administered by different routes including injection and implantation. It was difficult to make comparisons about potential effects due to means of administration because there were too many variables in the equation (chemical nature, dose, route, formulation, target species). If all uses were carried out in compliance with the established conditions of

use, the remaining residues could be regarded as safe. The safety margins might vary from one condition to the other and the consequences of non-compliance might also be different.

6.196 **Dr. Lucier** commented that the residues would be the same in terms of chemical structure, although the residue levels could be different quantitatively.

6.197 **Dr. McLean** observed that the control of the administration of hormones to animals as feed additives was by removing them from feed at a given time. In practice, because of carry-over in feed mixing plants and residues in storage silos and feeding stalls, there was not a sharply defined cut-off point. In the case of antibiotics, it was often necessary to use a dedicated mixing plant to avoid carry-over from treated to untreated feed. The dose absorbed could also vary depending on food intake and absorption from the gut. There was also the problem of accurately mixing small amounts of potent active ingredients through the feed. Injection was more accurate and reliable, and on balance the method of choice.

6.198 **Dr. Ritter** replied that potential adverse effects on human health invariably related to residues which exceeded acceptable limits. Proper use of growth promoting hormones as either implants or feed additives might result in residues which, if used in accordance with recommended and approved practice, should not exceed acceptable levels regardless of the method or means of administration. He noted that improperly placed implants could result in failure to properly identify implantation sites at slaughter and could thereby result in excessively high residues in those tissues which would otherwise be identified and removed. Properly located implants, when implanted in accordance with approved practice, should not result in unacceptable residues and hence there should be little impact on potential adverse human health effects regardless of the method or route of administration.

Question 22:

> With respect to Zeranol, Trenbolone and MGA, what are currently the technological limits of detection and/or quantitation of residues? Ie., what is the lowest level of residue which can be detected?

6.199 **Dr. André** observed that these hormones were considered as classical banned compounds (within the EC). They were controlled with methods whose limits of detection (LD) were equal or better than 2 ppb. However, most methods in use for screening purposes of these hormones were immunological ones. Their real limits of detection were usually lower than 0.5 ppb. Mass spectrometric methods allowed confirmation of results at this level. Furthermore, using techniques with high performance output such as high resolution mass spectrometry or MS-MS, the level of 10 ppt. or so could be reached.

6.200 **Dr. Arnold** replied that the technological limitations would allow the quantification of certain residues in certain tissues at concentrations below 1 ng/kg. This could not, however, be achieved in routine monitoring. Moreover, the limits of detection of current routinely applied methods may vary from country to country (within certain limits). Only few methods had been internationally collaboratively studied according to internationally harmonised protocols. Only few

methods were fully validated in accordance with the criteria first defined by the Codex Alimentarius and later adopted by the EEC in Directive 85/592.

6.201 **Dr. McLean** explained that there were two basic types of assays used. *Screening methods* were used to detect drugs for metabolites at the level of interest. These had high sample throughput and aimed to avoid false negative results. *Confirmatory methods* provided unequivocal identification of the drug and/or metabolites at the level of interest. The cost of analysis was considerably greater than for screening methods. These methods were constantly being reappraised.

6.202 **Dr. Ritter** responded that methodology for MGA had been reported[203] with a limit of detection of 5 ppb. and a limit of quantitation of 10 ppb., both in fat, the target tissue for this residue. LC methodology for the trenbolone acetate had been reported[204] with a limit of detection of 2 ppb in muscle and liver for β-trenbolone, and a limit of quantitation of 2 ppb in muscle and 4 ppb in liver for α-trenbolone in liver and kidney. GC/MS methodology for zeranol had been reported by Covey *et al* (1988) with a limit of detection of 0.1 ppb. and a limit of quantitation of 0.2 ppb. in liver or muscle. The Joint FAO/WHO Expert Committee on Food Additives (WHO, 1988) reported that radioimmunoassays could detect free and conjugated α- and β-trenbolone at levels of 75ng/kg in tissues. Radioimmunoassays were generally regarded as appropriate screening methods only, while conventional analytical procedures such as gas chromatography/liquid chromatography/mass spectrometry are generally regarded as suitable for confirmatory analysis.

Question 23:

> Can you describe how the EC ban is enforced in the EC's internal market both formally and in practice? How is the EC ban enforced at the EC's borders both formally and in practice? How are the conditions linked to the exceptions to the ban (i.e. administration of hormones for therapeutic and zootechnical purposes) enforced, both formally and in practice, in the EC's internal market and at the EC's borders? What is the formal content and practical effect of the EC's control programme which ensures that imported products do not receive treatment more favourable than domestic products?

6.203 **Dr. André** noted that this question was not related to scientific expertise. From a personal point of view he believed that the important number of workshops, international congresses (e.g. Congress on Anabolizing Agents in Gent : 1992, 1993, 1994; Euroresidue I in 1990, Euroresidue II in 1993, Euroresidue III in 1996), laboratory networks system, European research programmes, as well as the development of Quality Assurance Systems in Europe had to be considered.

---

[203] Anderson and Fesser (1996).
[204] Shih-Hsien Hsu *et al*. (1988).

6.204 **Dr. Arnold** replied that since its entry into force Council Directive 86/469/EEC had essentially harmonised the control of residues in live animals and meat. Starting from 1987, EC member States presented an annual updated national residue control plan for approval by the Commission. The results of residue controls were also reported to the Commission. The Directive was very clear and relatively inflexible in what concerned the identification of the substances and the species of animals to be checked and the number of samples to be taken. Unfortunately, a major part of the analytical capacities of the laboratories of the EC member States had to be used regularly to monitor substances which did not necessarily present the real problem areas (e.g., the stilbene oestrogens).

6.205 The scientific concept behind sampling, however, was not clear and was subject to different interpretations. It seemingly mixed elements of a statistically based monitoring system with other concepts. The reporting format was only semi-quantitative with respect to the reported residue contents of positive samples. In consequence, the results could not be used to compare the situation in the EC member States or, for example, to conduct a crude assessment of exposure of European consumers to residues of anabolic substances.

6.206 Dr. Arnold further explained that a network of reference laboratories had recently been set up with an outstanding European reference laboratory on top. However, the moderate financial contribution to the European reference laboratories from the Commission was given only on an annual basis, leading to difficulties in ensuring experienced permanent staff in these institutes. The quality of the national reference laboratories co-ordinating the activities of the routine laboratories carrying out the daily work could not be judged. Although it was not known how many routine laboratories were accredited nationally, it was obvious that systems of quality management had not yet been established everywhere in the Community.

6.207 The endogenous production in the animals of oestradiol-17β, testosterone and progesterone causes difficulties in the control of their use. MRLs have not been set, and cannot be set, for the therapeutic and zootechnical uses, because the distribution of the three natural hormones in the three categories of animals (untreated animals, animals illegally treated for growth promotion, and animals legally treated for the permitted purposes) largely overlap. Because withdrawal times could not be enforced on a broad scale and distribution chains were insufficiently controlled, only limited attempts - requiring a lot of man-power and other resources - could be made to enforce compliance. If there was a suspicion, of course, the animal involved can be traced back and the producer questioned about, e.g., the prescription of the drug, the veterinarian involved etc. The main difficulty was to identify suspect animals in order to start further investigations and measures. Only the discovery of an injection site or an implant containing illegal substances could provide proof of a treatment. Decision limits for the levels of oestradiol-17β had provisionally been established in order to identify suspect animals.

6.208 Enforcement was difficult if people did not want to comply with the legal rules - which otherwise would perfectly guarantee consumer protection. It appeared that illegal anabolic hormones were readily available. The expectation of extra profits was an incentive for the continued the use of these substances including beta agonists, not only for farmers but also for participants in the illegal network of distribution.

6.209 **Dr. Arnold** recalled that the requirements of Directive 86/469/EEC also applied to third countries exporting live animals and meat to the Community. Missions were regularly sent to these countries to evaluate their systems of residue monitoring and surveillance. At the border, enforcement relied entirely on the discriminating power of analytical methods. This was not possible in the case of meat from animals treated for therapeutic or zootechnical purposes, because this meat was not different from meat obtained from animals never treated or treated with the same substances for growth promotion. Although domestically produced and imported products were formally treated equally, the possibility of detecting illegal practices of growth promotion (illegal referring to non-compliance with EU legislation, not to uses which were also prohibited in the country of origin) was probably significantly greater for domestically produced meat because of the possibilities to inspect production plants with a history of non-compliance, to take samples from live animals, etc.

6.210 **Dr. Ritter** indicated that he had no expertise with regard to EC enforcement, in relation to a discussion about the number of animals checked per year in the European Communities and other countries. However, he noted that the number of samples taken could be misleading. The intent of any monitoring programme was the development of a programme that had the statistical confidence necessary to detect violations to the extent that the compound was used, to identify residue levels which were out of compliance. The relevant question was whether the monitoring programme was statistically confident and able to detect compliance. Most monitoring programmes were intended to detect a 5 per cent violation rate 95 per cent of the time. The number of samples that were required to do that varied from country to country and from commodity to commodity because it was a function of the use practices for the substances involved.

Question 24:

> What analytical methods, or other technical means, of residue detection exist to control the use of the six hormones in dispute for growth promotion purposes in accordance with good animal husbandry practice and/or good veterinary practice. What means exist to control the use by farmers of the six hormones in dispute for growth promotion purposes in accordance with good animal husbandry practice and/or good veterinary practice? What are their respective cost implications?

6.211 **Dr. André** replied that since these hormones were prohibited within Europe, their control was included in national plans, the aim of which was to survey their misuse. Analytical methods were available both for screening purposes and confirmatory purposes. For screening purposes, several methods had

been developed. Research was also carried out to prove the exogenous origin of natural hormones, when detected in urine samples, based on methods used in human for doping control. For confirmatory purposes, different methods existed, with most of the available methods being based on GC-MS detection and identification. These techniques had been developed for matrices like urine, fat, tissue, faeces or injection sites.

6.212 **Dr. Arnold** noted that the analytical community of the European Communities was very active. To provide the appropriate methodology to detect illegal practices of growth promotion - particularly the potentially hazardous practices involving black market drugs - was a great challenge for the scientists working in both academic and official laboratories. As a result, a large number of probably valid - although not always validated - methods relying on different principles was available. Furthermore, in the European Communities it was possible to inspect farms and sample live animals, with the consequence of fines or legal prosecution in case of violations.

6.213 **Dr. McLean** indicated that descriptions of analytical methods use were published by the regulatory authorities of many countries. Control of use by farmers was done through legislation which detailed restrictions on the sale, possession and use of the various hormonal preparations. The cost of these measures varied from country to country and the cost of analysis depends on the drug in question and whether screening or confirmatory methods were employed.

6.214 **Dr. Ritter** responded that the residue detection methodology utilized to control the use of the six growth promoting hormones generally followed those procedures described in question 22. Detection methodologies for veterinary drug residues were largely described by two main types of analysis (Blanchflower, 1995). Screening methods generally had a high sample throughout, permitting analysis of large numbers of samples in a relatively short period of time, and at minimal cost. They generally had a low probability of false negatives and could detect, but not accurately quantify, potentially positive samples. Screening methods for the growth promoters were typically represented by the radio immunoassays. In contrast, confirmatory methods were used to confirm unequivocally, and to quantitate, the presence of a drug residue. They were characterized by relatively low throughput and high cost both in terms of equipment and supplies, and a low probability of false positives.

6.215 Control of veterinary drugs used in food production by farmers was generally achieved by national authorities through imposition of regulations requiring that drugs of this type be dispensed only on the written authority of a properly qualified veterinarian and in compliance with relevant use information established by appropriate national regulatory authorities. Compliance was further assured through rigorous monitoring and, where appropriate, through enforcement activity. Cost implications generally related to the increased cost associated with the requirement that such drugs only be administered under the authority of a properly qualified veterinarian. Costs would also be proportional to the rigour

with which a monitoring and compliance programme was designed and implemented.

Question 25:

> What analytical methods, or other technical means, exist to control the use of the six hormones in dispute according to the conditions set out in the proposal of the EC Commission in 1984 (COM(84)295 final) and what are their respective cost implications?

6.216 **Dr. André** noted that this twelve year old proposal had been rejected by the European Parliament.

6.217 **Dr. Arnold** recalled that this proposal had envisaged the controlled use of the three natural hormones for growth promotion and proposed re-visiting the prohibitions of trenbolone acetate and zeranol after a scientific evaluation of these substances. In analytical terms, the enforcement problems would have been similar to those of today because residues in meat remaining after the (proposed) legalised uses for growth promotion would not have differed significantly from residues found after illegal uses in most cases. The pharmaceutical industry could have applied for marketing authorization of strictly formulated products, which would have been evaluated and approved under the veterinary medicines directives. There would have been competition between high-quality, efficacious and safe products and products of the black-market. However, Dr. Arnold could not judge whether this would have limited the growth of the now existing black market, thereby reducing the costs of enforcement.

6.218 **Dr. McLean** noted that the methods proposed in that Directive were similar to the methods now used in other countries. However, the passage of time had permitted better analytical technology and techniques and increased automation, often resulting in increased laboratory throughput at decreased cost per sample. Farmers were also much better educated about the need to avoid residues which exceeded the MRL. The Community would now be in a much better position to screen for residues in meat products than it was in 1984.

Question 26:

> Are there other products (including veterinary drugs) commonly used in the production of meat and animal products which have comparable potential adverse effects on human or animal health as the six hormones in question? If so, what analytical methods, or other technical means, of residue detection exist to control their use in accordance with good animal husbandry practice and/or good veterinary practices. What technical means exist to control their use by farmers in accordance with good animal husbandry practice and/or good veterinary practice? How do the cost implications for controlling the use of these other products differ from those used to control the use of the six hormones in question?

6.219 **Dr. André** responded that to the extent a compound was active as a drug, it could exert toxic effects. Drugs were submitted to regulation and were registered for precise indications, under precise conditions, including data on MRLs

and definition of withdrawal periods (see also response to question 10). Several methods for control were available. Drugs could only be registered for use when a method designed for residue control existed. Networks of laboratories and control plans were set up for drugs according to the same scheme as the one used for illegal drugs.

6.220 For products for which particular conditions of use were indicated, the control was usually in the hands of practitioners. New recording systems were under development (see response to question 1). Controls by official bodies (e.g. Veterinary Inspection Services) were effective in some countries. In other countries regulations were changing in order to apply EC Directive 96/23, allowing for more controls to be performed on the farm itself. This was particularly true for the hormones in dispute, as for other banned compounds (chloramphenicol, rhonidazol, etc.).

6.221 **Dr. Arnold** indicated that a rather large number of active principles (probably a few hundred) were used as veterinary drugs in one or all countries involved in this dispute. Some substances were so active that their therapeutic doses were as low as micrograms per kilogramme of body weight of the animal. Other substances were used in both veterinary medicine and in crop protection, with some transfer of residues from animal feed via products of animal origin to the human consumer. Considerable progress had been made to regulate these substances on the basis of "tolerances" for residues or MRLs. Many of the underlying ADIs had been proposed by JECFA. More JECFA evaluations had indirectly been appreciated and found acceptance (e.g., in the MRL setting process within the European Union) as one would conclude from the list of substances which had formally passed the elaboration process of the Codex Alimentarius Commission.

6.222 In the European Communities, no new active principle had been placed on the market since 1992 unless a Community MRL had been established under the provisions of regulation 2377/90. New animal drug applications had to be accompanied by a proposed regulatory method suitable to enforce tolerances/MRLs. The main performance characteristics (accuracy, precision, limit of detection, limit of quantification, specificity) and the ruggedness, practicability, applicability, susceptibility to interference of the methods were reviewed together with the other documentation relating to the quality, safety and efficacy of the drug.

6.223 The review of the old substances, however, was still ongoing. The evaluation of the old substances had also begun in the pesticides sector. The majority of these substances had a long history of uses. Although they had never been evaluated according to contemporary safety requirements, they could probably be regarded as safe in the light of the experience with these substances. Should new evidence indicate that human health hazards could arise from the permitted uses of these substances, the competent authorities would withdraw the respective products until the problems were clarified. There were some examples, however, where highly efficacious substances with a long history of use had to be with-

drawn from the market of veterinary drugs for food animals when more contemporary standards were applied in their re-evaluation (e.g., chloramphenicol, nitrofuranes, nitroimidazoles).

6.224 When old substances were reviewed in the Community to establish MRLs, the Committee for Veterinary Medicinal Products always considered the available analytical methodology. An MRL was not proposed if no analytical method was available. The review of the methods and international harmonisation of methods suitable for the enforcement of Codex Standards was conducted by the FAO/WHO Codex Committee for Residues of Veterinary Drugs in Foods.

6.225 The more difficult problem was to monitor so many substances in all foods of animal origin. The chemical properties of these substances were so different that it was impossible to include all residues in a few multi-residue methods. There were substances requiring special equipment for their detection. It was not practically feasible to monitor all potential residues in all food commodities every year. The most reasonable approach was to categorise compounds according to potential hazard and the likely exposure of consumers to the residues. Some compounds required inclusion in residue-monitoring programmes every year; others might be selected for longer cycles. For a few compounds, perhaps no monitoring was necessary. Directive 86/469/EEC covered veterinary drug residues in meat. Starting in 1988, EC member States and countries exporting meat to the Community had to submit residue control plans also for these substances. EC member States had more flexibility to adapt the plans to the actual needs (e.g., areas of risk). The new legislation adopted in 1996 enlarged the scope to cover other foods than meat. An increasing number of screening tests were now available which were based, e.g. on microbiological inhibition or immunochemistry. These methods were suitable to identify suspect "positives" (samples violating MRLs) and exhibit a low rate of "false-negative" results. However, an important aspect of the control of "good practices" was the control of distribution; distribution of veterinary drugs was not harmonised in the Community.

6.226 **Dr. McLean** replied that many products used in animal production had the potential to cause adverse effects on human or animal health. The hazard was identified and managed through the use of "good practice", the application of an MRL, residue surveys and legal sanctions for violations (see also responses to questions 11, 22 and 24). There was no significant difference in the cost implications for controlling the use of other veterinary drugs when compared with the hormones.

6.227 **Dr. Ritter** replied that there were a variety of products, including veterinary drugs and pesticides, which were utilized in the production of meat and animal products. Establishment of MRLs for other production aids, including both veterinary drugs and pesticides, implied that these chemicals could also be used essentially free of potential adverse effects in the human population, provided that appropriate conditions had been followed in the use of the production aid. Simply stated, once MRLs had been established, adherence to internationally

accepted maximum limits implied that all products carry similar risks, or more appropriately stated, a similar lack of risk, as did the hormones at issue in this dispute.

6.228 Control of use was generally accommodated through appropriate control of sale (restriction of use generally associated with "prescription" drugs) and rigorous monitoring and compliance programmes, further supported by appropriate enforcement action. In regard to analytical methodology available for detection and monitoring purposes, both screening and confirmatory methods were utilized. Availability of appropriate and reliable analytical methodology for other production aids, such as veterinary drugs, varied somewhat with the specific agent and might range from difficulties of bound residues with carbadox and nitrofuran, to the special and important considerations which were necessary when assessing the microbiological risk due to residues of antimicrobial drugs in food.

Question 27:

> What potential adverse effects on human health arise from the occasional consumption of meat containing residues in excess of the Codex MRL in the case of Zeranol and Trenbolone?

6.229 **Dr. André** noted that all of the previously described potential adverse effects on human health may arise. With regard to their hormonal effects, the lower the frequency and the level of residue, the smaller is the risk of health hazards. With regard to their potential carcinogenic effects, the frequency of consumption and the level of residue was not of concern.

6.230 **Dr. Arnold** indicated that if the residues were due to treatment of the animals and not to contamination of the meat and the meat was not an injection site so that the causes of the violation of the MRLs were limited to biological variability of the animals response to treatment; he did not know of any specific adverse effect on human health which could arise from the occasional consumption of such meat because of non-compliance with the established conditions of use, and if this was a single, rare or occasional event. Any such event would, however, require regulatory action and - where indicated - legal prosecution in order to guarantee the integrity of the margin of safety which had been found to be required to ensure the medium and long-term protection of the consumers' health.

6.231 **Dr. Lucier** responded that it would be necessary to conduct formal risk assessments to estimate exposure-effect relationships following different levels of exposure for the six hormones. In order to be useful, endpoints of concern needed to be determined (i.e., cancer, hormonal effects, etc.) and dose response models applied and/or developed that made use of all available and relevant information. It might be necessary to conduct additional research to put the risk assessments on a credible scientific foundation. It should be noted, however, that one would never have all the scientific information needed to remove all uncertainty in risk assessments. Priorities had to be agreed upon regarding which pieces of information are most critical. It was also important to note that selection of the risk assessment. model could influence the result. Threshold or linear models might

give different results although if "mimicking of hormone effects" were determinative, then the issue of threshold was not relevant since physiological levels of the natural hormone exceeded any threshold that might exist (see response to question 8). The synthetic hormones could exert toxic effects not only related to their hormone action but also because of other structural/functional properties.

6.232 **Dr. McLean** observed that the occasional consumption of meat containing levels in excess of the Codex MRL was of no health concern. The degree of excess would need to be defined, but the type of toxic response and NOEL would give some guidance. It must be remembered that the NOEL was derived taking into account studies involving administration for a lifetime, with the lowest effect level based on a response which could be as minor as a body weight change.

6.233 **Dr. Ritter** replied that in view of several assumptions inherent in the models utilized to develop MRLs, which overestimated safety (NOEL, application of safety factors, assumption that MRL was always present and that dietary exposure to residues would occur daily for an entire lifespan), it is most unlikely that significant potential adverse effects on human health would arise from the occasional consumption of meat containing residues in excess of the Codex MRL for zeranol and trenbolone. It was, however, important to note that the potential for adverse effects increased as a function of both the frequency and exposure level regarding consumption of residues in meat in excess of the Codex MRL for both trenbolone and zeranol.

Question 28:

> How would you assess the feasibility of labelling with respect to meat products from animals treated with growth-promoting hormones? How does this compare with the feasibility of labelling in other food safety contexts?

6.234 **Dr. André** indicated that this question was not related to scientific expertise, but to political decision. However, such labelling would be consistent with the traceability concept which was rapidly being improved in European countries (ready to be implemented in France). However, this implied that an adequate control to qualify products would have to be established; in the case of residues of hormones, detection in meat did not stand in the way of feasible labelling.

6.235 **Dr. Arnold** said that in his view it was not feasible to control labelling, since it could not be confirmed through laboratory testing whether an animal had ever been treated with growth promoters. If the objective was to verify that something had never been used, e.g., a pesticide, the situation was similar. The chances to detect food-irradiation, on the other hand, were much better. Also, if genetically modified organisms were involved in food production, it was sometimes possible to routinely detect the altered genetic material. There seemed to be no generally valid answer to this question.

6.236 **Dr. Lucier** replied that meat products could be labelled to indicate that they were from animals treated with growth-promoting agents so that consumers would have as much information as possible to decide which meat to buy. If growth-promoting agents produced meat with lower fat content, a consumer with

cardiovascular disease might specifically want to buy meat from a growth-promoted animal.

6.237 **Dr. McLean** observed that the effective labelling of treated meat would necessitate identification of the animal at birth, the farm, sale, slaughter, processing and on to the consumer. The logistics of the process would be complex and make it difficult to regulate, especially in the case of processed meat products. The cost would far outweigh any perceived benefit. The same problem arose with the feasibility of labelling other foods, but because of the complex process for meat processing, it was much more expensive. In his view, the money spent on such a labelling process would be better spent on ensuring microbiological safety of food. Food contaminated with microbes and their toxins disabled or killed many people every year. The adverse effects of veterinary drugs or agricultural chemicals were rarely reported, but reports of food poisoning from microbial contamination were very common. For example, a recent outbreak of *Escherichia coli* food poisoning in Scotland made 400 people seriously ill and killed 17, while a similar outbreak in Japan infected 10,000 and killed 11 (Coghlan, A (1997) New Scientist *153* (2066)7).

6.238 **Dr. Ritter** replied that the issue of labelling of food products was the subject of intense public debate, to which there was no easy resolution. The issue with regard to the feasibility of labelling in the case of the hormones could therefore relate as much to the objective of such a strategy as to its feasibility. Use of the natural gonadal hormones in meat production produced residue levels consistent with those which might typically be expected in meat products from untreated animals. Other than to fulfil a "right to know" objective, labelling in this case would not appear to provide information of value to consumers in a health related context. Particularly noteworthy was that as residue levels are comparable in both treated and untreated animals, and as exogenous hormones are, in any case, quantitatively and qualitatively indistinguishable from those endogenously present, it was unlikely that a labelling programme could be implemented at any practical level.

6.239 In the case of the synthetic hormones utilized in growth promotion, at least two had been subjected to international review and safe residue levels had been recommended. The purpose of such a labelling programme would be unclear given that an international review had already concluded that residues at or below proposed levels did not constitute a risk to consumers, even under the exaggerated calculations and assumptions utilized in the development of MRLs.

Questions 29-34 were follow-up questions to those presented earlier, and the responses to the follow-up questions have been included with the responses to the earlier questions.

Question 35:

> With reference to therapeutic and zootechnical use of the natural hormones at issue, do you believe that the EC Directive 88/299 „ensures that there are no residues left in meat for human consumption“ (para 19, EC first submission in the Canadian complaint)?

6.240 **Dr. Arnold** replied that no such insurance can be given. The meat would always contain residues even if withdrawal times were observed. The concept of "no residue" had been largely abandoned some 20 years ago when it became evident that "no residue" was a function of the limit of detection of the analytical method. All *permitted* substances, including the hormones, were regulated on the basis of an "acceptable residue" in the EEC. The "no residue" concept still applied to banned substances, but this was trivial. In the case of hormones it was acceptable if the sum of endogenous plus exogenous hormones was at or within physiological limits.

6.241 The response of **Dr. Ritter** to this question is contained in his response to question 20 above.

VII. INTERIM REVIEW

7.1 On 21 May 1997, the European Communities and the United States requested the Panel to review, in accordance with Article 15.2 of the DSU, the interim report that had been issued to the parties on 7 May 1997. The European Communities also requested the Panel to hold a further meeting with the parties to discuss the points raised in its written comments and other points which they would develop during that meeting.

7.2 We decided to hold concurrent interim review meetings with the parties for both this dispute and the parallel panel requested by Canada. This decision was, *inter alia*, based on the similarities of both cases and the fact that the interim reports in both cases only differ in the description of the arguments of the parties, whereas the sections dealing with the scientific experts and the legal findings in the two cases are almost identical. In light of that decision, we also decided, on Canada's request and after consultations with the parties involved, to make a copy of the sections of our interim report dealing with our consultation with scientific experts and our findings, together with the comments submitted in that regard by the European Communities and the United States, available to Canada. By letter of 3 June 1997, the European Communities objected to both decisions, arguing that they affected due process and its rights of defense and, consequently, its rights and obligations under the WTO Agreement. It made, however, no specific claims of prejudice. Since we could not see how the European Communities could be prejudiced by these decisions, we rejected this objection.

7.3 In a letter dated 28 May 1997, the United States requested that, during the meeting with the parties, the Panel direct the European Communities not to raise any comments that were not provided in the EC's letter of 21 May 1997. It further requested that the Panel disregard any such comments, including the comments that the European Communities has said in part C of its letter that it will be submitting with respect to some unspecified number of paragraphs in excess of 49 paragraphs of section 7 of the interim report. The United States argued that to do otherwise would create serious prejudice to the United States, which could hardly be expected to be prepared to rebut such comments.

7.4 Article 15.2 of the DSU provides the following:

> "... Within a period of time set by the panel, a party may submit a written request for the panel to review *precise aspects* of the interim report prior to circulation of the final report to the Members. At the request of a party, the panel shall hold a further meeting with the parties *on the issues identified in the written comments*..." (emphasis added).

It appeared to us that the European Communities, by only enumerating the numbers of the paragraphs of the findings section of our interim report in relation to which it has concerns and not stating in its written comments the precise aspects it wishes the Panel to review, did not respect the wording of Article 15.2 of the DSU. We considered, however, that the main object and purpose of Article 15.2 is to make sure that the other party is aware of the issues which will be raised at the interim review meeting in order to allow it to prepare its rebuttal. In light of the fact that the EC's written request for review of the findings section only related to factual aspects, *i.e.*, the correct reflection of the EC arguments and the names of and references to individual scientific experts, we considered that the United States would not be unduly prejudiced by allowing the European Communities to present these factual points at the interim review meeting. We, therefore, decided that the European Communities could raise these points on the conditions that it would limit itself to factual issues and to the paragraph numbers it had enumerated in its written comments. We note that this decision corresponds to what the United States requested in its letter of 28 May 1997.

7.5 The Panel met with the parties on 4 June 1997 in order to hear their arguments concerning the interim report. We carefully reviewed the arguments presented by the European Communities and the United States and the responses offered by both sides.

7.6 The European Communities requested us to find that Articles 15.2 and 15.3 of the DSU and the general principle of due process prevent the Panel from modifying aspects of the interim report on which the parties did not submit comments. However, at the end of the interim review meeting the European Communities appeared to modify this request by asking the Panel to review its findings in light of the factual comments made. We considered that no provision in the DSU limits us to only modify those paragraphs commented upon by the parties. Article 15.3 of the DSU only provides that "[t]he findings of the final panel report shall include a discussion of the arguments made at the interim review stage...".

7.7 The European Communities made two types of comments on the findings section of the interim report. The first concerned 20 paragraphs in which the European Communities is stated to have argued or agreed to something which, according to the European Communities, does not or not completely reflect the EC's position taken during the proceedings. These comments related to the following paragraphs: 8.105, 8.109, 8.111, 8.112, 8.115, 8.131, 8.175, 8.176, 8.187, 8.190, 8.193, 8.204, 8.205, 8.213, 8.220, 8.224, 8.228, 8.232, 8.243 and 8.274.

Since these proposed changes concerned the representation of the EC's own legal or factual arguments, we accepted most of them.

7.8 The second type of comments made by the European Communities related to paragraphs where the phrase "the scientific experts advising the Panel" is used without, according to the European Communities, citing the names of the scientists nor the place where they have made the statements the Panel is invoking. It also argued that frequently the reference provided does not reflect the views of all the scientists. The European Communities also requested us to review the accuracy of the factual information contained in several paragraphs. We carefully considered all the factual comments thus made and, where we agreed with them, modified those paragraphs accordingly.

7.9 The European Communities also requested us to include in the final report the procedural decisions taken by the Panel during the course of its work. We added these decisions in a new Section B on organizational issues.

7.10 The United States commented on the section of our findings related to the scope of the measures in dispute. In response, we expanded our reasoning in these paragraphs. It also requested the Panel to make additional findings on Articles 2.2, 2.3 and 5.6 of the SPS Agreement. For the reasons set out in the report, we did not consider it necessary to address these claims in order to resolve the matter in issue in this dispute.[205] The United States also requested the deletion of paragraphs 8.72 to 8.77. Since we considered these paragraphs to be vital to our consideration of this case, we rejected this request. The United States further submitted corrections of its own arguments and factual elements and suggested several drafting changes, most of which have been taken into account in our final report. It argued, for example, that our findings under Article 5.5 of the SPS Agreement with respect to the endogenous production of the hormones, the hormones used for therapeutic or zootechnical purposes and the hormones present in other foods, inaccurately ascribe to its arguments under Article 5.5 which it made under Articles 2 and 5.6. This remark is reflected in paragraph 8.171. Nevertheless, we considered it appropriate, *inter alia*, for the overall structure of our report, to address these situations under Article 5.5.

7.11 Both parties also suggested further changes or additions in respect of the interim report's descriptive sections which we took into account in re-examining that part of the report. In this context, the European Communities requested us to append the transcripts of the joint meeting with the experts advising the Panel to the descriptive part of the report, arguing that many important statements made by the experts in these meetings are not reflected in Section 6 of the interim report. In order to increase the transparency of our work and to take into account most of the comments made by the European Communities on the descriptive

[205] See Appellate Body Report on "United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India", adopted on 23 May 1997, WT/DS33/AB/R, DSR 1997:I, 323 at 340.

part of the interim report, we decided to annex the transcripts of the joint meeting with the experts of 17-18 February 1997 to our final report.

VIII. FINDINGS

A. Claims of the Parties

8.1 This dispute arises essentially from the following facts. In 1981 the Council of the European Communities ("EC Council") adopted Directive 81/602/EEC[206], *inter alia*, requiring the EC member States of the European Communities to prohibit the administration to farm animals of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action. Directive 81/602/EEC further provided that pending adoption of a decision of the EC Council on the administration to farm animals for growth promotion purposes[207] of oestradiol-17β, testosterone, progesterone, zeranol and trenbolone[208] EC member States could continue to apply the national regulations in force concerning those substances.[209] In 1988 the EC Council adopted Directive 88/146/EEC[210] which brought the administration to farm animals for growth promotion purposes of these five hormones within the general prohibition imposed by Directive 81/602/EEC. The 1988 Directive also required the prohibition of importation from third countries of animals and of meat from animals to which substances with thyrostatic, oestrogenic, androgenic or gestagenic action have been administered.[211] Two exceptions to this general ban are provided in Directive 88/299/EEC[212]: (i) the administration for therapeutic treatment[213] of oestradiol-17β, testosterone, progesterone and some of their derivatives; and (ii) the administration for zootechnical treatment[214] of substances having an oestrogenic, androgenic or gestagenic action which are authorized in accordance with EC Directives on veterinary medicinal products.[215] On 29 April 1996, the EC Council adopted Directive 96/22/EC[216] (repealing and replacing Directives 81/602/EEC,

---

[206] *EC Official Journal*, L 222, 7 August 1981, p.32.

[207] Article 5 of Directive 81/602/EEC uses the term "for fattening purposes". However, during the Panel proceedings and in this report the term "for growth promotion purposes" is used.

[208] The five hormones are the subject of this dispute. A sixth hormone in dispute, melengestrol acetate or MGA, falls under the general prohibition of Directive 81/602/EEC and is addressed in paragraph 8.4.

[209] See para. 2.2.

[210] *EC Official Journal*, L 70, 16 March 1988, p.16.

[211] See para. 2.3.

[212] *EC Official Journal*, L 128, 21 May 1988, p.36.

[213] *Therapeutic* treatment means treatment of a disease or other health problem.

[214] *Zootechnical* treatment for the purposes of the EC measures in dispute means, *inter alia*, treatment for the synchronization of oestrus, termination of unwanted gestation, the improvement of fertility and the preparation of donors and recipients for the implantation of embryos (Article 2, paragraph 1(b) of EC Directive 88/299/EEC).

[215] See para. 2.4.

[216] *EC Official Journal*, L 1125, 23 May 1996, p.3.

88/146/EEC and 88/299/EEC) which confirms and extends the above-mentioned prohibitions. This 1996 Directive will enter into force on 1 July 1997.[217]

8.2 The United States claims that the European Communities, by banning the importation of meat and meat products from animals to which any of six specific hormones have been administered for purposes of promoting the growth of the animals, has acted inconsistently with the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), in particular Articles 2, 3 and 5; the Agreement on Technical Barriers to Trade ("TBT Agreement"); and the General Agreement on Tariffs and Trade 1994 ("GATT"), in particular Articles I and III.

8.3 The European Communities rejects these claims.

8.4 The six hormones in dispute are: oestradiol-17β, testosterone, progesterone, zeranol and trenbolone (the five hormones mentioned above which were brought within the general prohibition required by Directive 81/602/EEC by Directive 88/146/EEC) and melengestrol acetate ("MGA"; a sixth hormone falling under the general prohibition of Directive 81/602/EEC). Oestradiol-17β is a natural hormone with oestrogenic action (*i.e.*, responsible for female characteristics); testosterone is a natural hormone with androgenic action (*i.e.*, responsible for male characteristics); progesterone is a natural hormone with gestagenic action (*i.e.*, responsible for maintaining pregnancy); zeranol is a synthetic hormone with oestrogenic action (which mimics the action of oestradiol-17β); trenbolone is a synthetic hormone with androgenic action (which mimics the action of testosterone); and MGA is a synthetic hormone with gestagenic action (which mimics the action of progesterone).[218] Natural hormones are hormones which are produced endogenously in animals and humans. Synthetic hormones are hormones which are artificially produced. Oestradiol-17β, testosterone and progesterone are hereafter also referred to as the three natural hormones; zeranol, trenbolone and MGA are hereafter also referred to as the three synthetic hormones.

B. Organizational Issues

1. Scientific Evidence

8.5 In the course of these proceedings, we considered several issues related to the gathering and submission of scientific evidence. These concerned the appointment of scientific experts to advise the Panel, the deadline for submission of scientific evidence by the parties to the dispute and a request by the European Communities to ask specific national and international authorities to provide the Panel with scientific studies and data.

8.6 Article 11.2 of the SPS Agreement provides the following:

---

[217] See para. 2.5.
[218] See para. 2.8.

> "In a dispute under this Agreement involving scientific or technical issues, *a panel should seek advice from experts* chosen by the panel in consultation with the parties to the dispute. To this end, *the panel may, when it deems it appropriate, establish an advisory technical experts group*, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative" (emphasis added).

Article 13 of the DSU reads as follows:

> "1. Each panel shall have the right to seek information and technical advice *from any individual or body which it deems appropriate* ...
>
> 2. Panels may seek information *from any relevant source* and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, *a panel may request an advisory report in writing from an expert review group*. Rules for the establishment of such a group and its procedures are set forth in Appendix 4" (emphasis added).

8.7 As outlined above[219], we decided to request the opinion of experts on certain scientific and other technical matters raised by the parties to this dispute. We note that both parties to this dispute assumed that in seeking advice from scientific experts, we would request an advisory report from an "expert review group" as provided for in Article 13.2 and Appendix 4 of the DSU. We considered, however, that neither Article 11.2 of the SPS Agreement nor Article 13.2 of the DSU limits our right to seek information from *individual* experts as provided for in Article 11.2, first sentence, of the SPS Agreement and Articles 13.1 and 13.2, first sentence, of the DSU. For our examination of this dispute, we considered it more useful to leave open the possibility of receiving a range of opinions from individual experts on specific scientific and technical questions, rather than to establish an expert review group which would have been required to reach a consensus view on the basis of general terms of reference given to it by the Panel.

8.8 We chose the scientific experts in consultation with the parties to the dispute in accordance with Article 11.2 of the SPS Agreement. A list of names of individuals expert in the subject matter before the Panel was provided by the Codex Commission secretariat as well as by the International Agency for Research on Cancer ("IARC"). The parties were given the opportunity to comment on the names stated in this list and in particular to submit any compelling objections they might have with regard to any of the individuals appearing on this list. The parties were invited to nominate one expert each, not necessarily from the list provided by the Panel. The Panel then selected three additional individuals from

[219] See paras. 6.1 ff.

the list taking into account the comments of the parties. We also sought information from the Codex Commission secretariat which answered our questions in writing and also sent an expert to our oral hearing with the experts.[220]

8.9 The procedures we adopted for our consultation with the experts and the views they expressed are set out in paragraphs 6.1 and following. It is of particular importance that we made clear to the experts advising the Panel that we were not seeking a consensus position among the experts but wanted to hear all views.[221] However, we also pointed out at the joint meeting with experts that, in order to gain time, where an expert agreed with a statement made or answer provided by another expert, the former expert did not have to take the floor.[222] Any reference made in our findings to "scientific experts advising the Panel" (or "experts" or "scientific experts") refers to one or more of the five individual experts we thus appointed and, as the case may be, the expert sent by the Codex Commission secretariat. This phrase does not refer to nor includes the scientists who were part of the delegations of the parties to this dispute. These are referred to in this report by name, followed by the name of the delegation of which they were part.

8.10 With respect to the submission of scientific evidence by the parties to this dispute, we decided that they could submit written material on new scientific evidence to support their arguments by no later than 8 February 1997. We took this decision in order to ensure that both the parties and the scientific experts advising the Panel would get an opportunity to examine the scientific evidence before the 17-18 February joint meeting with the experts.

8.11 The European Communities also requested that the United States provide the Panel the originals of the studies and other relevant data on which its competent authorities based the decision to authorize the use of the hormones at issue. It also considered that the originals of the studies and other data on which the 1988 JECFA Report based its recommendations should be provided to the Panel. As far as the studies and data used by US authorities is concerned, we did not consider this information to be relevant to address the EC measures in dispute. Similarly, we did not consider it necessary to request the studies and data on which the 1988 JECFA Report is based since it was our understanding that both parties involved in this dispute participated in the elaboration of this report.

2. Parallel Panel Requested by Canada

8.12 In the course of our work, we also considered several issues related to the parallel existence of this Panel, requested by the United States, and the panel requested by Canada. Although different panels, both panels relate to the same

[220] The parties' arguments with respect to the appointment of the experts are set out in paras. 6.3 ff.
[221] See Transcripts of the joint meeting with experts of 17 February 1997, para. 45.
[222] *Ibid.*, para. 88.

EC measures, were dealt with by the same panel members and were assisted by the same scientific experts. These issues relate to the organization of joint meetings and the access by parties in one of these panel proceedings to materials submitted to the other panel.

8.13 In this respect we note, as a general guideline, Article 9.3 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), which reads as follows:

> "If more than one panel is established to examine the complaints related to the same matter, to the greatest extent possible the same persons shall serve as panelists on each of the separate panels and *the timetable for the panel process in such disputes shall be harmonized*" (emphasis added).

8.14 Prior to our meeting with scientific experts, we decided to hold that meeting jointly for both this Panel and the parallel panel requested by Canada. This decision stemmed from the similarities of the two cases (the same EC measures are at issue and both cases are dealt with by the same panel members) and our decision to use the same scientific experts in both cases. In addition, we considered that, from a practical perspective, there was a need to avoid repetition of arguments and/or questions at our meetings with the scientific experts. The European Communities objected to this decision arguing that one joint meeting with the experts, instead of two separate meetings, was likely to affect its procedural rights of defence. Where it made precise claims of prejudice to its rights of defence, we took corrective action.[223]

8.15 In view of our decision to hold a joint meeting with experts, we also decided to give access to all of the information submitted under each panel proceeding to the parties in the other panel proceeding, including the parties' second written submissions, written versions of oral statements, questions raised by the Panel and the parties in each case and the answers we received, as well as all scientific documentation submitted by the parties. By doing so, we understood that, in this Panel, we could also consider, where appropriate, the materials submitted before the panel requested by Canada.[224] The European Communities objected to this decision arguing that it was most likely going to affect its substantive and procedural rights of defence. It made, however, no specific claims of

---

[223] The European Communities argued that a joint meeting with experts deprived it of its right to present its legal and scientific positions twice (a first time before this Panel and a second time before the panel requested by Canada). In light of this objection we decided that the European Communities would be allowed to address the joint meeting twice (a first time after the United States and a second time after Canada). See Transcripts of the joint meeting with experts of 17 February 1997, paras.1-2.

[224] This does, of course, not mean that, in this Panel, the United States has incorporated or agreed with the arguments submitted by Canada in the parallel panel it requested or that we have to deal, in this Panel, with the arguments and claims submitted by Canada in the other panel. It only means that, where we considered it appropriate, we would be able to invoke or address, in this Panel, factual elements, scientific evidence or arguments submitted by the European Communities or Canada to the parallel panel requested by Canada.

prejudice. We considered that providing all information to all parties involved in both panels would increase the transparency of our work, without depriving parties of their substantive or procedural rights, and is in line with the object and purpose of Article 9.3 of the DSU calling for a harmonization of timetables of both panels. On these grounds we rejected the EC's objection.

C. General Interpretative Issues

1. Scope of the Measures in Dispute

8.16 The United States contests the EC ban on imports of *meat* and *meat products* from *cattle*, treated with any of *six specific hormones* (oestradiol-17β, testosterone, progesterone, zeranol, trenbolone and MGA) for *growth promotion* purposes. The United States does not challenge the EC ban on imports of meat and meat products from cattle treated with hormones *other* than the six specified or treated with *any* hormones for purposes *other* than growth promotion.[225]

8.17 At the end of the Panel proceedings, the United States argued that its complaint was not limited to meat and meat products of bovine origin (*i.e.*, originating from cattle) but also extended to, for example, lamb meat. In this regard the United States referred to an Annex to its first submission where it is stated that zeranol is approved *in the United States* for use in lambs. We note, however, that, although technically within the terms of reference of the Panel[226], at no point in the Panel proceedings did the United States raise specific arguments or submit factual or scientific evidence against a ban imposed by the European Communities on the use of hormones in farm animals other than cattle. We further note that all scientific studies invoked by both the United States and the European Communities relate to risks to human health or cattle from the ingestion or administration of hormones; not risks to any other animals. We find, therefore, that the EC ban in so far as it relates to meat or meat products from farm animals other than cattle falls outside the scope of this dispute.

8.18 At the end of the Panel proceedings, the United States also seemed to argue that its complaint was not limited to meat and meat products but also extended to live animals.[227] However, our terms of reference direct us to examine "the matter referred to the DSB by the United States in [document WT/DS26/6, *i.e.*, the request for the establishment of a panel by the United States]". In that document the United States only claimed that the contested EC measures "adversely affect imports of meat and meat products".[228] We therefore consider that the matter referred to in that document is limited to meat and meat products and

---

[225] See para. 3.1.

[226] The request for the establishment of a panel by the United States of 25 April 1996 (WT/DS26/6), refers to "meat and meat products" without explicit limitation to meat and meat products of bovine origin (see para. 1.4).

[227] See para. 4.9.

[228] See para. 1.4.

thus find that the EC ban on imports of live animals falls outside our terms of reference.

8.19 Finally, we note that the European Communities argues that its import ban on *live animals* to which any of the six hormones have been administered, is necessary for the protection of both human and animal health.[229] However, the European Communities does not make this argument with respect to its import ban on *meat* or *meat products*. Specifically, the European Communities has not argued that its import ban on meat or meat products is necessary for the protection of animal health either inside or outside the EC territory. Since the animal health arguments invoked by the European Communities exclusively relate to its import ban on *live animals* and considering the finding reached above that the EC ban on imports of live animals treated with hormones does *not* fall within the scope of this dispute, we find that within the scope of this dispute we need not take into account the arguments made by the European Communities which relate to animal health.[230]

2. Application of the SPS Agreement, the TBT Agreement and GATT

8.20 The United States invokes arguments relating to three different agreements: the SPS Agreement, the TBT Agreement and GATT. The European Communities, in turn, invokes the same three agreements in its defense. We next examine which of these agreements apply to the present dispute.

8.21 With respect to the SPS Agreement, both parties agree that the EC measures in dispute are sanitary measures in the sense of Paragraph 1(b) of Annex A of the SPS Agreement.[231] Paragraph 1(b) of Annex A defines a sanitary measure as

> "any measure applied to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs".

Footnote 4 to Annex A specifies that "contaminants" include, for the purposes of Annex A, "pesticide and veterinary drug residues and extraneous matter". Since the six hormones in dispute are veterinary drugs, the parties agree that the alleged risks at issue arise from contaminants.

8.22 We agree with the parties that the EC measures in dispute are "applied to protect human ... life or health" within the territory of the European Communities

---

[229] See para. 4.208.

[230] Our finding that animal health does not fall within the scope of this dispute does, of course, not mean that we cannot take into account scientific evidence relevant for risks to human life or health which is derived from studies or tests applied to animals.

[231] See paras. 4.7-4.8.

from risks arising from "contaminants", namely residues of six specific hormones, in foods (according to paragraph 1(b) of Annex A). That the contested EC measures are, *inter alia*, "applied to protect human ... life or health" can be inferred from the preambles to, and legislative history of, Directives 81/602/EEC and 88/146/EEC.[232] Since both parties agree that the contested EC measures are "sanitary measures", we see no need to further examine in this dispute the definition of measures "applied to protect human ... life or health".

8.23 Both parties also agree that, according to Article 1.1 of the SPS Agreement, the SPS Agreement is applicable to this dispute.[233] Article 1.1 provides that the SPS Agreement

> "applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade".

We agree with the parties that the EC measures "may, directly or indirectly, affect international trade". It cannot be contested that an import ban affects international trade.

8.24 With respect to the application *ratione temporis* of the SPS Agreement to the EC measures in dispute, we note that the SPS Agreement entered into force on 1 January 1995 (the date of entry into force of the WTO Agreement of which, according to Article II:2 of that Agreement, the SPS Agreement is an integral part). The EC measures in dispute, however, were enacted *before* 1 January 1995 (namely 31 July 1981 and 7 March 1988), thus raising the issue of whether the SPS Agreement applies to these measures.

8.25 Article 3.2 of the DSU directs us to clarify the provisions of the SPS Agreement "in accordance with customary rules of interpretation of public international law". According to established practice, the fundamental rules of treaty interpretation set out in the Vienna Convention on the Law of Treaties ("Vienna Convention") form part of these customary rules of interpretation.[234] The general principle in international law, as embodied in Article 28 of the Vienna Convention, is that "[u]nless a different intention appears from the treaty or is otherwise established, its provisions do *not* bind a party in relation to ... any *situation* which *ceased to exist before* the date of the entry into force of the treaty ..." (emphasis added). The EC measures can, in this context, be considered as continuing "situations" which were enacted *before* the entry into force of the SPS Agreement but which did *not* cease to exist *after* that date (contrary to the situation envisaged in Article 28). In line with Article 28 of the Vienna Convention, the

---

[232] See paras. 2.2-2.3.

[233] See paras. 4.5 and 4.8.

[234] See Appellate Body Reports on "United States - Standards for Reformulated and Conventional Gasoline", adopted on 20 May 1996, WT/DS2/AB/R, DSR 1996:I, 3 at 15-16 and "Japan - Taxes on Alcoholic Beverages", adopted on 1 November 1996, WT/DS8/AB/R, DSR 1996:I, 97 at 104-105.

SPS Agreement should, therefore, in principle apply to these EC measures, unless an intention to the contrary can be established.[235]

8.26 An examination of the SPS Agreement reveals no intention to the contrary. Indeed, several provisions of the SPS Agreement confirm the general principle that the SPS Agreement should also apply to sanitary measures which were enacted before its entry into force but which remain in force thereafter. Except for Article 14 which authorizes delays in the application of some or all of the provisions of the SPS Agreement for least-developed and other developing countries, no transition periods are provided for. The fact that Article 14 explicitly provides for a two-year transition period for developing countries with respect to some of their *existing* sanitary and phytosanitary measures, confirms that the SPS Agreement generally applies to measures enacted before the entry into force of the SPS Agreement but which are maintained in force after that date. This is also confirmed in several provisions of the SPS Agreement which explicitly address situations where Members "maintain" a sanitary or phytosanitary measure, such as Article 2.2 ("Members shall ensure that any sanitary ... measure ... is based on scientific principles and is not *maintained* without sufficient scientific evidence ..."), Article 3.3 ("Members may introduce or *maintain* sanitary ... measures ... if ..."), Article 5.6 ("... when establishing or *maintaining* sanitary ... measures ... Members shall ensure that ...") and Article 5.8 ("... a specific sanitary ... measure introduced or *maintained* by another Member ...").

8.27 We finally note that according to Article XVI:4 of the WTO Agreement, each Member "shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements [including the SPS Agreement]". This provision confirms that measures which already existed as of the date of entry into force of the SPS Agreement also need to be consistent with the requirements imposed by that Agreement.

8.28 Thus, we find that the SPS Agreement is applicable to this dispute.

8.29 In respect of the applicability of the TBT Agreement to this dispute, we note that Article 1.5 of the TBT Agreement reads as follows:

> "The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures".[236]

---

[235] We refer, in this respect, to the Reports of the Panel and Appellate Body on "Japan - Taxes on Alcoholic Beverages", adopted on 1 November 1996 (WT/DS8/R and WT/DS8/AB/R), where both the Panel and the Appellate Body applied GATT (which entered into force on 1 January 1995) to the Japanese Liquor Tax Law (of 1953 and last amended on 1 May 1994), even though that Japanese measure had been enacted and most recently been amended *before* the entry into force of GATT, on the implicit ground that the Japanese measure remained in force *after* that date. The same reasoning was applied in the Reports of the Panel and Appellate Body on "United States - Standards for Reformulated and Conventional Gasoline", *op. cit.*

Since the measures in dispute are sanitary measures, we find that the TBT Agreement is not applicable to this dispute.

8.30 We finally note that this dispute relates to trade in goods (*in casu* imports of meat and meat products) and that on its face GATT applies.[237] In this context, we note that the United States only invokes GATT after having addressed the SPS Agreement and that the European Communities does not invoke any GATT provision other than Article XX(b) as a justification for the EC measures in dispute.

3. Relationship Between the SPS Agreement and GATT

8.31 Since both the SPS Agreement and GATT apply to this dispute, we next examine the relationship between these two agreements.

8.32 The parties to the dispute present diverging views with respect to whether we should first address GATT or the SPS Agreement. However, neither of the parties claims that the relevant provisions of the SPS Agreement and GATT are in conflict. Therefore, we do not need, as a preliminary matter, to address the General Interpretative Note to the Multilateral Agreements on Trade in Goods which only applies "[i]n the event of conflict between a provision of [GATT] and a provision of another Agreement in Annex 1A [*inter alia*, the SPS Agreement]".

8.33 The European Communities makes a distinction between the "substantive" and "procedural" provisions of the SPS Agreement. According to the European Communities, the substantive provisions only interpret Article XX(b) of GATT[238], without adding any new obligations, while the procedural provisions contain requirements additional to GATT. Therefore, the European Communities concludes, the "substantive" provisions of the SPS Agreement can only be addressed if recourse is made to GATT Article XX(b), *i.e.*, if, and only if, a violation of another provision of GATT is first established. The additional "procedural" provisions, on the other hand, can be examined directly and independently of a prior GATT violation.[239]

8.34 The United States argues that the SPS Agreement is the *lex specialis* for a review of sanitary measures and should, therefore, be addressed first. The United

---

[236] Similarly, but less explicitly, Article 1.4 of the SPS Agreement provides that "[n]othing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement".

[237] With respect to the application *ratione temporis* of GATT to this particular case, the same reasoning and findings apply as those developed for the application *ratione temporis* of the SPS Agreement in paragraphs 8.24 and 8.25.

[238] Article XX(b) of GATT reads as follows: "Subject to the requirement that such measures are not applied in a manner which constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: ... (b) necessary to protect human, animal or plant life or health".

[239] See para. 4.4.

States claims that the application of the SPS Agreement does not require a prior violation of GATT since the SPS Agreement is a "free-standing" agreement which applies to all sanitary measures and imposes requirements additional to those in Article III or the exceptions in Article XX of GATT.[240]

8.35 In examining the relationship between GATT and the SPS Agreement, we recall the fundamental rules of treaty interpretation set out in the Vienna Convention.[241] Article 31 of the Vienna Convention prescribes that a treaty has to be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".[242]

8.36 We first consider the wording of Article 1.1 of the SPS Agreement which reads as follows:

> "This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement".

According to Article 1.1 of the SPS Agreement, two requirements need to be fulfilled for the SPS Agreement to apply: (i) the measure in dispute is a sanitary or phytosanitary measure[243]; and (ii) the measure in dispute may, directly or indirectly, affect international trade.[244] There are no additional requirements. The SPS Agreement contains, in particular, no explicit requirement of a prior violation of a provision of GATT which would govern the applicability of the SPS Agreement, as asserted by the European Communities.

8.37 We further note that the distinction proposed by the European Communities between "substantive" and "procedural" provisions of the SPS Agreement has no basis in the text of that Agreement and would, in any event, seem to be difficult to apply to most provisions contained therein. For example, the obligation to base a sanitary measure on a risk assessment in accordance with Article 5 of the SPS Agreement includes both substantive and procedural elements.[245]

8.38 Moreover, we find the EC claim that the SPS Agreement does not impose "substantive" obligations additional to those already contained in Article XX(b) of GATT not to be persuasive. It is clear that some provisions of the SPS Agree-

---

[240] See para. 4.5.

[241] The legal basis for the Panel to invoke the Vienna Convention is outlined above in paragraph 8.25 and footnote 234.

[242] According to Article 32 of the Vienna Convention, recourse may only be had to supplementary means of interpretation "in order to confirm the meaning resulting from the application of Article 31" or in case Article 31 leaves the meaning "ambiguous or obscure" or leads to "a result which is manifestly absurd or unreasonable".

[243] As defined in Paragraph 1 of Annex A of the SPS Agreement, quoted and discussed in paras. 8.21 and 8.22.

[244] See para. 8.23.

[245] See paras. 8.112 ff.

ment elaborate on provisions already contained in GATT, in particular Article XX(b). The final preambular paragraph of the SPS Agreement provides, indeed, that the Members desired "to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)". Examples of such rules are, arguably, some of the obligations contained in Article 2 of the SPS Agreement. However, on this basis alone we cannot conclude that the SPS Agreement only applies, as Article XX(b) of GATT does, if, and only if, a prior violation of a GATT provision has been established. Many provisions of the SPS Agreement impose "substantive" obligations which go significantly beyond and are additional to the requirements for invocation of Article XX(b).[246] These obligations are, *inter alia*, imposed to "further the use of harmonized sanitary and phytosanitary measures between Members"[247] and to "improve the human health, animal health and phytosanitary situation in all Members".[248] They are not imposed, as is the case of the obligations imposed by Article XX(b) of GATT, to justify a violation of another GATT obligation (such as a violation of the non-discrimination obligations of Articles I or III).

8.39 We note in this respect that the general approach adopted in Article XX(b) of GATT is fundamentally different from the approach adopted in the SPS Agreement. Article XX(b), which is not limited to sanitary or phytosanitary measures, provides for a general *exception* which can be invoked to justify any violation of another GATT provision. The SPS Agreement, on the other hand, provides for specific *obligations* to be met in order for a Member to enact or maintain specific types of measures, namely sanitary and phytosanitary measures.

8.40 The conclusion that the SPS Agreement contains obligations which are not already imposed by GATT is confirmed in Article 2.4 of the SPS Agreement which provides that "[s]anitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)". Indeed, to presume that one set of obligations (*in casu* GATT) is met because another set of obligations (*in casu* the SPS Agreement) has been fulfilled, seems to imply that the latter set of obligations imposes at least as many as, and probably more obligations than, the former. Support for this conclusion is also found in Article 3.2 of the SPS Agreement which provides that "[s]anitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or

[246] One example is the obligation contained in Article 3.1 of the SPS Agreement which provides that "[t]o harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations, where they exist ...".

[247] Preambular paragraph 6 of the SPS Agreement.

[248] Preambular paragraph 2 of the SPS Agreement.

plant life or health, and presumed to be consistent with the relevant provisions of this Agreement *and* of GATT 1994" (emphasis added). While both agreements may apply in a given factual situation, the foregoing provision nonetheless establishes the SPS Agreement as an agreement which imposes obligations which are different from those imposed by GATT.

8.41 We therefore find that, in accordance with the ordinary meaning to be given to the terms of the SPS Agreement in their context and in the light of its object and purpose (in conformity with Article 31 of the Vienna Convention), there is no requirement, in any of the provisions of the SPS Agreement, that a prior violation of a GATT provision need be established before the SPS Agreement applies.

8.42 Having reached the conclusion that we are not *per se* required to address GATT claims prior to those raised under the SPS Agreement, we must then decide which of the two agreements we should examine first in this particular dispute. The SPS Agreement specifically addresses the type of measure in dispute. If we were to examine GATT first, we would in any event need to revert to the SPS Agreement: if a violation of GATT were found, we would need to consider whether Article XX(b) could be invoked and would then necessarily need to examine the SPS Agreement; if, on the other hand, no GATT violation were found, we would still need to examine the consistency of the measure with the SPS Agreement since nowhere is consistency with GATT presumed to be consistency with the SPS Agreement. For these reasons, and in order to conduct our consideration of this dispute in the most efficient manner, we shall first examine the claims raised under the SPS Agreement.

D. The SPS Agreement

1. Overview of the Provisions in Dispute

8.43 The United States claims violations of Articles 2, 3 and 5 of the SPS Agreement. Article 2 elaborates on the basic rights and obligations of Members under the SPS Agreement. Article 3 deals, more specifically, with the objective of harmonization of sanitary measures on the basis of international standards, guidelines or recommendations. Article 5 deals, in turn, with the obligation of risk assessment and the determination and application by Members of their appropriate level of sanitary protection.

8.44 Article 3.1 requires Members to base their sanitary measures on international standards, guidelines or recommendations except as otherwise provided for in the SPS Agreement, and in particular in Article 3.3. We note, therefore, that even if international standards may not, in their own right, be binding on Members, Article 3.1 requires Members to base their sanitary measures on these standards.

8.45 According to Article 3.2 sanitary measures which conform to international standards, guidelines or recommendations are presumed to be consistent with both the SPS Agreement and GATT. We shall therefore, as a first step, examine

whether there are international standards, guidelines or recommendations with respect to the EC measures in dispute and, if so, whether the EC measures are *based on* these standards, guidelines or recommendations in accordance with Article 3.1.

8.46 If there are international standards, guidelines or recommendations and the European Communities has *not* based its measures thereon, we will need, as a second step, to examine whether the European Communities can justify its measures under Article 3.3 since Article 3.1, which imposes the requirement to base sanitary measures on international standards explicitly refers to Article 3.3 as providing for an exception to this requirement.

8.47 Finally, if there are no international standards, guidelines or recommendations with respect to the EC measures in dispute, or to some of them, there would be no standards, guidelines or recommendations for these measures to be based on in line with Article 3.1. However, even in that case the consistency of the EC measures in dispute with Articles 2 and 5 of the SPS Agreement would still need to be examined.

2. Burden of Proof

8.48 Given the nature of disputes under the SPS Agreement, which imposes substantive and procedural requirements raising various, and in this case complex, issues of fact, the allocation of the burden of proof is of particular importance. It involves consideration of the wording, general outline and object and purpose of the SPS Agreement as a whole. We, therefore, first examine this issue in general before addressing the specific burden of proof for each of the provisions in dispute in more detail below.

8.49 In stating its claims under the SPS Agreement, the United States seems to presume that the European Communities bears the burden of proof. The United States argues that the SPS Agreement, *inter alia*, requires the European Communities to base its sanitary measures on a risk assessment and prohibits the European Communities from maintaining such measures without scientific evidence. According to the United States, the SPS Agreement does not allow for measures to be maintained without scientific evidence until such time as science proves "beyond doubt" that there is *no* risk (against which a sanitary measure can protect, for example, consumers). The United States seems, therefore, to conclude that it is up to the European Communities to provide evidence that there is a risk to be protected against and that there has been a risk assessment. It is not up to the United States to prove that there is *no* risk or that the European Communities did *not* carry out a risk assessment.[249]

8.50 The European Communities argues that the burden of proof should rest on the party challenging the consistency of sanitary measures with the SPS Agree-

[249] See para. 4.101.

ment (*in casu* the United States). The European Communities claims, *inter alia*, that it is up to the United States to provide evidence that the use of the hormones in dispute for growth promotion is safe and without risk.

8.51 In addressing the burden of proof under the SPS Agreement, we consider that, as is the case in most legal proceedings, the initial burden of proof rests on the complaining party in the sense that it bears the burden of presenting a *prima facie* case of inconsistency with the SPS Agreement. It is, indeed, for the party that initiated the dispute settlement proceedings to put forward factual and legal arguments in order to substantiate its claim that a sanitary measure is inconsistent with the SPS Agreement. In other words, it is for the United States to present factual and legal arguments that, if unrebutted, would demonstrate a violation of the SPS Agreement. Once such a *prima facie* case is made, however, we consider that, at least with respect to the obligations imposed by the SPS Agreement that are relevant to this case, the burden of proof shifts to the responding party.[250]

8.52 In our view, the allocation of evidentiary burden under the SPS Agreement to the Member imposing a sanitary or phytosanitary measure flows directly from the wording of many of the provisions contained in that Agreement and in particular the first three words thereof:

> "*Members shall ensure* that..." (*e.g.* Articles 2.2, 2.3, 5.1 and 5.6 of the SPS Agreement; emphasis added).

8.53 Moreover, the wording of Article 5.8 (although this provision relates more to transparency than to any requirement of legal justification) further supports our reading of this assignment of burden of proof to the party imposing the measure:

> "When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Mem-

---

[250] Two provisions of the SPS Agreement do, however, explicitly confer the burden of proof upon the exporting Member (*i.e.*, the Member contesting the sanitary or phytosanitary measure), namely Article 4.1 on equivalence and Article 6.3 on pest- or disease-free areas or areas of low pest or disease prevalence. The fact that in these instances the burden of proof is explicitly conferred upon the exporting Member confirms that under other SPS provisions the burden of proof may shift to the Member imposing the sanitary or phytosanitary measure. We note, in this respect, the Report of the Appellate Body on "United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India" (adopted on 23 May 1997, WT/DS33/AB/R) which addressed the issue of burden of proof under the Agreement on Textiles and Clothing (the "ATC") as follows:

> "... a party claiming a violation of a provision of the *WTO Agreement* by another Member must assert and prove its claim. In this case, India claimed a violation by the United States of Article 6 of the *ATC*. We agree with the Panel that it, therefore, was up to India to put forward evidence and legal argument sufficient to demonstrate that the transitional safeguard action by the United States was inconsistent with the obligations assumed by the United States under Articles 2 and 6 of the *ATC*. India did so in this case. And, with India having done so, the onus then shifted to the United States to bring forward evidence and argument to disprove the claim. This, the United States was not able to do and, therefore, the Panel found that the transitional safeguard action by the United States "violated the provisions of Articles 2 and 6 of the ATC", DSR 1997:I, 323 at 336-337.

> ber is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, *an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure*" (emphasis added).

8.54 Finally, we note that this assignment of burden of proof to the party imposing the measure is also supported by Article 3.2 which introduces a presumption of consistency with the SPS Agreement for sanitary measures which conform to international standards, guidelines or recommendations. Article 3.2 states the following:

> "Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994".

Introducing a general presumption of consistency with an agreement in favour of a party (*in casu* the party imposing the measure) in the event that certain conditions are met, seems, indeed, to presuppose that the burden of proof under that agreement in principle (*i.e.,* in cases where these specific conditions are *not* met) rests on that party.

8.55 We thus find that, for the purposes of this dispute, the United States bears the burden of presenting a *prima facie* case of inconsistency with the SPS Agreement, after which the burden of proof shifts to the European Communities to demonstrate that its measures in dispute meet the requirements imposed by the SPS Agreement.

3. Article 3.1: Sanitary Measures Based On International Standards

8.56 Article 3.1 of the SPS Agreement reads as follows:

> "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3".

The first question we must address is whether there exist any "international standards, guidelines or recommendations" with respect to the administration of any of the six hormones in dispute for growth promotion purposes. For food safety, the health concern at issue in this dispute, paragraph 3(a) of Annex A of the SPS Agreement defines "international standards, guidelines or recommendations" as

> "the standards, guidelines and recommendations established by the *Codex Alimentarius Commission* relating to food additives, *veteri-*

> *nary drug* and pesticide *residues*, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice" (emphasis added).

8.57 In line with Article 3.1, we consider that if such Codex Alimentarius Commission standards, guidelines or recommendations ("Codex standards") exist with respect to the administration of any of the six hormones in dispute for growth promotion purposes, a sanitary measure taken by a Member should either be based on these standards or be justified under Article 3.3 of the SPS Agreement.

(a) Codex Standards

8.58 Within the scope of the measures in dispute, we note that Codex standards exist for five of the six hormones at issue (*i.e.*, for all hormones at issue other than MGA).[251] We will accordingly examine the definition and scope of application of these Codex standards and determine whether they apply to the EC measures in dispute.

8.59 The Codex Alimentarius Commission ("Codex"), an international body of which most WTO Members (including the United States and the EC member States of the European Communities) are members, establishes, *inter alia*, Acceptable Daily Intakes ("ADIs"), Maximum Residue Limits ("MRLs") and other recommendations for veterinary drugs. It does so on the basis of the advice of the Codex Committee on Residues of Veterinary Drugs in Foods and the recommendations of the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"). While Codex is composed of government representatives of EC member States, JECFA is composed of independent scientists. JECFA makes scientific evaluations and recommendations; Codex takes the decision whether or not to adopt these recommendations. However, once adopted Codex recommendations are, according to the General Principles of Codex, *not* binding upon Codex members. They are only of an advisory nature. The procedures to be followed to adopt a Codex recommendation have been outlined above.[252]

8.60 The goal of JECFA's evaluation of veterinary drugs is

> "*to establish safe levels* of intake by setting Acceptable Daily Intakes (ADIs) and to develop maximum residue limits when veterinary drugs are used in accordance with good veterinary practice" (emphasis added).[253]

The term "good veterinary practice" (as well as the term "good animal husbandry practice" often used in JECFA Reports) is for Codex purposes, according to the

[251] See paras. 2.20, 2.21 and 2.23.
[252] See paras. 2.15-2.16.
[253] See para. 2.14.

Codex expert advising the Panel[254], a synonym for what is known in Codex terminology as "Good Practice in the Use of Veterinary Drugs" ("GPVD"; hereafter also referred to as "good practice"), in turn defined as

> "the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions".[255]

8.61 An ADI set by Codex is "an estimate by JECFA of the amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime *without appreciable health risk* (standard man = 60 kg)" (emphasis added).[256] This ADI is derived from the experimental no observable effect level in the most appropriate animal species, by applying an appropriate safety factor. A Codex MRL, on the other hand, if implemented in national law, determines the amount of residues which is legally permitted or recognized as acceptable in food and is primarily a regulatory tool to ensure that intake does not exceed the ADI and that good practice is observed. A Codex MRL is frequently set at levels below (even far below) the theoretical safe levels determined from an ADI. Codex MRLs for veterinary drugs are normally expressed in µg/kg on a fresh weight basis in meat.[257]

8.62 With respect to the three natural hormones in dispute, *oestradiol-17β*, *progesterone* and *testosterone* (classified by Codex as "veterinary drugs"), similar Codex standards apply. For all three hormones, when used for growth promotion purposes, it was considered "unnecessary" to establish an ADI or MRL. For all three hormones the following footnote explained the word "unnecessary":

> "Establishing an ADI and an [MRL] for a hormone that is produced endogenously at variable levels in human beings was considered unnecessary by the Committee. Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health".[258]

The 32nd JECFA Report of 1988[259], on which the Codex standards are based, concluded for all three natural hormones administered for growth promotion purposes that the residue levels of each of these hormones when found in meat from animals treated with implants according to good animal husbandry practice are extremely low when compared with the amounts endogenously produced daily in human beings or normally present in the dairy products or tissues of untreated animals or other foods. According to JECFA, the potential toxic effect of resi-

---

254 See para. 2.19.
255 *Ibid.*
256 See para. 2.17.
257 See para. 2.18.
258 See para. 2.21.
259 See para. 2.22.

dues of these hormones is directly related to their hormonal effect. Since the additional residue levels in treated animals have no hormonal effect, the Report concluded that these residue levels are not capable of exerting any toxic effect. JECFA further noted that the total residue levels in treated animals fall well within the normal range of levels found in untreated animals of different types and ages. On the basis of this safety assessment and in view of the difficulty of determining the levels of residues attributable to the use of this hormone as a growth promoter in cattle (residues of endogenous natural hormones in meat cannot, according to JECFA, be practically distinguished from those exogenously administered), JECFA concluded that it was "unnecessary" to establish an ADI or MRL for these hormones.[260]

8.63 With respect to two of the three synthetic hormones at issue, *zeranol* and *trenbolone* (classified by Codex as "veterinary drugs"), the following Codex standards apply: an ADI of 0-0.5 and 0-0.02 μg/kg body weight, respectively, and an MRL of 2 μg/kg β-trenbolone in bovine muscle and 10 μg/kg α-trenbolone in bovine liver.[261]

8.64 The 32nd JECFA Report of 1988, on which the Codex standard for *zeranol* is based, noted that zeranol was shown to be a weak oestrogen which mimics the action of oestradiol-17β. The Report concluded that the toxic (*in casu* tumorigenic) effect of zeranol is associated with its hormonal (*i.e.*, oestrogenic) properties and that an ADI could thus be established on the basis of a no-hormonal-effect level. Adopting what it considered to be a conservative approach by using as a basis studies on ovariectomized female cynomolgus monkeys (highly sensitive to oestrogenic substances) and using a safety factor of 100, JECFA set an ADI for human beings of 0-0.5 μg/kg of body weight. For a 70 kg person consuming 500 g of meat daily over an entire lifetime, the maximum permissible or safe level of zeranol residues in meat would then, according to JECFA, be 70 μg/kg of edible tissue. However, the Report noted that when zeranol is administered to cattle according to the proposed good practice, the maximum mean residue levels would not exceed 0.2 μg/kg in muscle and 10 μg/kg in liver *at any time after implantation* (irrespective of the withdrawal period respected). These residue levels obtained on the basis of good practice are thus far below what JECFA determined to be the safety level of 70 μg/kg. However, in order to set a level which is detectable by using methods available for routine residue analysis, the official Codex MRL was increased to 2 μg/kg in muscle and set at 10 μg/kg in liver.[262]

8.65 Trenbolone acetate is the chemical form or ester used for the administration of *trenbolone*. Trenbolone, or trenbolone acetate ("TBA"), an androgen which mimics the action of testosterone, is rapidly hydrolysed after administra-

[260] See para. 2.22.
[261] See para. 2.23.
[262] See para. 2.24.

tion to cattle, the major metabolites (*i.e.*, compound into which TBA breaks down by chemical activity when entering the body) being α-trenbolone, occurring, *inter alia*, in liver, and β-trenbolone, present in muscle.[263] With respect to TBA, the 32nd JECFA Report of 1988 concluded that its potential toxic effects only arise as a consequence of its hormonal activity and concluded that, therefore, an ADI could be established on the basis of a no-hormonal-effect level.[264] Adopting what it considered to be a conservative approach by using as a basis studies on castrated male rhesus macaque monkeys which are highly sensitive to compounds with antigonadotropic activity and pigs which are a sensitive model for assessing hormonal effects of TBA and using a safety factor of 100, JECFA later set an ADI for human beings of 0-0.02 μg/kg of body weight (34th JECFA Report of 1989). The maximum ADI for a 60 kg person would thus be 1.2 μg of TBA residues. JECFA then set MRLs for β-trenbolone in muscle and α-trenbolone in liver of 2 μg/kg and 10 μg/kg respectively, based on average residue levels in heifers at 15-30 days after implantation of 300 mg TBA, noting that concentrations would even be lower at the proposed good practice. According to JECFA, the MRLs thus obtained on the basis of conservative estimates would not exceed the Codex ADI or safe level *at any time after implantation of the drug* (irrespective of the withdrawal period respected).

8.66 The European Communities argues that the Codex standards outlined above are not relevant to this dispute. It argues that there are no Codex standards for the *use* of hormone growth promoters, only Codex standards for *maximum residue levels* and that since the EC measures in dispute do not set maximum residue levels, there exist no Codex standards on which the EC measures need to be based. Moreover, the European Communities argues, the Codex standards invoked are *levels* of protection, not *measures*, and since there is no obligation in the SPS Agreement to adopt Codex recommended levels of protection, the standards invoked are irrelevant for the EC measures in dispute.[265]

8.67 The European Communities also notes that the decision by Codex (of July 1995) to formally adopt the five Codex standards at issue was taken by a majority of only 33 votes in favour, 29 votes against and 7 abstentions; a very close vote which is unusual in Codex practice where proposals are normally adopted by consensus, indicating that the issue of hormone growth promoters has been and continues to be very controversial.[266]

8.68 The European Communities finally argues that the process which led to the adoption of the Codex standards started long before the entry into force of the SPS Agreement and was only completed six months after that date. At the time the standards were discussed, Codex members were, therefore, according to the

[263] See para. 2.25.
[264] *Ibid*.
[265] See para. 4.79.
[266] See para. 4.77.

European Communities, unaware of the fact that the Codex standards, which within the Codex system are only of an advisory nature, would in the future become "binding" by virtue of the SPS Agreement.[267] The European Communities seems to consider this element as a reason to disregard these Codex standards in this dispute.

8.69 In considering these EC arguments, we note that Article 3.1 unambiguously prescribes that "... Members shall base their sanitary ... measures on international standards ... *where they exist* ..." (emphasis added). Paragraph 3 of Annex A of the SPS Agreement states equally clearly that the international standards mentioned in Article 3:1 are "for food safety, the standards ... *established by the Codex Alimentarius Commission* relating to ... *veterinary drug ... residues* ..." (emphasis added). No other conditions are imposed in the SPS Agreement on the relevance of international standards for the purposes of Article 3. Therefore, as a panel making a finding on whether or not a Member has an obligation to base its sanitary measure on international standards in accordance with Article 3.1, we only need to determine whether such international standards exist. For these purposes, we need not consider (i) whether the standards reflect *levels* of protection or sanitary *measures* or the *type* of sanitary measure they recommend, or (ii) whether these standards have been adopted by consensus or by a wide or narrow majority, or (iii) whether the period during which they have been discussed or the date of their adoption was before or after the entry into force of the SPS Agreement.[268]

8.70 We note that the five Codex standards outlined above are standards relating to veterinary drug residues as required in paragraph 3(a) of Annex A[269] and apply exclusively with respect to cattle and meat and meat products of bovine origin and with respect to five of the six hormones in dispute when these hormones are used for growth promotion purposes.[270] We recall the scope of the EC measures in dispute, in particular that they are limited to the EC ban on imports of meat and meat products of bovine origin from cattle treated with any of six specific hormones if the treatment with any of these substances is carried out for growth promotion purposes.[271] We find, therefore, that international standards exist with respect to the EC measures in dispute, to the extent they relate to five of the six hormones at issue (all but MGA), in the sense of Article 3.1 and paragraph 3(a) of Annex A. We must next determine whether the EC measures are *based on* these international standards in terms of Article 3.1.

---

[267] See para. 4.78.

[268] We recall in this respect that the Codex standards in dispute have in any event been adopted in July 1995, *i.e., subsequent* to the entry into force of the SPS Agreement on 1 January 1995. With respect to the timeframe for the application of the SPS Agreement in general, we refer to paragraphs 8.24 -8.27.

[269] See para. 8.56.

[270] See para. 2.20.

[271] See para. 8.16.

(b) Sanitary Measures *Based On* Codex Standards

8.71 The United States argues that the European Communities ignored the five Codex standards outlined above. Rather than establishing an ADI or MRL for any of these hormones, the United States submits, the European Communities has chosen to prohibit the sale of meat from any animal to which these hormones have been administered for growth promotion purposes, whether or not there is any residue of these hormones found in that meat.[272] The European Communities does not submit that its measures are based on the Codex standards, but rather argues that, as discussed above[273], there are no relevant Codex standards on which its measures in dispute need to be based.

(i) The Meaning of *Based On*

8.72 The SPS Agreement does not explicitly define the words *based on* as used in Article 3.1. However, Article 3.2, which introduces a presumption of consistency with both the SPS Agreement and GATT for sanitary measures which *conform to* international standards, equates measures *based on* international standards with measures which *conform to* such standards. Article 3.3, in turn, explicitly relates the definition of sanitary measures *based on* international standards to the level of sanitary protection achieved by these measures. Article 3.3 stipulates the conditions to be met for a Member to enact or maintain certain sanitary measures which are *not* based on international standards.[274] It applies more specifically to measures "which result in a *higher level* of sanitary ... protection than would be achieved by measures based on the relevant international standards" or measures "which result in a *level* of sanitary ... protection *different* from that which would be achieved by measures based on international standards". One of the determining factors in deciding whether a measure is *based on* an international standard is, therefore, the level of protection that measure achieves. According to Article 3.3 all measures which *are* based on a given international standard should in principle achieve the *same* level of sanitary protection. Therefore, if an international standard reflects a specific level of sanitary protection and a sanitary measure implies a *different* level, that measure cannot be considered to be *based on* the international standard.

8.73 We find, therefore, that for a sanitary measure to be *based on* an international standard in accordance with Article 3.1, that *measure* needs to reflect the same level of sanitary protection as the *standard*.[275] In this dispute a comparison

---

[272] See para. 4.64 and 4.67.

[273] See paras. 8.66 -8.69.

[274] Article 3.1 explicitly refers to Article 3.3 as providing for exceptions to the general obligation to base sanitary measures on international standards: "... Members shall base their sanitary ... measures on international standards ..., except as otherwise provided for in this Agreement, and *in particular in paragraph 3*" (emphasis added).

[275] We recall, however, that, given the exceptions provided for in Article 3.3, the requirement that a sanitary measure reflects the same level of protection as the relevant international standard is in no

thus needs to be made between the level of protection reflected in the EC measures in dispute and that reflected in the Codex standards for each of the five hormones at issue.

8.74 Without limiting the possibilities of how a *level of protection* may be expressed for a particular substance, we consider that in the specific field of veterinary drugs (including the six hormones at issue), a level of protection can be directly linked to the *amount of residues* of that drug allowed either to be ingested by humans on a daily basis or to be present in a particular food.[276] A level of protection can thus, *inter alia*, be expressed by way of setting a maximum amount of residues allowed for daily intake by humans over a lifetime (often defined as acceptable daily intake or ADI[277]) and (or) by way of adopting a maximum amount of residues allowed to be present in a particular food (often defined as maximum residue limit or MRL[278]). However, the fact that an ADI or MRL can *reflect* a *level* of protection (without *stricto sensu* itself *being* a level of protection), does not exclude, as the European Communities has argued, that an ADI or MRL can also be a sanitary *measure* in the sense of the SPS Agreement.

(ii) Comparison of Levels of Sanitary Protection

8.75 In this dispute, two of the international standards applicable, namely the Codex standards with respect to *zeranol* and *trenbolone* (two synthetic hormones), provide for an ADI of 0-0.5 and 0-0.02 μg/kg of body weight, respectively, and an MRL of 10 μg/kg for bovine liver and 2 μg/kg for bovine muscle for zeranol and an MRL of 10 μg/kg α-trenbolone for bovine liver and 2 μg/kg of β-trenbolone for bovine muscle.[279] These ADIs and MRLs reflect the level of protection set by the Codex standards.[280] To determine whether the EC measures in dispute with respect to zeranol and trenbolone are based on these Codex standards, we need to examine whether the level of protection reflected in the EC measures is the same as the level of protection expressed by the Codex standards.[281] Since the EC measures in dispute do not allow the presence of any residues of these two hormones in any meat or meat product or any of these residues to be ingested by humans (imposing what it calls a "no residue" level), the level of protection reflected in the EC measures is significantly *different* from the level of protection set by the Codex standards (a "no residue" level as opposed to an ADI of maximum 0.5 and 0.02 μg/kg of body weight and an MRL of 2 and 10 μg/kg for, respectively, bovine muscle and bovine liver). The EC measures in

---

way absolute. This requirement is only imposed for a measure to be *based on* such international standard in accordance with Article 3.1.

[276] The concept of "appropriate" level of protection is examined in paragraph 8.79.

[277] See paras. 8.59 ff.

[278] *Ibid.*

[279] See paras. 8.63-8.65.

[280] See para. 8.74.

[281] See para. 8.73.

dispute, in as far as they relate to zeranol and trenbolone, are, therefore, not *based on* existing international standards as specified in Article 3.1.

8.76 When establishing the other three Codex standards applicable to the EC measures in dispute, Codex considered it "unnecessary" to set an ADI or MRL for residues of *oestradiol-17β, testosterone* and *progesterone* (the three natural hormones).[282] The amount of residues of these hormones administered for growth promotion purposes allowed by these Codex standards is, therefore, in any event higher than zero (a maximum level of such residues has not even been prescribed; this level is hereafter referred to as an "unlimited residue level"). The EC measures in dispute, on the other hand, do not allow the presence of any residues of these three hormones administered for growth promotion purposes (again imposing what the European Communities calls a "no residue" level). The level of protection reflected in the EC measures is, therefore, significantly *different* from the level of protection reflected in the Codex standards (a "no residue" level as opposed to an unlimited residue level). The EC measures in dispute, in so far as they relate to oestradiol-17β, testosterone and progesterone, are, therefore, not *based on* existing international standards as specified in Article 3.1.

8.77 We thus find that the EC measures in dispute (except to the extent they relate to the hormone MGA) result in a different level of sanitary protection than would be achieved by measures based on the relevant Codex standards and are, therefore, not *based on* existing international standards as specified in Article 3.1.

8.78 We next examine whether the EC measures with respect to five of the six hormones in dispute, which are not based on existing international standards, otherwise are consistent with the requirements of the SPS Agreement (sections 4 and 5). We then address the EC measures which relate to the sixth hormone, MGA, for which no international standard exists (section 6).

4. Article 3.3: Sanitary Measures Not Based on International Standards

8.79 The fact that the EC measures for oestradiol-17β, testosterone, progesterone, zeranol and trenbolone are not based on existing international standards does not necessarily mean that those measures are inconsistent with the requirements of the SPS Agreement. Article 3.3 reads as follows:

> "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in ac-

[282] See para. 8.62.

> cordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement".

A footnote to Article 3.3, first sentence, then specifies:

> "For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection".

The concept of an "appropriate level of sanitary protection" is defined in paragraph 5 of Annex A of the SPS Agreement as:

> "The level of protection deemed appropriate by the Member establishing a sanitary ... measure to protect human, animal or plant life or health within its territory".

A Note to this paragraph adds the following:

> "Many Members otherwise refer to this concept as the 'acceptable level of risk' ".

(a) Requirements for Justification

8.80 For a sanitary measure to be justified under Article 3.3 the measure needs, first of all, to "result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations". We recall the comparison made above between the level of protection reflected in the EC measures and that implied in the Codex standards for each of the hormones at issue, in particular that the level reflected in the EC measures is *different* from that implied in the Codex standards.[283] For purposes of our analysis under Article 3.3, we assume that the former level is *higher* than the latter, in line with the first sentence of Article 3.3. In addition, the sanitary measure needs to fulfil one of the following two conditions:

- there is a "scientific justification" for imposing the measure, i.e., the Member imposing the measure has determined "on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of [the SPS] Agreement, ... that the relevant international standards, guidelines or recom-

[283] See para. 8.77.

mendations are not sufficient to achieve its appropriate level of sanitary ... protection" ("the first exception"); *or*

- the measure is "a consequence of the level of sanitary ... protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5" ("the second exception").

However, according to the second sentence of Article 3.3, even if one of these conditions is fulfilled, the party imposing the measure must still comply with the other provisions of the SPS Agreement.

8.81 We will consider first whether either the first or the second exception outlined above is met. In doing so, we first address the relationship and difference between these two exceptions. The United States argues that both exceptions have the same effect since both refer to a situation where the basis for departing from the relevant international standard is that the international standard is not sufficient to achieve the Member's appropriate level of protection.[284] The European Communities argues that the first exception is fulfilled when the international standard is inadequate, faulty or obsolete from a scientific point of view and that, according to the second exception, a Member is in any case entitled to introduce or maintain measures which aim at achieving its appropriate level of protection, to be determined in accordance with Article 5 of the SPS Agreement.[285]

8.82 We note that both exceptions explicitly refer to other provisions of the SPS Agreement. The first exception contains the following reference: "... on the basis of an examination and evaluation of available scientific information *in conformity with the relevant provisions of [the SPS] Agreement* ..." (emphasis added). The second exception refers to "... the relevant provisions of *paragraphs 1 through 8 of Article 5*" (emphasis added). Article 3.3, second sentence, in turn, explicitly states that even if the sanitary measure at issue falls under one of the two exceptions of Article 3.3, first sentence, the sanitary measure in question still needs to be consistent with all provisions of the SPS Agreement other than Article 3.

8.83 We find, therefore, that, whatever the difference might be between the two exceptions, a sanitary measure can only be justified under Article 3.3 if it is consistent with the requirements contained in Article 5. If we were to find that the EC measures in dispute are inconsistent with the requirements imposed by Article 5, these measures cannot be justified under Article 3.3. However, even if we find that the EC measures at issue are consistent with the requirements imposed by Article 5, this will still not be sufficient for these measures to be justified under Article 3.3 since to reach that conclusion we also need to find that the EC meas-

[284] See para. 4.91.
[285] See para. 4.90.

ures in dispute fulfil all provisions of the SPS Agreement other than Articles 3 and 5 (*in casu* Article 2).

(b) Burden of Proof

8.84 We recall the findings made above on the burden of proof under the SPS Agreement[286], in particular that for the obligations imposed by the SPS Agreement that are relevant to this case, the party contesting a sanitary measure (*in casu* the United States) bears the initial burden of proof in that it has to present a *prima facie* case of inconsistency with the SPS Agreement, after which the burden of proof shifts to the party imposing the measure (*in casu* the European Communities).

8.85 We consider that this allocation of burden to the party imposing a sanitary measure is, for the reasons set out above[287], applicable to Article 3.3 and particularly justified under the first sentence thereof which contains specific requirements to be fulfilled for a Member to justify a sanitary measure which is *not* based on an international standard.

8.86 One purpose of the SPS Agreement, as explicitly recognized in the preamble, is to promote the use of international standards, guidelines and recommendations. To that end, Article 3.1 imposes an obligation on all Members to base their sanitary measures on international standards except as otherwise provided for in the SPS Agreement, and in particular in Article 3.3 thereof. In this sense, Article 3.3 provides an *exception* to the general obligation contained in Article 3.1. Article 3.2, in turn, specifies that the complaining party has the burden of overcoming a presumption of consistency with the SPS Agreement in the case of a measure based on international standards. It thereby suggests by implication that when a measure is not so based, the burden is on the respondent to show that the measure is justified under the exceptions provided for in Article 3.3.

8.87 We find, therefore, that once the complaining party provides a *prima facie* case (i) that there is an international standard with respect to the measure in dispute, and (ii) that the measure in dispute is *not* based on this standard, the burden of proof under Article 3.3 shifts to the defending party.[288]

---

[286] See paras. 8.48-8.55.

[287] See paras. 8.51-8.54.

[288] This approach is in line with established practice under GATT 1947 and GATT 1994 where, for example, the burden of proof to justify an inconsistency with another GATT provision under Article XX also rests on the defending party. See Panel Report on "Canada - Administration of the Foreign Investment Review Act", adopted on 7 February 1984, BISD 30S/140, p.164, para. 5.20; on "United States - Section 337 of the Tariff Act of 1930", adopted on 7 November 1989, BISD 36S/345, p.393, para.5.27 and on "United States - Standards for Reformulated and Conventional Gasoline", *op. cit.*, p.38, para. 6.20. In this respect, we also note that the Report of the Appellate Body on "United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India" stated the following with respect to the burden of proof under Articles XX and XI:2(c)(i) of GATT: "Articles XX and

8.88 Since in this dispute we have already found that there exist international standards[289] and that the EC measures at issue are not based on these standards[290], we find that the burden of justifying the measures in dispute under Article 3.3, and in particular under the first sentence thereof, rests on the European Communities.

8.89 *In summary*, in sections 3 and 4 we have found that: (i) there exist international standards, as defined in Article 3.1 and paragraph 3(a) of Annex A of the SPS Agreement, with respect to the EC measures in dispute to the extent they relate to five of the six hormones at issue (all but MGA); (ii) the EC measures in dispute, in as far as they relate to these five hormones, are *not based on* these international standards, as required in Article 3.1; and (iii) the EC measures, to the extent they are *not* based on these international standards, can only be justified under Article 3.3 if these measures meet, *inter alia*, the requirements imposed by Article 5.

8.90 In the next section we will, therefore, examine whether the EC measures in dispute *with respect to the five hormones at issue for which international standards exist* are consistent with the requirements imposed by Article 5.

5. Article 5: "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection"

(a) Risk Assessment and Risk Management

8.91 Article 5 of the SPS Agreement deals mainly[291] with two separate aspects of a Member's decision to enact or maintain a sanitary measure. These two aspects are separated in the SPS Agreement, which provides for specific rights and obligations in respect of each of them.

8.92 The *first aspect* relates to the exercise of assessing the risks to human, animal or plant life or health against which a sanitary measure is intended to protect. This is referred to in the SPS Agreement as *risk assessment*.[292] With respect to food safety, the potential adverse effects (if any) related to a specific

---

XI:(2)(c)(i) are limited exceptions from obligations under certain other provisions of the GATT 1994, not positive rules establishing obligations in themselves. They are in the nature of affirmative defences. It is only reasonable that the burden of establishing such a defence should rest on the party asserting it", DSR 1997:I, 323 at 337.

[289] See para. 8.70.

[290] See para. 8.77.

[291] Except for Article 5.8 which has not been invoked in this dispute.

[292] See the title of Article 5 of the SPS Agreement ("Assessment of risk ...") and Annex A of the SPS Agreement providing a definition for "risk assessment".

substance are established together with the probability of occurrence of any such effects.[293]

8.93 According to Article 5.1, a Member needs to ensure that its sanitary measures are *based on* an assessment of risks. The obligation to base a sanitary measure on a risk assessment may be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement which provides that "Members shall ensure that any sanitary ... measure is *applied only to the extent necessary to protect* human, animal or plant life or health, is *based on scientific principles* and is *not maintained without sufficient scientific evidence* ..." (emphasis added). Articles 5.1 to 5.3 sum up factors a Member needs to take into account in making this assessment of risks.[294]

8.94 As will be outlined below[295], an assessment of risks is, at least for risks to human life or health, a *scientific* examination of data and factual studies; it is not a policy exercise involving social value judgments made by political bodies.

8.95 The *second aspect* of a Member's decision to enact or maintain a sanitary measure relates, *inter alia*, to the determination and application of the *appropriate level of sanitary protection* by that Member against the risks to human, animal or plant life or health which have been assessed in accordance with Articles 5.1 to 5.3. This aspect is commonly referred to by the parties to this dispute as an essential part of *risk management*.[296] The Member wishing to impose a sanitary measure must decide the extent to which it can accept the potential adverse effects related to a specific substance which have been identified in the risk assessment.

8.96 Articles 5.4 to 5.6 are particularly relevant to the risk management decision. Article 5.4 establishes the objective of minimizing negative trade effects in the *determination* by a Member of its appropriate level of protection. Article 5.5 aims at achieving consistency in the *application* of the concept of appropriate level of protection. Article 5.6, in turn, provides that the sanitary *measure* which is finally adopted shall not be more trade-restrictive than required to achieve the appropriate level of protection of the Member concerned. Articles 5.4 to 5.6 may be viewed as specific applications of the basic obligations provided for in Article 2.2 which, *inter alia*, states that "Members shall ensure that any sanitary or phytosanitary measure is *applied only to the extent necessary to protect* human, animal or plant life or health" (emphasis added) and Article 2.3 which provides that "Members shall ensure that their sanitary and phytosanitary measures do *not arbitrarily or unjustifiably discriminate between Members* where identical or simi-

---

[293] See the definition of "risk assessment" contained in paragraph 4 of Annex A of the SPS Agreement, discussed below in para. 8.98.

[294] Article 5.7 deals with cases where relevant scientific evidence is insufficient at which point a Member may, under certain conditions, take provisional sanitary measures. The European Communities has explicitly stated that this provision does not apply to the EC measures in dispute.

[295] See paras. 8.98 and 8.104-8.107.

[296] See paras. 4.97 and 4.101.

lar conditions prevail ..." and that "Sanitary and phytosanitary measures *shall not be applied in a manner which would constitute a disguised restriction* on international trade" (emphasis added).

8.97 As will be outlined below[297], the risk management phase involves *non-scientific* considerations, such as social value judgments.

(b) Articles 5.1 to 5.3: Risk Assessment

8.98 According to Article 5.1:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations".

Paragraph 4 of Annex A of the SPS Agreement defines "risk assessment" with respect to contaminants (including residues of the hormones at issue) as

> "the *evaluation* of the *potential* for *adverse effects* on human or animal health arising from the presence of ... contaminants ... in food, beverages or feedstuffs" (emphasis added).

Guided by the wording of these provisions, we consider that, in this dispute, a risk assessment carried out in accordance with the SPS Agreement should (i) *identify* the *adverse effects* on human health (if any) arising from the presence of the hormones at issue when used as growth promoters *in meat or meat products*, and (ii) if any such adverse effects exist, *evaluate* the *potential* or probability of occurrence of these effects.

8.99 Article 5.1 provides in general terms, without any limitation in time, that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks ...". It does not prevent that with respect to a sanitary measure enacted *before* the entry into force of the SPS Agreement, the risk assessment is carried out or invoked *after* the entry into force of that Agreement (and thus *after* the enactment of the sanitary measure in question). However, the fact that a sanitary measure may be enacted *before* the entry into force of the SPS Agreement does not mean that, once the SPS Agreement entered into force, there is no obligation for the Member in question to base that measure on a risk assessment.[298] Moreover, the more general obligation contained in Article 2.2 of the SPS Agreement explicitly provides that "Members shall ensure that any sanitary or phytosanitary measure ... is based on scientific principles and is not *maintained* without sufficient scientific evidence ..." (emphasis added).

---

[297] See paras. 8.160 ff.

[298] Our reasoning and general finding with respect to the application *ratione temporis* of the SPS Agreement developed in paras. 8.24-8.27 also applies to Article 5.1 of that Agreement.

8.100 We also recall our finding reached above on the specific burden of proof under Article 3.3[299], in particular that the burden of proving that the requirements imposed by Article 3.3 (*inter alia*, consistency with Article 5) are met, rests with the Member imposing a sanitary measure which deviates from an international standard. Since the EC measures examined in this section (relating to all hormones in dispute other than MGA) are not based on existing international standards and need to be justified under the exceptions provided for in Article 3.3, the European Communities has the burden of proving that its measures are based on a risk assessment in accordance with Article 5.

8.101 In this respect we consider at the outset that it is for the European Communities to submit evidence before the Panel that its measures are based on a risk assessment; it is not for the Panel itself to conduct its own risk assessment on the basis of scientific evidence gathered by the Panel or submitted by the parties during the Panel proceedings.

8.102 We next examine: (i) the techniques and factors to be taken into account in a risk assessment in accordance with Article 5; (ii) whether the European Communities has demonstrated the existence of such a risk assessment; and (iii) assuming that such risk assessment exists, whether the European Communities has demonstrated that its measures at issue are based on this risk assessment.

(i) Techniques and Factors to be Taken Into Account

8.103 None of the parties suggest that there are "risk assessment techniques developed by the relevant international organizations" in the sense of Article 5.1 which have to be taken into account in a risk assessment for the hormones at issue.[300] We note, however, that, even though no formal decision has as yet been taken by Codex with respect to risk assessment techniques, Codex, and more particularly JECFA, has a long-standing practice with respect to the assessment of risks related to veterinary drug residues (including hormone residues). The techniques thus developed have been outlined above.[301] We also note the Report of the Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues convened at the request of Codex in March 1995. In this Report "risk assessment" is defined as follows:

> "The scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk,

[299] See paras. 8.84-8.88.
[300] See para. 4.113.
[301] See paras. 8.59 ff.

> and also qualitative expressions of risk, as well as an indication of the attendant uncertainties" (p.6).[302]

8.104 Article 5.2 provides for the factors which a Member has to take into account in the assessment of risks:

> "In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment".

8.105 None of the parties involved in this dispute has argued that any factors listed in Article 5.2 other than the following three are relevant for an assessment of risks related to the hormones at issue in this case:

(i) available scientific evidence;

(ii) relevant processes and production methods; and

(iii) relevant inspection, sampling and testing methods.

In particular, we note that none of the parties has argued that factors not listed in Article 5.2, such as consumer preferences, can be taken into account in a risk assessment in accordance with Article 5.

8.106 Article 5.3 sums up relevant economic factors to be taken into account in assessing risks to *animal* or *plant* life or health. Since the scope of this dispute is limited to issues of *human* life or health[303], Article 5.3 has no application to the matter under consideration.

8.107 We finally note that the parties agree that, for the purposes of the EC measures in dispute, a risk assessment in accordance with Article 5 is a *scientific* process aimed at establishing the *scientific* basis for the sanitary measure a Member intends to take.[304]

(ii) The Existence of a Risk Assessment

8.108 The European Communities has referred to the following scientific evidence concerning the five hormones at issue:[305]

- the 1982 Report of the EC Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Com-

---

[302] A revised version of this definition has been accepted at the 12th session of the Codex Committee on General Principles held in November 1996 and reads as follows: "A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization; (iii) exposure assessment, and (iv) risk characterization" (Codex Alimentarius Commission, CX/GP96/3).

[303] See para. 8.19.

[304] See paras. 4.111 and 4.123.

[305] See para. 4.28.

mittee for Food on the basis of the Report of the Scientific Group on Anabolic Agents in Animal Production[306] ("Lamming Report");

- the 1983 Symposium on Anabolics in Animal Production of the *Office international des epizooties* ("OIE")[307] ("1983 OIE Symposium");
- the 1987 Monographs of the International Agency for Research on Cancer ("IARC") on the Evaluation of Carcinogenic Risks to Humans, Supplement 7[308] ("1987 IARC Monographs");
- the 1988 and 1989 JECFA Reports[309];
- the 1995 European Communities Scientific Conference on Growth Promotion in Meat Production[310] ("1995 EC Scientific Conference");
- articles and opinions by individual scientists relevant to the use of hormones (three articles in the journal Science, one article in the International Journal of Health Service, one report in The Veterinary Record and separate scientific opinions of Dr. H. Adlercreutz, Dr. E. Cavalieri, Dr. S.S. Epstein, Dr. J.G. Liehr, Dr. M. Metzler, Dr. Perez-Comas and Dr. A. Pinter, all of whom were part of the EC delegation at our joint meeting with experts).[311]

8.109 The European Communities also referred to several reports of the European Parliament (the Nielsen Report of 1981, the first Collins Report of 1985, the second Collins Report of 1989 and the Pimenta Report of 1989) and opinions of the EC Economic and Social Committee (of 1981 and 1984).[312] However, we recall the findings we reached above, in particular that risk assessment is a scientific process. Thus, we consider that the non-scientific reports and opinions of the European Parliament and the EC Economic and Social Committee, which *evaluate* the scientific and other reports submitted to them, are not part of the *risk assessment* process, but of the *risk management* process, further elaborated below.[313]

---

306 See para. 2.28.
307 See paras. 4.16 and 4.132.
308 See para. 4.129.
309 See paras. 2.22-2.25.
310 See para. 2.33.
311 With respect to the scientific evidence referred to by the European Communities in relation to the potential adverse effects of the hormones at issue on the health or life of *live animals*, we recall our findings reached in paragraph 8.19 that the animal health arguments invoked by the European Communities exclusively relate to the EC import ban of *live animals* (which does not fall within the scope of the EC measures in dispute) and that these arguments need, therefore, not to be taken into account within the scope of this dispute.
312 See paras. 4.21; 4.29; 4.36 and 4.40.
313 See paras. 8.160 ff.

8.110 We next consider whether the scientific evidence and attendant evaluation referred to by the European Communities constitutes a risk assessment in the sense of Article 5. We recall that under the SPS Agreement a risk assessment should, for the purposes of this dispute, identify the adverse effects on human health arising from the presence of the specific hormones at issue when used as growth promoters in meat or meat products and, if any such adverse effects exist, evaluate the potential or probability of occurrence of these effects.[314] We further recall that a risk assessment should be a scientific examination of data and studies[315] and that the SPS Agreement sets out factors which need to be taken into account in a risk assessment.[316] We finally recall that no risk assessment techniques, as referred to in Article 5.1, have as yet been formally adopted by Codex.[317] The Agreement does not further specify the requirements of what constitutes a risk assessment in accordance with Article 5.

8.111 We note that the European Communities has invoked several scientific reports which appear to meet these minimum requirements of a risk assessment (in particular the Lamming Report and the 1988 and 1989 JECFA Reports) and that the scientists advising the Panel seemed to consider these reports, from a scientific and technical point of view, to be risk assessments.[318] We shall, therefore, for the purposes of this dispute, assume that the European Communities has met its burden of demonstrating the existence of a risk assessment carried out in accordance with Article 5.

(iii) Sanitary Measures to be Based on a Risk Assessment

8.112 Article 5.1 requires Members to "ensure that their sanitary ... measures ... are *based on* an assessment ... of the risks to human ... life or health". It does not, however, specify how to determine whether a measure is *based on* a risk assessment. In our view, this determination has both a procedural and a substantive aspect.

Procedural Requirements

8.113 Notwithstanding the fact that Article 5 does not contain specific procedural requirements for a Member to *base* its sanitary measures *on* a risk assessment, we consider that, according to the ordinary meaning of the words *based on*

---

[314] See para. 8.98.
[315] See para. 8.107.
[316] See paras. 8.104 and 8.105.
[317] See para. 8.103.
[318] See, in general, answers by experts to Panel Questions 5 and 13, paras. 6.51 ff. and 6.142-6.147 and, in particular, Dr. Arnold at para. 6.57, Dr. McLean at para. 6.145 and opinion of Dr. Ritter, Transcripts of the joint meeting with experts of 17 February 1997, paras. 20 and 352.

put in their context and in light of the object and purpose of Article 5[319], there is a minimum procedural requirement contained in Article 5.1. In our view, the Member imposing a sanitary measure needs to submit evidence that at least it actually *took into account* a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as *based on* a risk assessment.

8.114 We note that in this dispute the European Communities, which has the burden of proving that it based its measures on a risk assessment, has not provided any evidence that the studies it referred to (in so far as they can be considered as part of a risk assessment) or the scientific conclusions reached therein, have actually been taken into account by the competent EC institutions either when it enacted these measures (in 1981 and 1988) or at any later point in time. We note, in this respect, that none of the preambles to the EC measures at issue mention any of the scientific studies referred to by the European Communities. These preambles only refer to the non-scientific reports and opinions of the European Parliament and the EC Economic and Social Committee, which cannot be considered as part of a risk assessment.[320]

8.115 In particular with respect to the *articles and opinions of individual scientists* on which the European Communities focused our attention, we note that the European Communities has argued that some of these articles and opinions (in particular those published in 1995 and 1996) are what it called "new evidence" of which it was only informed during the Panel process.[321] In so far as that is the case, these articles and opinions cannot for the purposes of this dispute be considered as part of a risk assessment on which the European Communities based its measures unless there would be some evidence that the competent EC institutions actually considered these articles and opinions or reexamined the potential risks related to the specific substances at issue in light of these articles and opinions. In that event, the European Communities would then have confirmed or changed its earlier conclusions on the basis of such consideration or reexamination. According to the terms of reference given to us as a dispute settlement panel, we have no mandate to reexamine the risk assessment referred to by the European Communities in light of this "new evidence", nor to make our own risk assessment. These articles and opinions, in so far as they constitute "new evidence" gathered by the European Communities during the Panel process can,

---

[319] In accordance with the rules of treaty interpretation contained in Article 31 of the Vienna Convention.

[320] See para. 8.109.

[321] See paras. 4.143-4.148 and 4.192. However, later on in the Panel process, the European Communities confirmed that many of these articles and opinions constitute evidence which was already taken into account in the other studies referred to by the European Communities. In so far as this is correct, see paras. 8.132 ff.

therefore, from a procedural point of view, not be considered as part of a risk assessment on which the European Communities based its measures in dispute.[322]

8.116 For these reasons, we find that the European Communities has not met its burden of proving that it met the minimal procedural requirement contained in Article 5.1 and that, therefore, the EC measures in dispute are inconsistent with the requirements of Article 5.1.

Substantive Requirements

8.117 Even if the European Communities would have fulfilled these minimum procedural requirements, there would still be a need to examine the substantive requirements contained in Article 5.1. From a substantive point of view, we consider that in this dispute we should, in accordance with the ordinary meaning of the words *based on* put in their context and in light of the object and purpose of Article 5[323], proceed as follows to determine whether the EC measures at issue are *based on* a risk assessment: (i) we need to identify the scientific conclusions reached in each of the studies referred to by the European Communities; (ii) we need to identify the scientific conclusion reflected in the EC measures in dispute; and (iii) we need to determine whether the scientific conclusion reflected in the EC measures can be considered as being in conformity with any of those reached in the studies referred to by the European Communities.

8.118 For purposes of this analysis, we first address the studies referred to by the European Communities which *specifically* address one or more of the hormones in dispute when used for growth promotion purposes before examining the studies which *generally* relate to one or more of these hormones.

1. *Scientific Conclusions Reached in the Studies Referred to by the European Communities which Specifically Address One or More of the Hormones in Dispute when Used for Growth Promotion Purposes*

8.119 The *Lamming Report* came to the following conclusions with respect to the potential for adverse effects on human health arising from the presence in meat of residues of the hormones in dispute administered for growth promotion purposes:

> "5.1. The Scientific Working Group is of the opinion that the use of oestradiol-17β, testosterone and progesterone [the three natural hormones in dispute] and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application, *would not present any harmful effects to the health of*

[322] These articles and opinions are, from a substantive point of view, further addressed in paras. 8.130 ff.

[323] In accordance with the rules of treaty interpretation contained in Article 31 of the Vienna Convention.

> *the consumer when used under the appropriate conditions as growth promoters in farm animals*.
>
> 5.2. Evaluation of the data on 'trenbolone' and 'zeranol' [two of the three synthetic hormones in dispute] revealed that some data on the hormonal no-effect-level and the toxicology of these compounds and their metabolites are still missing.
>
> 5.3. The Scientific Working Group considers it necessary that additional information be provided before a final conclusion can be given on trenbolone and zeranol" (emphasis added).[324]

The Scientific Working Group continued its review of trenbolone and zeranol up to 1985 but was dismantled by the EC Commission just before it was to submit its final report.

8.120 Some of the members of the group published, in their personal capacity, the unofficial report in "The Veterinary Record". The conclusions reached with respect to the potential for adverse effects on human health arising from the presence in meat of residues of *trenbolone* and *zeranol* administered for growth promotion purposes, were the following:

> "(1) We have examined the extensive data available concerning the toxicology of trenbolone and zeranol.
>
> "(2) We believe there is adequate evidence from both short term and long term tests that these compounds and their metabolites found as residues do not show significant genotoxic potential.
>
> ...
>
> "(5) *The levels of trenbolone and zeranol and their major metabolites found in edible tissue, following accepted husbandry practices, are substantially below the hormonally effective doses in animal test systems and therefore do not present a harmful effect to health*" (emphasis added).[325]

8.121 With respect to the *1983 OIE Symposium*, we note that the report of the symposium consists of a book with a series of articles by individual scientists or groups of scientists. No formal scientific conclusion was agreed by all participants or by the OIE itself. The book contains, however, a foreword to the articles which includes the following statement with respect to the potential for adverse effects on human health arising from the presence in meat of residues of the three natural hormones in dispute administered for growth promotion purposes:

> "The myth that all anabolics are dangerous to human health is still very much alive in many countries. It must be discredited. *There is common agreement with the proof presented at this meeting that*

[324] See para. 2.28.
[325] See para. 4.35.

> *the endogenous anabolics (natural hormones) such as 17β-estradiol, progesterone, and testosterone, when administered as implants in animals, are not hazardous to man*" (emphasis added).

The European Communities invokes two specific quotes from individual articles submitted at the OIE Symposium in support of its measures.[326] However, these quotes, which only stress the inherent uncertainties of scientific evidence and the evolving character of science, do not seem to invalidate the "common agreement" outlined in the foreword quoted above.

8.122 The *1988 JECFA Report* came to the following conclusion with respect to the potential for adverse effects on human health arising from the presence in meat of residues of all three natural hormones in dispute administered for growth promotion purposes:

> "The Committee therefore concluded that the amount of exogenous [oestradiol-17β, testosterone and progesterone] ingested in meat from treated animals would be *incapable of exerting a hormonal effect, and therefore any toxic effect, in human subjects*.
>
> The Committee considered an ADI unnecessary for a hormone that is produced endogenously in human beings and shows great variation in levels according to age and sex. *The Committee concluded that residues arising from the use of [any of the three natural hormones in dispute] as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health ...*
>
> On the basis of its safety assessment of residues of [any of the three natural hormones in dispute], and in view of the difficulty of determining the levels of this hormone as a growth promoter in cattle, the Committee concluded that it was unnecessary to establish an Acceptable Residue Level" (emphasis added).[327]

As outlined above[328], the *1988 and 1989 JECFA Reports* set ADIs and MRLs for zeranol and trenbolone (two of the three synthetic hormones in dispute). JECFA reached the conclusion that their toxic effects are linked to their hormonal effects and that, therefore, a no-hormonal-effect level could be established which would ensure that residues up to such level are safe. JECFA also concluded that the safety level or ADI it thus adopted would not be exceeded at any time after proper implantation (irrespective of the withdrawal period respected).

8.123 The Steering Committee of the *1995 EC Scientific Conference* came to the following conclusions with respect to the potential for adverse effects on human

[326] See paras. 4.16 and 4.128.
[327] See para. 2.22.
[328] See paras. 8.63-8.65.

health arising from the presence in meat of residues of the hormones in dispute administered for growth promotion purposes:

> "When used as growth promoters, the naturally occurring gonadal steroid hormones (oestrogen, testosterone and progesterone) can increase the growth rate, the proportion of lean meat to fat and the food-conversion efficiency of some species of animals ... while the residues of hormone in the resulting meat are within the normal physiological range ... To the extent that improved food-conversion efficiency reduces excretion of nitrogen and phosphorus per unit of meat production, the environmental benefits (while small) are likely to be positive. That is the basis on which the *Steering Group endorses the conclusions of Working Group II that the conditions defined in countries where the use of these hormones as growth promoters is permitted are a reasonable safeguard of public health*.
>
> Several materials similar in their physiological effects to the natural sex hormones (such as trenbolone and zeranol) are also used as growth promoters in meat production ... *The Steering Committee endorses the opinion of Working Group II that the definition of the MRL for trenbolone and its metabolites reached by various international committees* [*inter alia*, JECFA] *provide reasonable protection of public health*" (emphasis added).[329]

The relevant conclusions of Working Group II of the Conference on "Assessment of Health Risk", which specifically address the safety of the hormones at issue when used as growth promoters, read as follows:

> "Natural sex hormones
>
> *At present, there is no evidence for possible health risks to the consumer due to the use of natural sex hormones for growth promotion, since:*
>
> - Residue levels of these substances measured in meat of treated animals fall within the physiological range observed in meat of comparable untreated animals.
> - The daily production of sex hormones by humans is much higher than the amounts possibly consumed from meat, even in the most sensitive humans (prepubertal children and menopausal women).
> - Due to an extensive first-pass metabolism, the bioactivity of ingested hormones is low, thus providing a further safety margin.

[329] See para. 2.33.

Zeranol and trenbolone

...

At the doses needed for growth promotion, residue levels are well below the levels regarded as safe (the MRLs). There are, at present, no indications of a possible human health risk from the low levels of covalently-bound residues of trenbolone" (emphasis added).[330]

8.124 As can be deduced from all conclusions outlined above, none of the scientific evidence referred to by the European Communities which specifically addresses the safety of some or all of the hormones in dispute when used for growth promotion, indicates that an identifiable risk arises for human health from such use of these hormones if good practice is followed. All of the scientific studies outlined above came to the conclusion that the use of the hormones at issue (all but MGA, for which no evidence was submitted) for growth promotion purposes is safe; most of these studies adding that this conclusion assumes that good practice is followed. We note that this conclusion has also been confirmed by the scientific experts advising the Panel.[331]

2. *Scientific Conclusions Reached in the Studies Referred to by the European Communities which Generally Relate to One or More of the Hormones in Dispute*

8.125 The European Communities puts particular emphasis on the 1987 IARC Monographs and the articles and opinions of individual scientists outlined above.

---

[330] See para. 2.33.

[331] See answers by experts to Panel Question 7, paras. 6.93 ff, including the answers by Dr. André (at para. 6.93) and, albeit slightly qualified, Dr. Lucier (at para. 6.95: "Dr. Lucier responded that, to his knowledge, there was no piece of scientific evidence to indicate that any of the six hormones in question had unequivocally caused adverse effects in humans when administered and used properly. However, there was some information available which raised concern for a slight effect on the incidence of human disease"). In this respect, we note Dr. Lucier's statement that, according to his tentative estimates, between zero and one person in a million who eat 500 grams of meat, treated with oestrogens for growth promotion purposes in accordance with good practice, per day over their lifetimes, get cancer (see Transcripts of the joint meeting with experts of 18 February 1997, paras. 742 and 819). This 0-1 in a million risk is caused by the *total* amount of oestrogens in treated meat (the amount of endogenous oestrogens being highly variable and, according to Dr. Lucier, already being carcinogenic), not by the small fraction thereof which is added for growth promotion purposes and which is relevant for the purposes of this dispute. Moreover, this estimate only represents a statistical range of 0 to 1 in a million, not a scientifically identified risk. The concept of "zero risk", to which this statement is closely related, is further dealt with in paras. 8.149 ff. We note, finally, that all experts confirmed that there is no evidence that particular or more significant health problems exist in countries where the hormones at issue are allowed for administration as growth promoters as compared to countries where such use is prohibited (see answers by experts to Panel Question 9, paras. 6.118-6.122).

8.126 The *1987 IARC Monographs*, in so far as they relate to human health[332], contain evidence with respect to three general categories of hormones, namely oestrogens, androgens and progestins, without distinguishing the specific hormones falling within each of these categories or the natural hormones from the synthetic hormones.[333] The Monographs classify oestrogens as agents which are carcinogenic (meaning that there is sufficient evidence of carcinogenicity in humans); androgens as agents which are probably carcinogenic; and progestins as agents which are possibly carcinogenic.[334]

8.127 We note that the scientific evidence included in these Monographs relates to the carcinogenic potential of entire *categories* of hormones or the hormones at issue *in general*. The Monographs do not consider the carcinogenic potential of these hormones when used specifically for growth promotion purposes or with respect to residue levels comparable to those present after such use.[335] Moreover, the Monographs do not specifically evaluate, as is required on the basis of paragraph 4 of Annex A of the SPS Agreement[336], the potential for adverse effects arising from the presence *in food* (*in casu* meat or meat products) of residues of the hormones in dispute or from residue levels comparable to those present in food.

8.128 We further note that, according to the scientific experts advising the Panel, the data and studies contained in these Monographs with respect to the carcinogenic potential of the hormones in dispute have been fully taken into account in the 1988 and 1989 JECFA Reports which, at several occasions, explicitly refer to these Monographs.[337] Nowhere do the 1988 and 1989 JECFA Reports reject the conclusions reached in the 1987 IARC Monographs. On the contrary, the Monographs constitute part of the evidence on which the JECFA Reports are based. JECFA recognized that all five hormones at issue have a carcinogenic potential but concluded that this potential was linked to the hormonal effect of these hormones.[338] Since JECFA considered that the additional residues

---

[332] In this respect, we recall our finding that within the scope of this dispute we need not to take into account the arguments made by the European Communities which relate to animal health (see para. 8.19).

[333] As outlined in paras. 2.8 and 2.9, oestradiol-17β and zeranol are oestrogens; testosterone and trenbolone are androgens and progesterone is a progestin.

[334] See para. 4.129.

[335] See also answer by Dr. Arnold to Panel Question 6, para. 6.83.

[336] See para. 8.98.

[337] See answers by experts to Panel Question 5 where all experts confirm that the JECFA Reports took into account cancer risks (para. 6.51 ff.). See, in particular, statements made by Dr. Randell, the Codex expert, at the joint meeting with experts of 17 February 1997 (Transcripts, paras. 239, 297 and 436 and by Dr. McLean at the joint meeting with experts of 18 February 1997 (Transcripts, para. 823).

[338] The link made by JECFA between hormonal and toxic effect does not contradict the conclusions in the IARC Monographs; on the contrary, since the latter state the following: "There is a basic incongruity between the human data and the animal carcinogenicity data. As noted earlier, however, *the effects of these chemicals* [*inter alia*, the general categories to which the hormones in dispute

of the three natural hormones present in treated meat are not capable of exerting any toxic effect, it decided that it was unnecessary to set ADIs or MRLs for these hormones.[339] With respect to zeranol and trenbolone, JECFA identified a no-hormonal-effect level and adopted, on that basis, ADIs and MRLs which, if respected, would ensure the safe use of these hormones.[340] The IARC Monographs and JECFA Reports did not, therefore, reach contradictory but rather complementary scientific conclusions.

8.129 For these reasons, we consider that the 1987 IARC Monographs, in so far as they can be regarded as part of a risk assessment for the specific hormones at issue when used as growth promoters in the sense of Article 5.1, have been taken into account in, and do not contradict, the other studies referred to by the European Communities (in particular the 1988 and 1989 JECFA Reports) which explicitly conclude that the specific use of these hormones as growth promoters in accordance with good practice is safe.

8.130 The European Communities finally invokes several *articles and opinions of individual scientists*. These articles and opinions deal with the carcinogenic or genotoxic potential of hormones and criticize the scientific methodology or conclusions of the other studies referred to by the European Communities. A summary of the content of some of these articles and opinions is contained in paragraphs 4.131-4.136 and 4.180. The scientific evidence included in these articles and opinions relates to the carcinogenic or genotoxic potential of entire *categories* of hormones or the hormones at issue *in general*; not when used specifically for growth promotion purposes or with respect to residue levels comparable to those present after such use.[341] Moreover, these articles and opinions do not specifically evaluate, as is required on the basis of paragraph 4 of Annex A of the SPS Agreement, the potential for adverse effects arising from the presence *in food* (*in casu* meat or meat products) of residues of the hormones in dispute or from residue levels comparable to those present in food.

8.131 Of the articles and opinions invoked, the European Communities has put much emphasis on the opinion of Dr. Liehr, a scientist with the EC delegation, on "Potential Genotoxicity of Hormones". We note the statement by Dr. Liehr himself that the evidence he submitted is only based on tests carried out at elevated doses of oestrogens and that the relevance of these high dose effects to potential risks related to the low levels of oestrogens in meat from growth promoted animals has not yet been evaluated.[342] Moreover, we recall that this opinion only

---

belong] *in humans appear, at least in most cases, to be linked to the hormonal milieu*" (emphasis added).

[339] See para. 8.62.

[340] See paras. 8.63-8.65.

[341] See para. 2.22.

[342] See para. 4.143. In this respect, we also note the following statements by Dr. Liehr: "... we have no genotoxicity data at low levels" and "... I agree ... that at the moment this is an interesting hypothesis and I have never labelled it more than a hypothesis and I also agree ... that many pieces are

applies to one of the hormones in dispute, namely, oestradiol-17β and does not address the use of this hormone as a growth promoter.

8.132 We further note that, according to the Codex expert advising the Panel, most of the evidence contained in these articles and opinions and the potential risks addressed therein were already evaluated and taken into account in the 1988 and 1989 JECFA Reports.[343] Indeed, in the event these articles and opinions should be considered as evidence which was, as the European Communities itself argued at the end of the Panel proceedings, not "new" but was already taken into account in the 1988 or 1989 JECFA Reports, the Lamming Report or the 1995 EC Scientific Conference, these articles and opinions would then not invalidate or contradict the scientific conclusions reached in these other studies, which specifically address the use of the hormones in dispute for growth promotion purposes, but rather constitute part of the evidence on which these studies are based.

8.133 We also note that, even if these articles and opinions could be considered as scientific evidence which is part of a risk assessment for the specific hormones at issue when used as growth promoters in the sense of Article 5.1 and which was not yet considered in the other studies invoked by the European Communities, the scientific experts advising the Panel were of the view that this evidence, *as it stands today*, does not invalidate or contradict the scientific conclusions reached in the other studies invoked by the European Communities which specifically relate to the safety of the hormones at issue when used for growth promotion purposes:

> *Dr. McLean*:
>
> "Some of the new data that has been submitted particularly relies upon *in vivo* and *in vitro* carcinogenicity testing and also some of the mutagenicity testing but I do not believe that it is any more significant than the sort of data that was available at the time the original appraisal was made [in the 1988 and 1989 JECFA Reports]".[344]
>
> *Dr. Arnold*:
>
> "... from my point of view, the significant new evidence which has been produced since that Committee [the 32nd and 34th meetings of JECFA] did not invalidate the basic conclusions and therefore I still am feeling very comfortable with the conclusions although I

missing ..." (Transcripts of the joint meeting with experts of 17 February 1997, para. 330). The fact that Dr, Liehr repeatedly called for a more thorough scientific examination of the risks related to oestrogens and for more data, reveals that the studies he provided to us do not yet contain conclusive evidence of an identifiable risk.

[343] See Transcripts of the joint meeting with experts of 17 February 1997, para. 297. See also answers by experts to Panel Question 5, paras. 6.51 ff.

[344] Transcripts of the joint meeting with experts of 17 February 1997, para. 4.

admit that a lot of new evidence has been produced by the scientific community".[345]

Dr. Ritter:

"The nature of scientific interpretation is that legitimate bona fide knowledgeable scientists may reach different conclusions from the same set of data. But I think the consensus opinion of that Conference [the 1995 EC Scientific Conference] was that the weight of evidence used then continues to prevail now, and that the assessments and conclusions drawn then are still consistent with the available information now".[346]

"I agree that there is further work that is indicated. I agree that statements made by scientists, such as Dr. Liehr, will continue to contribute to our understanding, but I also agree that the totality of evidence, re-evaluated as recently as December 1995 [by the 1995 EC Scientific Conference], suggests that the way in which these substances are used and the residues which they produce, do not constitute a risk to human health".[347]

Dr. Lucier:

"There is a group of scientists [including Dr Liehr, a scientist with the EC delegation] who are looking at the role of oxidated damage and genotoxicity of oestrogens ... But for this narrow purpose that we are talking about today, about the influence of this on additional risk from oestrogens from eating, consuming meat containing oestrogens from growth promoted animals, it doesn't have too much consequence. ... I would come up with the same answer either case; there would be no difference in the risk. So I think in that respect whether or not oestrogen is genotoxic, has less consequence then what we talked about up to this point in time".[348]

8.134 For these reasons, we find that the European Communities has not demonstrated that the scientific evidence it referred to, which generally addresses the safety of some or all of the hormones in dispute, would indicate that an identifiable risk arises for human health from the use of these hormones for growth promotion purposes if good practice is followed. In this respect we recall that all scientific experts advising the Panel confirmed this conclusion and stated that, as of today, no scientific evidence is available which concludes that an identifiable

---

345 Transcripts of the joint meeting with experts of 17 February 1997, para. 356.
346 *Ibid.*, para. 352.
347 *Ibid.*, para. 424.
348 The other scientist advising the Panel, Dr. André did not explicitly express his view on this issue but did not contest the statements made by the other scientists. Dr. McLean has furthermore answered in the affirmative when asked whether he believed that the Codex standards are fully adequate to address the problem (Transcripts of the joint joint meeting with experts of 17 February 1997, para. 9).

risk arises from the use of any of the hormones at issue for growth promotion purposes in accordance with good practice.[349]

8.135 The finding we thus make does, of course, not exclude that future scientific developments could require modifications to the scientific conclusions reached in the studies referred to by the European Communities.

3. *Scientific Conclusion Reflected in the EC Measures*

8.136 The European Communities bans the use for growth promotion purposes of any of the hormones in dispute, including the use of these hormones in accordance with good practice. During the Panel proceedings it has made clear that it considers *any* residue level of these hormones to be unsafe for human health, setting its level of protection at a "zero residue" level. The scientific conclusion reflected in the EC measures in dispute is thus that the use of the hormones in dispute for growth promotion purposes, *even in accordance with good practice*[350], poses an identifiable risk to human health.

4. *The Conformity of the Scientific Conclusion Reflected in the EC Measures with the Scientific Conclusions Reached in the Studies Referred to*

8.137 In our view, the scientific conclusion reflected in the EC measures in dispute, *i.e.*, that the use of the hormones in dispute for growth promotion purposes, even in accordance with good practice, is *not* safe, does not conform to any of the scientific conclusions reached in the evidence referred to by the European Communities. All the evidence referred to by the European Communities which specifically relates to the use of the hormones at issue for growth promotion purposes concludes that the use of these hormones as growth promoters in accordance with good practice *is* safe.[351] Moreover, none of the evidence referred to by the European Communities which generally deals with one or more of the hormones in dispute contradicts this conclusion.[352] The EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, allegedly necessary to protect human health, in so far as it also applies to meat and meat products from animals treated with any of these hormones *in accordance with good practice*, is, therefore, not based on the scientific evidence submitted to the Panel.

8.138 The European Communities, however, submits the following additional arguments (sections 5 and 6). We note that these arguments have not been supported by scientific evidence other than the evidence examined above. We con-

---

[349] See footnote 331.

[350] Since, according to the experts advising the Panel (answers by experts to Panel Question 3, paras. 6.32 ff), any use of the hormones in dispute will always leave some residue level, albeit a very small one, the administration of these hormones in accordance with good practice will also leave some residue and thus not achieve the EC "zero residue" level of protection.

[351] See para. 8.124.

[352] See para. 8.134.

sider it nonetheless appropriate to examine whether these arguments demonstrate that the EC measures in dispute are, from a substantive point of view, based on a risk assessment in accordance with Article 5.1.

5. *General Categories of Risks Invoked by the European Communities*

8.139 The European Communities argues that it has based its ban on the existence of the following categories of risks related to the hormones at issue: (i) risks arising from the nature and mode of action of the hormones; (ii) risks arising from the action of metabolites; (iii) risks arising from the action of combinations (or cocktails) of hormones and from multiple exposure of humans; (iv) risks arising from problems related to detection and control of hormones; (v) risks arising from the administration and use of hormones; and (vi) risks arising from various other parameters, in particular the inherent limits to science.[353]

8.140 The United States argues that the European Communities has never performed an appropriate assessment of these alleged risks and has, in any event, not relied on, nor put forward, any assessment of these risks that could serve as a basis for the EC ban.[354]

8.141 We recall that the European Communities has not referred to any scientific evidence, other than that examined above[355], in which the categories of risks put forward by the European Communities have been assessed and that none of the scientific evidence referred to by the European Communities reached the conclusion that any of the hormones in dispute when administered for growth promotion purposes in accordance with good practice has an adverse effect on human health.[356]

8.142 Moreover, with respect to the alleged risks related to the *nature and mode of action of the hormones* in dispute (including carcinogenicity and long-term effects) and the action of *metabolites or combinations of and multiple exposure to these hormones* (*i.e.*, the first three categories of risks invoked by the European Communities), we note the statements of the scientific experts advising the Panel that the available data relating to these risks have all been taken into account by the JECFA Reports and/or the Lamming Report and/or the 1995 EC Scientific Conference.[357] All three reports concluded that these risks do not materialize if the hormones in dispute are used as growth promoters in accordance with good practice. The European Communities has not provided any evidence to the contrary. The EC import ban of meat and meat products from animals treated

---

353 See para. 4.126.
354 See para. 4.110.
355 See paras. 8.119 ff.
356 See para. 8.137.
357 See answers by experts to Panel Question 5, paras. 6.51 ff., in particular the answers by Dr. Arnold, Dr McLean and Dr Ritter and the opinions of Dr. Randell, paras. 6.166 (see also Transcripts of the joint meeting with experts of 17 February 1997, paras. 239, 297, 374 and 436 and of 18 February 1997, paras. 730 and 823).

with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones *in accordance with good practice*, is, therefore, not *based on* an assessment of these categories of risks.

8.143 In addition, with respect to the alleged risks arising from problems related to the *detection, control, administration and use* of the hormones in dispute (*i.e.*, the fourth and fifth category of risks invoked by the European Communities), we note that the European Communities has not referred to evidence, other than that outlined above[358], in which an assessment is made of the possible adverse health effects related to the potential abuse of these specific hormones when used for growth promotion purposes. The European Communities has restricted itself to pointing out the condition contained in many of the scientific conclusions mentioned above, namely that the safety of the hormones is to a certain extent conditional upon their administration in accordance with good practice[359], without further providing an assessment of the potential adverse effects related to non compliance with such practice.

8.144 We further note that the European Communities argues that if it were to allow the use of the three *natural* hormones at issue it would encounter special problems in *inspecting, sampling or testing* for residues of these hormones in meat. These problems relate, according to the European Communities, to the inherent characteristics of the natural hormones which make them indistinguishable from natural hormones present endogenously in meat or present in meat subsequent to therapeutic or zootechnical use of these hormones.[360]

8.145 We recall that, in this dispute, the factors which can be taken into account in a risk assessment under Articles 5.1 and 5.2 are limited to "available scientific evidence" and "relevant inspection, sampling and testing methods".[361] To the extent that the problems in inspecting (sampling and testing) natural hormones would actually pose a risk and could thus, arguably, be taken into account as a risk arising from "relevant inspection, sampling and testing methods" in the sense of Article 5.1, we consider that the European Communities encounters the same problems in inspecting for natural hormones under its current regime. The EC ban of natural hormones used for growth promotion purposes, combined with its tolerance for these hormones when used for therapeutic or zootechnical purposes

---

[358] See paras. 8.119 ff.

[359] However, we note, in this respect, the statements made by some of the scientific experts advising the Panel that even if good practice is not followed the use of the five hormones at issue will in many cases still be safe (see answers by experts to Panel Question 17, paras. 6.172-177, in particular the answers by Dr. Arnold, Dr. McLean and Dr. Ritter and opinions of Dr. McLean, Dr. Randell and Dr. Arnold, Transcripts of the joint meeting with experts of 17 February 1997, respectively at paras. 3, 26 and 166). We also recall the conclusions reached by JECFA that the MRLs (*i.e.*, the levels which are set on the basis of good practice) it established for zeranol and trenbolone are far higher than the safety levels for these hormones.

[360] See para. 4.113.

[361] See para. 8.105.

or when present endogenously in meat and other foods, would seem to cause more problems in inspecting for banned natural hormones than a regime where the use of all natural hormones would be allowed in combination with, for example, a maximum residue or tolerance level for all natural hormones in any meat regardless of the origin and use of these hormones. Indeed, only under the EC current regime does the problem of how to distinguish between endogenous and added natural hormones arise; under a regime with an MRL or tolerance level for all natural hormones there would be no need to distinguish endogenous from added natural hormones.

8.146 With respect to the alleged risks related to the *control* (or, in other words, the abuse) of the hormones at issue (both natural and synthetic), we further note that even though a Member would seem to be able to take into account risks arising from difficulties of inspecting, sampling or testing which are specific to a particular substance in a particular food, the "relevant inspection, sampling and testing methods" referred to in Article 5.2, do not seem to cover the general problem of control (such as the problem of ensuring the observance of good practice) which can exist for any substance. The risks related to the general problem of control do not seem to be specific to the substance at issue but to the economic or social incidence related to a substance or its particular use (such as economic incentives for abuse). These non-scientific factors should, therefore, not be taken into account in risk assessment but in *risk management*. Moreover, even if these factors could be taken into account in a risk assessment, we note that the European Communities has not provided convincing evidence that the control (or the prevention of abuse) of the hormones in dispute is more difficult than the control of other veterinary drugs the use of which it allows. It has neither provided evidence that control would be more difficult under a regime where the hormones in dispute were allowed under specific conditions than under the current EC regime where the hormones in dispute when used as growth promoters are banned. The experts advising the Panel made clear that the potential for abuse under both regimes would be comparable, some noting that abuse would probably occur more frequently under a regime where the hormones are banned compared to one allowing the controlled use of prescribed products in predetermined dosages with well-defined educational programmes, good communication between the different actors involved and appropriate penalties for misuse.[362] In this context, we note, therefore, that banning the use of a substance does not necessarily offer better protection of human health than other means of regulating its use.

8.147 In this respect, we finally note that for the three natural hormones in dispute, the European Communities has, for control purposes, adopted MRLs and thereby accepted tolerance levels which are higher than the "zero residue" level

[362] See, for example, answers by Dr. André and Dr. Ritter to Panel Question 14, paras. 6.149 and 6.155 and opinions of Dr. Arnold, Dr. Lucier and Dr. André, Transcripts of the joint meeting with experts of 17 February 1997, paras. 269 and 274 and of 18 February 1997, paras. 829 and 830.

reflected in the measures in dispute. In so doing, the European Communities itself seemingly confirms the scientific conclusions reached in all the scientific evidence examined above, namely that residues of these hormones, including when used as growth promoters, are safe below a certain level, and contradicts the conclusion reflected in the EC measures in dispute, namely that only a "zero residue" level ensures the protection of EC consumers.

8.148 For all the reasons outlined above[363], we find that the EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones *in accordance with good practice*, is not *based on* an assessment of the fourth or fifth category of risks invoked by the European Communities.

8.149 In the sixth general category of risks invoked by the European Communities (risks arising from various other parameters), the European Communities argues that none of the studies it referred to as part of a risk assessment proves beyond doubt or concludes in an unqualified manner that the presence of residues of the hormones in dispute in meat or meat products present *no risk whatsoever*. The European Communities refers, *inter alia*, to the conclusions of the 1988 JECFA Report which state that residues arising from the hormones at issue used as growth promoters are only *unlikely* to pose a hazard to human health and to the basic premise of JECFA recommendations which aim at establishing standards which correspond to a *no appreciable* or *no significant* risk increase due to the exposure to the substances in question and not to a *zero* risk increase. The European Communities apparently considers, therefore, that this residual risk, albeit minute and not appreciable, constitutes the risk (derived from a *risk assessment*) on which the EC ban is based in accordance with Article 5.1, arguing that, according to EC *risk management*, risk other than zero is not acceptable.[364]

8.150 The United States argues that science can never prove beyond doubt that there is no risk and can only be used to determine whether there *is* a risk associated with the use of a particular substance; it cannot eliminate the possibility that a potential risk may be found in the future. According to the United States, the SPS Agreement does not allow measures to be maintained without scientific evidence until such time as science proves "beyond doubt" that there is *no* risk.[365]

8.151 We recall the conclusions we reached above on burden of proof, in particular that the European Communities has, with respect to its measures which deviate from international standards, the burden of proving the existence of a risk assessment (and, derived therefrom, an identifiable risk) on which the EC measures in dispute are based. It is not, in this dispute, for the United States to prove that there is *no* risk.

---

[363] See paras. 8.143-8.147.
[364] See para. 4.200.
[365] See para. 4.46.

8.152 We further note that, according to scientists advising the Panel, science can never provide a certainty, *i.e.* exclude once and for all that a specific substance can ever have adverse health effects.[366]

8.153 In this respect we also note that the sixth category of risks invoked by the European Communities is, as stated by the scientific experts advising the Panel[367] and admitted by the European Communities[368], not identifiable and that, therefore, these risks can *a priori* not be *assessed* by scientists (as required in Article 5.1). In this sense, these potential risks, which are present for any substance (also for substances or uses of substances allowed in the European Communities), are only the consequence of science not being capable of assuring that no risks will ever arise from a substance.

8.154 We finally note that the EC objective of "zero risk" cannot be achieved in practice; not even under the EC ban itself since the European Communities cannot guarantee that there is a zero probability that illegal use of the hormones at issue will occur. Moreover, this "zero risk" objective cannot, as further examined below[369], in any case be achieved for the three natural hormones in dispute since the European Communities allows the ingestion of these same hormones occurring endogenously in meat and other foods as well as the use of these hormones for therapeutic or zootechnical purposes.

8.155 The EC ban on the use of the hormones in dispute for growth promotion purposes is, therefore, not *based on* an assessment of the sixth and final category of risks invoked by the European Communities.

8.156 For these reasons, we find that the EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones *in accordance with good practice*, is not *based on* an assessment of any of the six general categories of risks invoked by the European Communities.

6. *The Precautionary Principle*

8.157 The European Communities also invokes the precautionary principle in support of its claim that its measures in dispute are based on a risk assessment. To the extent that this principle could be considered as part of customary international law *and* be used to interpret Articles 5.1 and 5.2 on the assessment of risks as a customary rule of interpretation of public international law (as that phrase is used in Article 3.2 of the DSU), we consider that this principle would

---

[366] See, for example, opinions of Dr. Arnold, para. 6.25 and Dr. Ritter, para. 6.92. In this respect, we note that the SPS Agreement explicitly deals with situations where there is scientific uncertainty regarding risks related to a substance, in Article 5.7 (discussed in paras. 8.248 ff.), but that the European Communities has not invoked this provision in this case.

[367] *Ibid.*

[368] See para. 4.197.

[369] See paras. 8.186 ff.

not override the explicit wording of Articles 5.1 and 5.2 outlined above, in particular since the precautionary principle has been incorporated and given a specific meaning in Article 5.7 of the SPS Agreement. We note, however, that the European Communities has explicitly stated in this case that it is not invoking Article 5.7.

8.158 We thus find that the precautionary principle cannot override our findings made above, namely that the EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones *in accordance with good practice*, is, from a substantive point of view, not *based on* a risk assessment.

8.159 *In summary*, in this section we have found that, even assuming that the European Communities has demonstrated the existence of a risk assessment in accordance with Article 5, it has not fulfilled the minimal procedural requirements contained in Article 5.1 to base its sanitary measures on a risk assessment. We have also found that, even if it would have fulfilled these minimal procedural requirements, the European Communities has not met its burden of proving that its measures in dispute, in so far as they also ban the import of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes in accordance with good practice, are, from a substantive point of view, based on a risk assessment. The EC measures in dispute, in so far as they relate to five of the six hormones at issue for which international standards exist, are, therefore, inconsistent with the requirements of Article 5.1. The fact that these measures are not based on existing international standards (contrary to Article 3.1)[370] cannot, therefore, be justified under Article 3.3 which includes as one of the requirements for justification, consistency with Article 5.1. The EC measures, in so far as they relate to five of the six hormones at issue for which international standards exist, are, therefore, also inconsistent with the requirements of Article 3.1.

(c) Articles 5.4 to 5.6: Risk Management

8.160 We recall that there is a distinction between *risk assessment* which is a *scientific* examination and *risk management* which involves social value judgments.[371] Once the risks have been assessed, *i.e.*, once the risks and their probability of occurrence identified, a Member will need to decide, on the basis of its own value judgments, whether it can accept these risks. In so doing a Member sets its "appropriate level of sanitary protection". The determination and application of the appropriate level of protection by a Member is part of risk management.

---

[370] See para. 8.77.
[371] See paras. 8.91 ff.

8.161 We recall the definition of "appropriate level of sanitary protection", namely:

> "The level of protection deemed appropriate by the Member establishing a sanitary ... measure *to protect human, animal or plant life or health* ..." (paragraph 5 of Annex A of the SPS Agreement; emphasis added).

We also note the wording of Article 5.5, further examined below:

> "... in the application of the concept of appropriate level of sanitary ... *protection against risks* to human life or health, or to animal and plant life or health, each Member shall avoid ..."

Guided by the wording of these provisions and the object and purposes of the SPS Agreement, we consider that if there is no scientific evidence of an identifiable risk, there is no basis on which to adopt a measure to achieve a level of sanitary protection under the SPS Agreement, except as provided in Article 5.7. If this were not the case, *i.e.*, if a Member could adopt a level of protection and implementing sanitary measures even if it did not provide scientific evidence of an identifiable risk, no effect would be given to the obligation contained in Article 5 to base sanitary measures on an assessment of risks. This approach would undermine the wording and object and purpose of the SPS Agreement.

8.162 We have found above[372] that the European Communities has not provided evidence of an identifiable risk related to the presence of five of the six hormones at issue for which international standards exist when these hormones are used for growth promotion purposes in accordance with good practice. Accordingly, the European Communities has not established the existence of any identifiable risk against which the EC measures at issue, in so far as they also ban the use of the five hormones when used as growth promoters in accordance with good practice, can protect human life or health. Since we considered above[373] that the adoption of a sanitary measure presupposes the existence of an identifiable risk (except as provided in Article 5.7), it is not possible for the European Communities to ban the use of these hormones as growth promoters in accordance with good practice.

8.163 However, even if we would have found that the European Communities met its burden of proving that its measures are based on an assessment of risks in accordance with Articles 5.1 and 5.2 and even if, for that reason, the European Communities could have adopted a measure to achieve its appropriate level of protection against these risks, there would still be a need to examine whether the determination and application of this level of protection is consistent with Articles 5.4 to 5.6. We will, therefore, next examine these provisions.

8.164 The parties to this dispute seem to agree that the establishment of an "appropriate level of sanitary protection" by a Member is a sovereign act, namely, as

---

[372] See para. 8.137.
[373] See para. 8.161.

the definition in paragraph 5 of Annex A of the SPS Agreement provides, the level of protection "*deemed appropriate by the Member* establishing a sanitary ... measure" (emphasis added). As outlined above[374], we note, however, that Members have agreed, in exercising their sovereign right to set their appropriate levels of protection, to observe the provisions of the SPS Agreement, in particular Articles 5.4 and 5.5 thereof. Furthermore, in choosing a measure to achieve that appropriate level of protection Members have agreed to observe the provisions of Articles 2, 5.1 to 5.3 and 5.6.

8.165 We finally recall our findings reached above on the specific burden of proof under Article 3.3.[375] In particular, we found that the burden of proving that the requirements imposed by Article 3.3 (*inter alia*, consistency with Article 5) are met, in order to justify a sanitary measure which deviates from an international standard, rests with the Member imposing that measure. Since the EC measures examined in this section (relating to all hormones in dispute other than MGA) are not based on existing international standards and need to be justified under the exceptions provided for in Article 3.3, the European Communities bears the burden of proving that the determination and application of its level of protection is consistent with Articles 5.4 to 5.6.

(i) Article 5.4: Minimizing Trade Effects

8.166 Article 5.4 provides the following:

> "Members *should*, when determining the appropriate level of sanitary or phytosanitary protection, take into account the *objective* of minimizing negative trade effects" (emphasis added).

Guided by the wording of Article 5.4, in particular the words "should" (not "shall") and "objective", we consider that this provision of the SPS Agreement does not impose an obligation. However, this objective of minimizing negative trade effects has nonetheless to be taken into account in the interpretation of other provisions of the SPS Agreement.

(ii) Article 5.5: Distinctions in Levels of Protection

8.167 Article 5.5 provides the following:

> "With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, *each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a dis-*

[374] See paras. 8.161 ff.
[375] See paras. 8.85 ff.

> *guised restriction on international trade*. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves" (emphasis added).

8.168 We note, in this respect, the basic obligations contained in Article 2.3:

> "Members shall ensure that their sanitary and phytosanitary measures *do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail*, including between their own territory and that of other Members. Sanitary and phytosanitary measures *shall not be applied in a manner which would constitute a disguised restriction on international trade*" (emphasis added).

Article 2.3 deals, in general terms, with *sanitary measures* which discriminate between Members or which are applied in a manner which would constitute a disguised restriction on international trade. Article 5.5, on the other hand, deals more specifically with *distinctions in levels of protection* (which will normally be reflected in one or more sanitary measures) which result in discrimination or a disguised restriction on international trade.

8.169 We consider that the first part of the first sentence of Article 5.5 ("*With the objective of achieving consistency* in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health ..."; emphasis added), unlike the second part, does not impose an obligation upon Members. Consistency is not imposed as an obligation but as an objective which nonetheless has to be taken into account in the interpretation of Article 5.5.

8.170 We further note that the Committee on Sanitary and Phytosanitary Measures, established by Article 12 of the SPS Agreement to "provide a regular forum for consultations", has been given a mandate by Article 5.5, second sentence, to "develop guidelines to further the practical implementation of this provision" and, in so doing, needs to "take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves". No such guidelines have to date been developed. However, considering the mandatory wording of the second part of the first sentence of Article 5.5 ("each Member *shall avoid* arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations ..."; emphasis added) and the existence of the basic obligations contained in Article 2.3[376], we find that the lack

[376] See para. 8.168.

of guidelines by the Committee in no way limits the legally binding nature of the second part of the first sentence of Article 5.5.

8.171 The United States argues that the European Communities fails to justify the following differences in regulatory treatment: (i) a ban on natural and synthetic hormones when used for growth promotion purposes as opposed to not setting any limit for residues of the natural hormones present endogenously in untreated meat and other foods (such as milk, cabbage, broccoli or eggs) and residues of these hormones when used for therapeutic or zootechnical purposes; and (ii) a ban on the hormones in dispute when used for growth promotion purposes as opposed to allowing the use of the veterinary drug carbadox as a growth promoter in swine production. Only with respect to the last mentioned difference in treatment does the United States invoke and address Article 5.5.[377]

8.172 The European Communities rejects these claims, arguing that it does not make distinctions in its levels of protection for different situations and that, even if it were to make such distinctions, these distinctions are justified and do not result in discrimination or a disguised restriction on international trade.[378]

The Three Elements Contained in Article 5.5

8.173 We next examine the elements that must be assessed to determine if a Member's sanitary measure does not conform to the requirements of the second part of the first sentence of Article 5.5. The relevant part of Article 5.5 reads as follows:

> "each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade".

8.174 The *first element* contained in Article 5.5 is that the Member concerned adopts different appropriate levels of sanitary protection in "different situations". The *second element* is that the distinction in levels of protection for the different situations is "arbitrary or unjustifiable". The *third element* is that the distinction in levels of protection results in "discrimination or a disguised restriction on international trade". In order to find a sanitary measure to be inconsistent with Article 5.5 all three elements need to be present.

8.175 As to the *first element*, the words "different situations" have been interpreted by the parties as follows. The European Communities argues that "different situations" only covers different situations for the *same residue* or for different residues where the *adverse health effect is the same*. According to the European Communities, "different situations" cannot mean that the same level of protection must be applied to similar health hazards, whatever their nature or

[377] See para. 4.220.
[378] See para. 4.218.

severity, coming from similar substances. The United States argues that the "different situations" referred to in Article 5.5 of necessity must be *comparable* situations. It argues, for example, that the purported health risk from carbadox and the hormones in dispute, when used for growth promotion, is in both instances, cancer in humans and that, therefore, the different situations invoked by the United States are comparable.[379]

8.176 We note that both parties in dispute agree that the scope of "different situations" contained in Article 5.5 includes situations which deal with the *same substance* as well as situations which involve the *same adverse health effect*. For this reason, considering the lack of guidelines by the Committee on Sanitary and Phytosanitary Measures and without further defining or limiting the scope of "different situations", we find that, for the purposes of this dispute, we can compare situations where the same substance or the same adverse health effect is involved as "different situations" in the sense of Article 5.5. For the sake of clarity in this particular case, we will hereafter refer to such "different situations" as "comparable situations" since these situations need to be compared for the purposes of Article 5.5 and are, therefore, "comparable".

8.177 The *second element* contained in Article 5.5 is that the distinction in levels of protection for comparable situations is "arbitrary or unjustifiable".

8.178 The United States argues that, in the absence of any principle or criterion that accounts for the selection of differing levels of sanitary protection, the distinction in the levels of protection is arbitrary and unjustifiable.[380] The European Communities argues that Article 5.5 clearly states that "arbitrary or unjustifiable" distinctions are to be avoided if, and only if, they result in discrimination or a disguised restriction on trade. If they do not result in discrimination or a disguised restriction on trade, the European Communities concludes, they are not prohibited by Article 5.5.[381]

8.179 The *third element* contained in Article 5.5 is that the distinction in level of protection results in "discrimination or a disguised restriction on international trade".

8.180 The United States has not presented a claim with respect to the term "discrimination"; only with respect to the term "disguised restriction on international trade". The United States argues that "a disguised restriction on international trade" is present in the context of Article 5.5 where a Member claims a legitimate basis for the difference in the chosen levels of protection being compared, but where instead the differing levels of protection are being employed for commercial reasons to restrict trade.[382] The European Communities argues that the measures in dispute do not result in discrimination and that the fact that sanitary meas-

379 See para. 4.220.
380 *Ibid.*
381 See para. 4.218.
382 See para. 4.221.

ures affect imports is not a sufficient reason to claim that they restrict trade, or even less, that they discriminate.

8.181 We note, first of all, the relation between this third element of "discrimination or a disguised restriction on international trade" in Article 5.5 and the basic obligations contained in Article 2.3 of the SPS Agreement providing that:

> "Members shall ensure that their sanitary and phytosanitary measures *do not arbitrarily or unjustifiably discriminate* between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures *shall not be applied in a manner which would constitute a disguised restriction on international trade*" (emphasis added).

We also note the relation between these two provisions and the language of the chapeau of Article XX of GATT which reads as follows:

> "Subject to the requirement that such measures are *not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination* between the countries where the same conditions prevail, *or a disguised restriction on international trade*, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: ...." (emphasis added).

8.182 With respect to the meaning of "discrimination" and "a disguised restriction on international trade" we recall the conclusions reached by the Appellate Body in its Report on "United States - Standards for Reformulated and Conventional Gasoline" where the terms "arbitrary or unjustifiable discrimination" and "a disguised restriction on international trade", contained in the chapeau of Article XX of GATT, were examined as follows:

> " 'Arbitrary discrimination', 'unjustifiable discrimination' and 'disguised restriction' on international trade may, accordingly, be read side-by-side; they impart meaning to one another. It is clear to us that 'disguised restriction' includes disguised *discrimination* in international trade. It is equally clear that *concealed* or *unannounced* restriction or discrimination in international trade does *not* exhaust the meaning of 'disguised restriction'. We consider that 'disguised restriction', whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception listed in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to 'arbitrary or unjustifiable discrimination', may also be taken into account in determining the presence of a 'disguised restriction' on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate

> use of the exceptions to substantive rules available in Article XX" (original emphasis).[383]

8.183 We further recall the Appellate Body Report on "Japan - Taxes on Alcoholic Beverages" where the Appellate Body found that for an internal tax measure to be inconsistent with the second sentence of Article III:2 of GATT, three separate issues must be addressed so as to give full meaning to the text and context of this provision: (i) the products need to be "directly competitive or substitutable"; (ii) they need to be "not similarly taxed"; and (iii) the dissimilar taxation needs to be "applied ... so as to afford protection to domestic production".[384] The Appellate Body found that the panel had erred in blurring the distinction between the second and third issue by equating dissimilar taxation (*i.e.*, tax difference above a *de minimis* level) with the separate and distinct requirement of demonstrating that the tax measure "affords protection to domestic production".[385] The Appellate Body then concluded the following:

> "As previously stated, a finding that 'directly competitive or substitutable products' are 'not similarly taxed' is necessary to find a violation of Article III:2, second sentence. Yet this is not enough. The dissimilar taxation must be more than *de minimis*. *It may be so much more that it will be clear from that very differential that the dissimilar taxation was applied "so as to afford protection". In some cases, that may be enough to show a violation*. In this case, the Panel concluded that it was enough. Yet in other cases, *there may be other factors that will be just as relevant or more relevant to demonstrating that the dissimilar taxation at issue was applied 'so as to afford protection'* ... And, in every case, a careful, objective analysis, must be done of each and all relevant facts and all relevant circumstances to determine 'the existence of protective taxation'. Although the Panel blurred its legal reasoning in this respect, nevertheless we conclude that it reasoned correctly that in this case, the Liquor Tax Law is not in compliance with Article III:2" (emphasis added).[386]

8.184 We consider the reasoning in both Appellate Body Reports to be equally relevant to the relationship between the three elements contained in Article 5.5. All three elements impart meaning to one another. Nevertheless, in order to give effect to all three elements contained in Article 5.5 and giving full meaning to the

---

[383] Appellate Body Report on "United States - Standards for Reformulated and Conventional Gasoline", adopted on 20 May 1996, WT/DS2/AB/R, DSR 1996:I, 3 at 23.
[384] Appellate Body Report on "Japan - Taxes on Alcoholic Beverages", adopted on 1 November 1996, WT/DS8/AB/R, DSR 1996:I, 97 at 116.
[385] Panel Report on "Japan - Taxes on Alcoholic Beverages", adopted on 1 November 1996, WT/DS8/R, paras. 6.33-34 and 7.1(ii).
[386] Appellate Body Report on Japan - "Taxes on Alcoholic Beverages", adopted on 1 November 1996, WT/DS8/AB/R, DSR 1996:I, 97 at 121.

text and context of this provision, we consider that all three elements need to be distinguished and addressed separately. However, we also agree that in some cases where a Member enacts, for comparable situations, sanitary measures which reflect different levels of protection, the significance of the difference in levels of protection combined with the arbitrariness thereof may be sufficient to conclude that this difference in levels of protection "result[s] in discrimination or a disguised restriction on international trade" in the sense of Article 5.5 (in line with the argument that the magnitude of the very differential of a dissimilar taxation may be enough to conclude that a dissimilar taxation is applied so as to afford protection, as provided for in the second sentence of Article III:2 of GATT).

8.185 We next examine, in light of the three elements of Article 5.5 outlined above, the distinctions in levels of sanitary protection allegedly made by the European Communities which have been invoked by the United States. In order to conduct our consideration of this dispute under Article 5.5 in the most efficient manner, we first address the alleged differences in treatment provided by the European Communities for the *natural hormones in dispute*. In this examination we compare the treatment of these hormones when used as growth promoters with both the treatment of these hormones occurring endogenously in meat and other foods (such as milk, cabbage, broccoli or eggs) and when used for therapeutic or zootechnical purposes. In a second step, we address the alleged differences in treatment provided by the European Communities for the *natural hormones in dispute as opposed to that of the synthetic hormones at issue*. In a third step, we address the alleged differences in treatment provided by the European Communities for *all hormones in dispute* (other than MGA) when used as growth promoters as opposed to that for *carbadox*, an antimicrobial growth promoter.

Natural Hormones for Growth Promotion Compared to (i) those Occurring Endogenously in Meat and Other Foods, and (ii) Those for Therapeutic or Zootechnical Purposes

1. *Comparable Situations with Different Levels of Sanitary Protection*

8.186 This examination involves a comparison of the levels of protection for the *same substance*, namely, respectively, oestradiol-17β, testosterone and progesterone, in different situations depending on the origin or use of that substance. Since we have found above that we can compare situations where the *same substance* is involved as "different" situations (which we refer to as "comparable" situations for the purposes of this dispute) in the sense of Article 5.5[387], we find that the treatment of the three natural hormones in dispute when used for growth promotion purposes as opposed to the treatment of these hormones which (i) oc-

[387] See para. 8.176.

cur endogenously in meat and other foods and (ii) which have been administered for therapeutic or zootechnical purposes, constitute comparable situations in the sense of Article 5.5.

8.187 The European Communities argues that the origin of these hormones (whether endogenously produced or exogenously administered) causes these hormones to be different, claiming that the hormones present endogenously in meat and other foods have formed part of the human diet for centuries. We note, however, that the European Communities did not submit any evidence in support of its claim that these hormones have different effects. Moreover, all scientific experts advising the Panel have concluded that residues of the three natural hormones present endogenously in meat and other foods or administered for therapeutic or zootechnical purposes are qualitatively the same as the residues of these hormones administered for growth promotion and that if any differences between these hormones could exist (e.g., differences in pathways taken or metabolites), these differences would in any event not have consequences for the potential adverse effects of these hormones.[388] Therefore, even if these hormones would not be totally identical substances, they pose, in any event, the *same adverse health effect* and can, therefore, according to our finding made above[389], be considered as comparable situations for the purposes of Article 5.5.

8.188 We next examine whether the European Communities has adopted a different level of protection for these comparable situations.

8.189 With respect to the three natural hormones administered *for growth promotion purposes*, the European Communities argues that its level of sanitary protection is concerned only with *added* hormones; in other words, the European Communities does not consider that it is acceptable to expose consumers to any hormones in their food over and above the levels which occur in nature, as any such additional exposure could be a hazard to health.[390]

8.190 The appropriate level of protection set by the European Communities for natural hormones present *endogenously* in meat and other foods or administered *for therapeutic or zootechnical purposes* is an unlimited residue level.[391] In other words, the European Communities has not adopted any maximum residue level for these categories of natural hormones.[392] With respect to oestradiol-17β when used *for therapeutic or zootechnical purposes*, this unlimited residue level of

---

[388] See answers by experts to Panel Questions 2 and 4, paras. 6.22-6.31 and 6.40-6.50 and opinions of all experts advising the Panel to an oral question asked by the US representative at the joint meeting with experts of 17 February 1997, Transcripts, paras. 77, 79, 84, 85 and 87.

[389] See para. 8.176.

[390] *Ibid*.

[391] *Ibid*.

[392] With respect to hormones administered for therapeutic treatment, the European Communities argues that in practice no residues of these hormones will be ingested by consumers because animals undergoing such treatment are not allowed to be slaughtered. However, the fact is that the European Communities has decided that the adoption of MRLs for these hormone residues is unnecessary and has thus not set any residue limit (see para. 8.190 *in fine*).

protection has recently been confirmed by the European Communities when it adopted the conclusions reached in the 1988 JECFA Report and classified this hormone, when used for therapeutic or zootechnical purposes, as a substance for which MRLs are unnecessary.[393] With respect to the two other natural hormones in dispute, progesterone and testosterone, when used for therapeutic or zootechnical purposes, no final decision has as yet been taken by the competent EC authorities.[394]

8.191 We thus find that the level of protection adopted by the European Communities for the three natural hormones in dispute when used for growth promotion and that adopted for the same hormones (i) occurring endogenously in meat and other foods and (ii) used for therapeutic or zootechnical purposes, is *different* ("no residue" level as opposed to an unlimited residue level) and that, therefore, distinctions in levels of protection for these comparable situations exist in the sense of the first element of Article 5.5.

2. *"Arbitrary or Unjustifiable" Difference in Levels of Sanitary Protection*

8.192 We next examine whether these two distinctions in levels of protection are "arbitrary or unjustifiable". We first address the distinction made between the three natural hormones when used as growth promoters and the same hormones occurring endogenously in meat and other foods. We then examine the distinction made between the three natural hormones when used as growth promoters and the same hormones when used for therapeutic or zootechnical purposes.

8.193 *Natural hormones used as growth promoters as opposed to those occurring endogenously in meat and other foods.* The European Communities has not provided any reasons, other than those addressed above, why it has adopted a different level of protection for the residues of these two categories of natural hormones. The European Communities has, in particular, not provided any evidence that the risk related to the natural hormones used as growth promoters is in any way higher than the risk related to natural endogenous hormones. We also recall that the experts advising the Panel concluded that both categories of hormones (either exogenously administered to animals or endogenously present in animals, meat, other foods or human beings) pose the same potential adverse effects.[395]

8.194 In this respect we further recall the conclusion reached in the 1988 JECFA Report that the total residue level of natural hormones in meat from *treated* animals (*i.e.*, the combination of natural hormones endogenously present and those added for growth promotion) falls well within the physiological range of levels

[393] See answer by Dr. Arnold to Panel Question 5, para. 6.55.
[394] *Ibid.*, para. 6.56.
[395] See para. 8.187 and, in particular, the footnote thereto.

found in meat from *untreated* animals, which levels vary according to the sex and age of the animal.[396] We also note that, according to data submitted to the Panel, the residue level of natural hormones in many natural products (such as eggs and soya oil) is much higher than the level of residues of these hormones administered for growth promotion as well as the total residue level of these hormones in treated meat.[397] In this respect, we further note that Codex has also established MRLs for substances which endogenously occur in natural products.[398]

8.195 With respect to the potential difficulties in detecting the presence of *natural* hormones used as growth promoters, we refer to our conclusions reached above[399], namely that only under the current EC regime (a ban) does the problem arise of how to distinguish between endogenous and added natural hormones whereas under a regime where one would allow the use of these hormones (with, for example, an MRL or tolerance level for all natural hormones) there would be no need to distinguish endogenous from added natural hormones. We also note that, in any event, the problem of detection would be the same for both natural hormones used as growth promoters and those occurring endogenously in meat and other foods (since the scientific experts stated that both are qualitatively the same[400]) and can, therefore, not justify a different treatment.

8.196 We finally note that even if some form of justification could be deduced from the arguments submitted by the European Communities, such could not, in any event, justify so significant a difference in levels of protection between a "no residue" level for natural hormones administered for growth promotion and an unlimited residue level for natural hormones endogenously present in meat and other foods.

8.197 We thus find that the European Communities has not met its burden of proving that the distinction it makes in levels of protection for residues of the three natural hormones in dispute when administered *for growth promotion purposes* and residues of the same natural hormones present *endogenously* in meat

---

396 See para. 8.62. This conclusion has not been contested by either the parties or experts advising the Panel. For example, according to data submitted to the Panel (the accuracy of which has not been disputed by the parties), the residue level of testosterone in 500 grams of *untreated* bull meat is 1,560 nanograms as opposed to 35 nanograms in 500 grams of meat from a heifer implanted with testosterone.

397 For example, according to data submitted to the Panel (the accuracy of which has not been disputed by the parties), the residue level of oestradiol-17β equivalents in a 50 to 60 grams hen's egg is 1,750 nanograms (in 10 ml of soybean oil, 20,000 nanograms) as opposed to 11.4 nanograms in 500 grams of steer meat implanted with oestradiol-17β and 75 nanograms in 500 grams of untreated cow meat. In other words, the oestrogen content of 1 hen's egg is equivalent to 76.5 kg of implanted steer beef. In this respect, we also note that a pre-puberty male child naturally produces 41,000 nanograms of oestrogens in 24 hours, an adult man 136,000 nanograms and a pregnant women 20,000,000 nanograms.

398 For example, MRLs have been adopted by Codex for (naturally occurring) cyanide in cassava flour and in Gari (a cassava product).

399 See para. 8.145.

400 See para. 8.187.

and other foods is justifiable and that, therefore, this particular distinction in levels of protection is "arbitrary or unjustifiable" in the sense of the second element contained in Article 5.5.

8.198 *Natural hormones used as growth promoters as opposed to those used for therapeutic or zootechnical purposes*. The European Communities argues that the use of the natural hormones for therapeutic and zootechnical purposes occurs on a small scale, is subject to very strict conditions (such as administration by a veterinarian and strict withdrawal periods) and normally only involves cattle intended for breeding, not for slaughter; whereas the use of these hormones as growth promoters occurs on a much larger scale and is more difficult and costly to control.[401] These differences in use and control, the European Communities argues, ensure that any risk related to the therapeutic or zootechnical use of these hormones is prevented and that in practice a level of "no residue" is achieved, as is the case for the use of these hormones as growth promoters. For these reasons, the European Communities concludes, the distinction in levels of protection is justified.[402]

8.199 We note that, according to scientific experts advising the Panel, zootechnical use of these hormones can occur on a large scale and at regular intervals, namely each year for oestrus synchronization of entire herds.[403] Moreover, even when these hormones are used for therapeutic or zootechnical purposes, all parties and scientific experts advising the Panel agree that some residue level, albeit a very small one, will always remain in the meat when the treated animal is eventually slaughtered.[404] Therefore, a "no residue" level cannot in practice be achieved when these hormones are used for therapeutic or zootechnical purposes.

8.200 However, since we have already concluded that the difference in levels of protection imposed in the European Communities for the three natural hormones when used *for growth promotion purposes* as opposed to those present *endogenously* in meat and other foods cannot be justified, we consider it unnecessary to decide whether or not the distinction made by the European Communities between natural hormones used as growth promoters and those used for therapeutic or zootechnical purposes is justified.

3. *Difference which Results in "Discrimination or a Disguised Restriction on International Trade"*

8.201 We next examine whether the difference in levels of protection between residues of the three natural hormones in dispute when administered *for growth*

---

401 See para. 4.71.
402 See para. 4.69.
403 See answers by experts to Panel Questions 19 and 20, paras. 6.183-6.193.
404 *Ibid.* See also opinions of all experts advising the Panel on a question by the US representative at the joint meeting with experts of 17 February 1997, Transcripts, paras. 90, 91, 93 and 95 and answers by experts to Panel Question 3, paras. 6.32-6.39 and para. 4.68.

promotion purposes and residues of the same natural hormones present *endogenously* in meat and other foods, results in discrimination or a disguised restriction on international trade within the meaning of the third element of Article 5.5.[405]

8.202 We recall the considerations made above on the relationship between the three elements contained in Article 5.5.[406] We recall, in particular, that in some cases the significance of the difference in levels of protection for comparable situations combined with the arbitrariness thereof may be sufficient to conclude that this difference in levels of protection results in "discrimination or a disguised restriction on international trade".

8.203 In this case, we note, firstly, the significance of the difference in levels of protection for the three natural hormones in dispute when administered *for growth promotion purposes* and residues of the same hormones present *endogenously* in meat and other foods, namely a "no residue" level as opposed to an unlimited residue level. We recall, secondly, that the European Communities has not provided any plausible justification for this significant difference. We note, finally, that this difference in levels of protection results in an import ban (on meat and meat products treated with any of the three natural hormones in dispute for growth promotion purposes) which restricts international trade. For these reasons, we find that the difference in levels of protection imposed by the European Communities for the three natural hormones in dispute when administered for growth promotion purposes and those present endogenously in meat and other foods, results in "discrimination or a disguised restriction on international trade" in the sense of Article 5.5.

8.204 We consider that this finding is further supported by two additional factors. Firstly, we recall some of the objectives (other than the protection of human health) that the European Communities had in mind when enacting or maintaining the EC ban on the use of the natural hormones for growth promotion purposes, as stated in the preambles of the EC measures in dispute[407] and in the re-

---

[405] Since we made no finding on the justifiability of the difference in levels of protection for the natural hormones in dispute when administered as growth promoters and those administered for therapeutic or zootechnical purposes, we do not address, for that additional difference in levels of protection, the third element of Article 5.5.

[406] See paras. 8.182-8.184.

[407] Such as preambles 5 and 6 to Directive 88/146/EEC which state, *inter alia*, the following:

> "Whereas the administration to farm animals of certain substances having a hormonal action is at present regulated in different ways in the Member States; ... whereas this divergence distorts the conditions of competition in products that are the subject of common market organizations and is a serious barrier to intra-Community trade;
>
> "Whereas these distortions of competition and barriers to trade must therefore be removed by ensuring that all consumers are able to buy the products in question under largely identical conditions of supply and that these products correspond to their anxieties and expectations in the best possible manner; whereas such a course of action is bound to bring about an increase in consumption of the product in question".

ports of the European Parliament and the opinions of the EC Economic and Social Committee referred to by the European Communities[408], namely harmonizing the regulatory schemes of the different EC Member States, thereby removing competitive distortions and barriers to intra-Community trade in beef, and bringing about an increase in the consumption of beef, thereby reducing the internal beef surpluses and providing more favourable treatment to domestic producers.

8.205 Secondly, we note that before the EC ban came into force, the percentage of animals treated with any of the hormones in dispute was significantly lower in the European Communities than in the United States. At that time, according to the European Communities, only four or five EC member States allowed the use of some of these hormones. One member State (the United Kingdom) which has replied to the EC's request for information on this issue, indicated that "anecdotal evidence suggests that growth promoting hormones may have been used [in] up to 40% of UK cattle prior to the ban".[409] On the other hand, according to a table provided by the United States, an average of 70 per cent of all US cattle were, at that time, treated with one or more of these hormones.[410] By banning the internal sale and import of meat treated with natural hormones for growth promotion purposes (which represents a significantly higher proportion of the total US meat supply than of the total European Communities meat supply) but continuing to allow any level of residues of these natural hormones present endogenously in meat, the European Communities favoured the consumption of domestic meat and, therefore, *de facto* discriminates against US meat in favour of EC meat. In this sense, the difference in levels of protection in the European Communities for residues of hormones present *endogenously* in meat and other foods and residues of the same natural hormones when administered *for growth promotion purposes* could be said to result in "discrimination or a disguised restriction on international trade".

8.206 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for residues of the three natural hormones in dispute administered for growth promotion purposes and residues of the same natural hormones present endogenously in meat and other foods, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, in so far as they relate to the three natural hormones at issue, are inconsistent with the requirements imposed in Article 5.5.

---

[408] Such as the Nielsen Report of 1981, the Collins Reports of 1985 and 1989 and the Pimenta Report of 1989 of the European Parliament and the opinions of the EC Economic and Social Committee of 1981 and 1984, outlined in paras. 2.28-2.33. See also Judgment of the Court of Justice of the European Communities in the case C-331/88, "The Queen v. The Minister for Agriculture, Fisheries and Food and the Secretary of State for Health, ex parte: Fedesa and Others", 1990, ECR I-4023, at p. I-4065, para. 25: "... the material made available to the Court ... shows that the possibility of a reduction in surpluses was indeed taken into consideration during the process leading to the adoption of the directive [*in casu*, Directive 88/146/EEC] ...".

[409] See para. 4.15, footnote 35.

[410] See para. 4.9, footnote 25.

Synthetic Hormones for Growth Promotion Compared to Natural Hormones

8.207 We next examine the alleged different treatment provided by the European Communities for, on the one hand, two of the three *synthetic hormones* in dispute for which international standards exist (zeranol and trenbolone)[411] and, on the other hand, the *natural hormones* in dispute occurring *endogenously* in meat and other foods.[412]

1. *Comparable Situations with Different Levels of Sanitary Protection*

8.208 In this examination we compare *different substances*, namely, respectively, zeranol and oestradiol-17β and trenbolone and testosterone. As outlined above[413], both synthetic hormones at issue are produced to mimic one of the natural hormones in dispute (zeranol mimics oestradiol-17β and trenbolone mimics testosterone). However, both parties in this dispute and the experts advising the Panel agree that the situations thus compared involve at least the *same adverse health effect*, namely carcinogenicity.[414]

8.209 Since we decided above that we can compare situations where the *same adverse health effect* is involved as "different" situations (which we refer to as "comparable" situations for the purposes of this dispute) in the sense of Article 5.5[415], we find that the treatment of zeranol and trenbolone and the treatment of the natural hormones in dispute which occur endogenously in meat and other foods, are comparable situations in the sense of the first element of Article 5.5.

8.210 We next examine whether the European Communities has adopted different levels of protection for these comparable situations.

8.211 With respect to zeranol and trenbolone, the European Communities adopted a "no residue" level as its appropriate level of protection.[416] As outlined above[417], the level of protection in the European Communities for the natural hormones present endogenously in meat and other foods is an unlimited residue level.

---

411 As mentioned above, the hormone MGA, for which no international standard exists, will be dealt with in a separate section in paragraphs 8.250 ff.

412 Since we made no finding on the difference in levels of protection for natural hormones administered as growth promoters and those administered for therapeutic or zootechnical purposes (see para. 8.200), we do not address the alleged difference in levels of protection for synthetic hormones administered as growth promoters and natural hormones administered for therapeutic or zootechnical purposes.

413 See para. 8.4.

414 See answers by experts to Panel Question 4, paras. 6.38-6.48. See also Transcripts of joint meeting with experts of 17 February 1997, paras. 342-348.

415 See para. 8.176.

416 See para. 4.93.

417 See para. 8.190.

8.212 We thus find that the levels of protection adopted by the European Communities for residues of zeranol and trenbolone and that for residues of the natural hormones in dispute which occur endogenously in meat and other foods are different ("no residue" level as opposed to an unlimited residue level) and that, therefore, a distinction in levels of protection for these comparable situations exists in the sense of the first element of Article 5.5.

2. *"Arbitrary or Unjustifiable" Difference in Levels of Sanitary Protection*

8.213 We next examine whether this difference in levels of protection is "arbitrary or unjustifiable". The European Communities has not provided convincing evidence that the synthetic hormones (which mimic the natural hormones) are inherently more dangerous than the natural hormones.[418] Most of the evidence referred to by the European Communities to prove potential risks relates to the natural hormones, in particular oestradiol-17β.[419] According to the scientists advising the Panel, synthetic hormones can also be better detected and controlled than natural hormones.[420] Moreover, the fact that ADIs and MRLs exist for zeranol and trenbolone and not for the natural hormones does not, according to the experts advising the Panel, *per se* mean that the latter are inherently safer than the former since the international standards for both synthetic and natural hormones reflect essentially the same level of protection, namely a "no appreciable risk" level.[421] Therefore, even if there could be valid reasons to subject the natural hormones to a treatment different from the synthetic hormones[422], the European Communities has not provided justification for so significant a difference in levels of protection as between a "no residue" level (for the synthetic hormones at issue) and an unlimited residue level (for the natural hormones endogenously present in meat and other foods). We recall, in particular, that the European Communities has not provided evidence that the use of zeranol or trenbolone for growth promotion purposes in accordance with good practice (for example, the

---

[418] See also answers by experts to Panel Question 4, paras. 6.40-6.50 and Transcripts of the joint meeting with experts of 17 February 1997, para. 348, where Dr. Lucier stated that in his opinion residues of synthetic hormones are of more concern than those of natural hormones because the risks related to the natural hormones are already there due to those occurring endogenously in the body, whereas residues of the synthetic hormones are new to the body. This difference does not, however, relate to the inherent characteristics of both categories of hormones, but to the fact that one category occurs endogenously in humans, whereas the other does not.

[419] See paras. 4.143 and 4.145.

[420] See answers by experts to Panel Question 22, paras. 6.199-6.202.

[421] See, for example, opinion of Dr. Randell, para. 6.76. We also note, in this respect, the opinion of Dr. Arnold, para. 6.45: "The potential risks arising from *other than* hormonal actions [related to the synthetic hormones] were qualitatively different. These risks were assessed during the review and approval process, and the approved conditions of use eliminated all unacceptable risks".

[422] See, for example, the Codex standards which have adopted MRLs for the synthetic hormones and not for the natural hormones.

Codex MRLs) is unsafe.[423] In other words, it has not submitted any justification for adopting a "no residue" level, instead of the Codex MRLs.

8.214 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for zeranol and trenbolone and the natural hormones in dispute which occur endogenously in meat and other foods. For these reasons, we find that the difference in levels of protection thus made by the European Communities is "arbitrary or unjustifiable" in the sense of the second element contained in Article 5.5.

3. *Difference Which Results in "Discrimination or a Disguised Restriction on International Trade"*

8.215 We recall the considerations made above on the relationship between the three elements contained in Article 5.5.[424] We recall, in particular, that in some cases the significance of the difference in levels of protection for comparable situations combined with the arbitrariness thereof may be sufficient to conclude that this difference in levels of protection results in "discrimination or a disguised restriction on international trade".

8.216 In this case, we note, firstly, the significance of the difference in levels of protection for zeranol and trenbolone and that for the natural hormones in dispute which occur endogenously in meat and other foods, namely a "no residue" level as opposed to an unlimited residue level. We recall, secondly, that the European Communities has not provided any plausible justification for this significant difference. We note, finally, that this difference in levels of protection results in an import ban (on meat and meat products treated with zeranol or trenbolone) which restricts international trade. For these reasons, we find that the difference in levels of protection imposed by the European Communities for zeranol and trenbolone and that for the natural hormones in dispute which occur endogenously in meat and other foods, results in "discrimination or a disguised restriction on international trade" in the sense of Article 5.5.

8.217 We consider that this finding is further supported by the two additional factors outlined above[425], which are equally valid for the distinction in levels of protection made by the European Communities for zeranol and trenbolone and the natural hormones in dispute which occur endogenously in meat and other foods.

8.218 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for zeranol and trenbolone and the natural hormones in dispute which occur endogenously in meat and other foods, in light of the three elements contained in Article 5.5, and that, there-

[423] See para. 8.15, 137.
[424] See paras. 8.182-8.184.
[425] See paras. 8.204 and 8.205.

fore, the EC measures in dispute, in so far as they relate to zeranol and trenbolone, are inconsistent with the requirements imposed in Article 5.5.

The Hormones in Dispute Compared to Carbadox

8.219 We next examine the alleged different treatment provided by the European Communities for five of the six hormones in dispute (all but MGA) when used for growth promotion purposes and carbadox. We recall that this agent is an antimicrobial growth promoter used as a feed additive in swine production.

1. *Comparable Situations with Different Levels of Sanitary Protection*

8.220 In this examination we compare *different substances*. However, both parties in this dispute and the experts advising the Panel agree that the situations thus compared involve the *same adverse health effect*, namely carcinogenicity.[426]

8.221 Since we have found above that we can compare situations where the *same adverse health effect* is involved as "different" situations (which we refer to as "comparable" situations for the purposes of this dispute) in the sense of Article 5.5[427], we find that the treatment of the five hormones at issue when used as growth promoters as opposed to that of carbadox are comparable situations in the sense of the first element of Article 5.5.

8.222 We next examine whether the European Communities has adopted a different level of protection for these comparable situations.

8.223 The United States argues that the EC level of protection for the hormones at issue when used for growth promotion is different from that for carbadox. The United States submits that with respect to the hormones at issue when used for growth promotion purposes the European Communities has suggested that its appropriate level of protection is "zero risk". With respect to carbadox, the United States argues that it is clear from the fact that the European Communities permits the use of carbadox and the sale and consumption of meat from animals to which carbadox has been administered, that the European Communities is choosing an appropriate level of protection that is less stringent than for the hormones involved in this dispute.[428]

8.224 With respect to the hormones in dispute when used for growth promotion purposes, the European Communities adopted a "no residue" level as its appropriate level of protection.[429] With respect to carbadox, the European Communities argues that, even though these substances are allowed, strict controls, specific characteristics of these substances and the way they are administered, ensure that

---

[426] See answers by experts to Panel Question 11, paras. 6.128-6.136 and para. 4.220.
[427] See para. 8.176.
[428] See para. 4.220.
[429] See para. 4.93.

no residue levels will remain in treated pigs when slaughtered and that, therefore, in the European Communities in practice the same level of protection applies to carbadox as the level adopted for the hormones in dispute, namely a "no residue" level.[430]

8.225 We note that the European Communities allows the use of carbadox as a growth promoter in pigs and has not set any MRL for that substance. The European Communities thus, in principle, accepts an unlimited residue level of these substances in pork meat. Moreover, we recall that, contrary to what the European Communities argues, a "no residue" level cannot be achieved in practice when use of the substance concerned is allowed (even under strict conditions) since there will always be some residue level of the substance or a metabolite, albeit a very small one, left in the meat, even after a long period of time.[431] We consider, for these reasons, that the European Communities cannot reasonably claim that its level of protection for carbadox is a "no residue" level.

8.226 We thus find that the level of protection adopted by the European Communities for the hormones at issue when used for growth promotion purposes as opposed to that adopted for carbadox is different (a "no residue" level as opposed to an unlimited residue level) and that, therefore, a distinction in the levels of protection for these comparable situations exists in the sense of the first element of Article 5.5.

2. *"Arbitrary or Unjustifiable" Difference in Levels of Sanitary Protection*

8.227 We next examine whether this distinction in levels of protection is "arbitrary or unjustifiable" in the sense of the second element of Article 5.5.

8.228 The United States argues that the risks related to carbadox are at least as serious as those related to the use of the hormones in dispute as growth promoters.[432] It refers to the 36th JECFA Report of 1991 which could not set an ADI for carbadox but did adopt MRLs for one of its metabolites, as opposed to the 32nd and 34th JECFA Reports of 1988 and 1989 which only adopted ADIs and MRLs for zeranol and trenbolone and considered MRLs for the three natural hormones to be unnecessary. The United States submits that none of the arguments put forward by the European Communities justifies a stricter level of protection for the hormones in dispute (which, according to the United States, are safe) than the level of protection for carbadox (a substance which, according to the United States, may pose serious risks).[433]

---

[430] EC second submission to the Panel on EC Measures Concerning Meat and Meat Products (Hormones) - Complaint by Canada, pp.9-10, paras. 35-36.

[431] See opinions of all experts advising the Panel in Transcripts of the joint meeting with experts of 17 February 1997, paras. 90, 91, 93 and 95 and answers to Panel Question 3, paras. 6.32-6.39.

[432] See para. 4.220.

[433] See paras. 4.220 and 4.221.

8.229 The European Communities claims that the distinction in levels of protection is justified on the following grounds: (i) carbadox is not a hormone; (ii) carbadox only indirectly acts as a growth promoter by combating the development of bacteria and by aiding the intestinal flora of piglets, thereby also exerting preventive therapeutic effects (whereas the hormones directly act as growth promoters and have no preventive therapeutic action when used as growth promoters); (iii) carbadox is only commercially available in prepared feedstuffs (not as injections or implants) in predetermined dosages; (iv) there are no alternatives to carbadox available which have the same therapeutic action; (v) carbadox cannot be abused since it only has growth promotion effects in piglets up to four months old and a withdrawal period of at least 28 days is fixed; and (vi) carbadox is used in such small quantities and is hardly absorbed that it leaves practically no residues at all in meat destined for human consumption.[434]

8.230 We note, first of all, that the European Communities has not submitted scientific evidence in support of these alleged justifications. We next examine the six arguments put forward by the European Communities in light of the opinions of the experts advising the Panel and the arguments submitted by the United States.

8.231 With respect to the first EC argument, *i.e.*, the fact that carbadox is a antimicrobial agent and not a hormone, the European Communities has not submitted any reason why this difference could in itself justify a different regulatory treatment in the light of their potential carcinogenic effect. We thus find that this argument does not justify the distinction in levels of protection for the five hormones at issue when used as growth promoters and carbadox.

8.232 The European Communities next argues that the five hormones at issue when used as growth promoters have no therapeutic effect on animals as opposed to carbadox which combats the development of bacteria and aids the intestinal flora of piglets. We note that, according to scientific experts advising the Panel, the hormones at issue when administered as growth promoters may also have beneficial effects (such as improved composition of the carcass upon treatment in terms of more lean meat and less fat).[435] Moreover, we recall that the hormones at issue are, effectively, used for therapeutic purposes and that such use of the three natural hormones in dispute is allowed in the European Communities. For these reasons, we consider that both the hormones in dispute and carbadox may have therapeutic effects and thus find that the second EC argument does not justify the

[434] EC second submission to the Panel on EC Measures Concerning Meat and Meat Products (Hormones) - Complaint by Canada, p.9, para. 35. We considered it appropriate to also address these EC arguments in this Panel report (for our reasoning on this issue see para. 8.15, 137).

[435] See answers by experts to Panel Question 2, paras. 6.22-6.31, in particular answers by Dr. Arnold, Dr. McLean and Dr. Ritter. See also opinion of Dr. Lucier, Transcripts of the joint meeting with experts of 18 February 1997, para. 742 where he feels unable, as a scientist, to compare the risks related to the hormones with their potential benefits.

distinction in levels of protection for the five hormones at issue when used as growth promoters and carbadox.

8.233 With respect to the third EC argument, *i.e.*, the fact that carbadox is only commercially available in prepared feedstuffs (not as injections or implants) in predetermined dosages and is, therefore, allegedly less open for abuse, we note that one of the scientific experts advising the Panel stated that injections or implants are more accurate and reliable methods to administer growth promoters than additives in feedstuffs (because of carry-over risks from treated to untreated feed).[436] The experts also stated that additives in feedstuffs pose additional risks in that they may harm the persons handling the feedstuff.[437] We also recall that, according to the experts advising the Panel, the commercially available products containing any of the five hormones at issue for implantation or injection also contain predetermined dosages of these hormones.[438] We thus find that the third EC argument does not justify the distinction in levels of protection for the five hormones at issue when used as growth promoters and carbadox.

8.234 Addressing the fourth EC argument that there are no alternatives to carbadox available which have the same therapeutic action, we note that one of the experts advising the Panel stated that there are readily available alternatives, such as oxytetracycline.[439] We thus find that this EC argument does not justify the distinction in levels of protection for the five hormones at issue when used as growth promoters and carbadox.

8.235 We recall the fifth EC argument, *i.e.*, that the potential for abuse is allegedly smaller for carbadox than for the hormones at issue since the former only exert growth promotion effects in piglets up to four months and are subject to a strict withdrawal period. We note that, according to the experts advising the Panel, there is no guarantee that the piglets treated with carbadox will not be slaughtered. Residues of this substance or its metabolites may thus enter the food chain. We also note that, as is the case for the use of carbadox in the European Communities, the use of the hormones at issue as growth promoters may also be made subject to strict conditions. We thus consider that the European Communities has not submitted evidence proving that carbadox can be more easily controlled than the five hormones at issue and find, therefore, that the fifth EC argument does not justify the distinction in levels of protection for the five hormones at issue when used as growth promoters and carbadox.

8.236 The European Communities further argues that carbadox is used in such small quantities and is hardly absorbed so that it leaves practically no residues at all in meat destined for human consumption. We recall that, according to the ex-

---

[436] See answers by experts to Panel Question 21, paras. 6.194-6.198, in particular answer by Dr. McLean at para. 6.197.

[437] See answers by experts to Panel Question 21, paras. 6.194-6.198, in particular answers by Dr. André and Dr. McLean at paras. 6.194 and 6.197.

[438] See answers by experts to Panel Question 15, paras. 6.156-6.166.

[439] See opinion of Dr. Arnold, para. 6.130.

perts advising the Panel, once a substance has been administered to an animal there will always be some residue level of this substance or a metabolite left, albeit a very small one, in the meat of that animal.[440] We further note that, according to the 36th JECFA Report of 1991 which assessed the risks related to carbadox, not only carbadox itself (for which no ADIs could be established) but also one of its metabolites, quinoxaline-2-carboxylic acid (for which an MRL was adopted) may present a health risk. We finally note that, according to the scientific experts[441], residue levels of the hormones at issue will also rapidly decline after administration to an animal or ingestion by humans. For these reasons, we find that the sixth EC argument does not justify the distinction in levels of protection for the five hormones at issue when used as growth promoters and carbadox.

8.237 The European Communities finally submits that it authorizes the use of about 10,000 to 15,000 veterinary medicinal products and that the fact that the United States limits its claim under Article 5.5 to only one substance, proves that the European Communities has already achieved a remarkable degree of consistency in its levels of sanitary protection. The European Communities also informed the Panel that the EC Council, by decision of 26 February 1996, already took action on its own initiative to review carbadox. We consider that these arguments do not justify the distinction which is currently still made by the European Communities in levels of protection for the five hormones at issue when used as growth promoters and carbadox. On the contrary, these arguments suggest an acknowledgment by the European Communities that the distinction in levels of protection it currently makes may not be justified and will be reviewed.

8.238 For the above reasons, we find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for the five hormones at issue when used as growth promoters and carbadox and that the European Communities has, *a priori*, not met its burden of justifying so significant a distinction between a "no residue" level for the hormones at issue when used as growth promoters and an unlimited residue level for carbadox. We find, therefore, that the distinction in levels of protection thus made by the European Communities is "arbitrary or unjustifiable" in the sense of the second element contained in Article 5.5.

3. *Difference Which Results in "Discrimination or a Disguised Restriction on International Trade"*

8.239 The United States submits that the distinction made by the European Communities in levels of protection for the hormones at issue when used as

[440] See para. 8.199 and, particularly with respect to carbadox, opinion of Dr. Lucier, Transcripts of the joint meeting with experts of 18 February 1997, para. 275.
[441] See, for example, opinion of Dr. Lucier, para. 6.37 and Dr. Arnold, Transcripts of the joint meeting with experts of 17 February 1997, para. 91.

growth promoters and carbadox results in a disguised restriction on international trade in the sense of the third element contained in Article 5.5. According to the United States, the European Communities swine industry (where growth promoters are allowed) is relatively more efficient and market-oriented than the European Communities beef industry (where growth promoters are banned), a sector where efficiency is not that important because of domestic price support measures, import protection and export subsidies. When banning hormones, the United States concludes, the European Communities clearly wanted to reduce beef supplies, a concern not present in the pork sector where the European Communities wanted, on the contrary, to preserve competitiveness and maintain export markets.[442]

8.240 We recall that the three elements contained in Article 5.5 all impart meaning to one another and that in some cases the significance of the difference in levels of sanitary protection for comparable situations combined with the arbitrariness of thereof, may be sufficient to conclude that this difference in levels of protection results in "discrimination or a disguised restriction on international trade".[443]

8.241 In this case, we note, firstly, the significance of the difference in levels of protection for the five hormones at issue when used as growth promoters and carbadox, namely a "no residue" level as opposed to an unlimited residue level. We recall, secondly, that the European Communities has not provided any plausible justification for this significant difference. We note, finally, that this difference in levels of protection results in an import ban (on meat and meat products treated with any of these five hormones at issue) which restricts international trade. For these reasons, we find that the difference in levels of protection imposed by the European Communities for the five hormones at issue when used as growth promoters and carbadox, results in "discrimination or a disguised restriction on international trade" in the sense of Article 5.5.

8.242 We consider that this finding is further supported by the two additional factors outlined above[444], which are equally valid for the distinction in levels of protection made by the European Communities for the five hormones at issue when used as growth promoters and carbadox.

8.243 We finally note that there is another factor which indicates that the distinction in treatment made by the European Communities for the hormones at issue when used as growth promoters and carbadox results in "discrimination or a disguised restriction on international trade". That is the fact that the hormones at issue, which are *banned* in the European Communities, are used for growth promotion in the *bovine* meat sector where the European Communities seemingly

[442] See para. 4.221.
[443] See paras. 8.182-8.184.
[444] See paras. 8.204 and 8.205.

wants to limit supplies[445] and is arguably less concerned with international competitiveness, whereas carbadox, which is *allowed* in the European Communities, is used for growth promotion in the *pork* meat sector where the European Communities has no domestic surpluses and where international competitiveness is a higher priority.

8.244 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for five of the six hormones at issue (all but MGA) when used as growth promoters and carbadox, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, in so far as they relate to these five hormones in dispute, are inconsistent with the requirements imposed in Article 5.5.

8.245 *In summary*, in this section we have found that the EC measures in dispute, both in so far as they relate to the two synthetic hormones (zeranol and trenbolone) and the three natural hormones at issue for which international standards exist, are inconsistent with the requirements contained in Article 5.5. The fact that the EC measures in dispute are not based on existing international standards (contrary to Article 3.1) can, for that reason, not be justified on the basis of Article 3.3. The EC measures, in so far as they relate to five of the six hormones at issue for which international standards exist, are, therefore, also inconsistent with the requirements of Article 3.1.

(iii) Article 5.6: Measures Not More Trade Restrictive than Required to Achieve the Appropriate Level of Protection

8.246 Article 5.6 reads as follows:

> "Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility".

A footnote to Article 5.6 states the following:

> "For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade".

[445] See also para. 8.204.

8.247 Since we found above that the EC level of protection reflected in the EC measures in dispute has been adopted in violation of Article 5.5, we do not consider it necessary to further examine whether these measures are also more trade restrictive than required to achieve that level in the sense of Article 5.6.

(d) Article 5.7: Provisional Sanitary Measures

8.248 Article 5.7 reads as follows:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".

8.249 We recall our finding reached above on the role of the precautionary principle in the SPS Agreement, in particular that this principle would not override the explicit wording of that Agreement, *inter alia*, because it has been incorporated in a specific form in Article 5.7.[446] In this dispute, the European Communities has explicitly stated that its measures are not provisional measures in the sense of Article 5.7. We do, therefore, not need to further examine this provision.

6. Sanitary Measures Where no International Standards Exist: Melengestrol Acetate ("MGA")

8.250 We recall that with respect to the third synthetic hormone in dispute, MGA, no international standard exists.[447] As outlined above, the European Communities is, therefore, not under an obligation to base its sanitary measure in respect of this hormone on an international standard in accordance with Article 3.1.[448]

8.251 However, even though no international standard exists for MGA, the EC measures in dispute relating to MGA still need to comply with the other provisions of the SPS Agreement. The United States has invoked violations of Articles 2 and 5. Since Article 2 provides for basic rights and obligations which are further specified in Article 5, we first examine the consistency of the EC measures

[446] See para. 8.158.
[447] See para. 8.70.
[448] See paras. 8.56 ff.

in dispute relating to MGA with the requirements of Article 5.[449] The consistency of the EC measures relating to all hormones in dispute (including MGA) with the requirements of Article 2 will be dealt with below.[450]

(a) Burden of Proof

8.252 We recall our finding reached above on the general burden of proof under the SPS Agreement[451], in particular that for the obligations imposed by the SPS Agreement that are relevant to this case, the party contesting a sanitary measure (*in casu* the United States) bears the burden of presenting a *prima facie* case of inconsistency with the SPS Agreement, after which the burden of proof shifts to the party imposing the measure (*in casu* the European Communities). We consider that, for the reasons mentioned above[452], this allocation of evidentiary burden is applicable to the obligations imposed on Members under Article 5. We recall, in particular, the wording of Article 5.1, especially the first three words thereof:

> "*Members shall ensure* that their sanitary ... measures are based on an assessment ... of the risks ..." (emphasis added)

and the wording of the second part of the first sentence of Article 5.5 :

> "... each *Member shall avoid* arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if ..." (emphasis added).

Therefore, in this dispute the United States has to present a *prima facie* case that the EC measures in dispute relating to MGA are *inconsistent* with the requirements of Article 5, after which the burden shifts to the European Communities to prove that it *has* complied with these requirements.

(b) Articles 5.1 to 5.3: Risk Assessment

8.253 With respect to Articles 5.1 to 5.3 dealing with the requirement of a *risk assessment*, the United States argues that the European Communities has not submitted any risk assessment for the hormone MGA and that the European Communities has, therefore, *a priori*, not based its measures with respect to MGA on any risk assessment as required by Article 5.1.[453] The United States further submits that its Food and Drug Administration has fully evaluated the safety of MGA and concluded that the use of this hormone as a growth promoter

---

[449] We only examine the consistency of the EC measures relating to MGA with the requirements contained in Articles 5.1 to 5.3 and 5.5. With respect to the other provisions of Article 5 we refer to our considerations set out in section 5 which equally apply to the EC measures relating to MGA.
[450] See para. 8.271.
[451] See paras. 8.48 ff.
[452] See paras. 8.52-8.54.
[453] See paras. 4.110-4.112.

does not present a risk to human health.[454] We find that the United States thus meets its burden of presenting a *prima facie* case of inconsistency with Article 5.1.

8.254 We recall our reasoning outlined above on the requirement of the *existence* of a risk assessment in accordance with Articles 5.1 to 5.3[455], in particular that with respect to the five other hormones in dispute we assumed that the European Communities met its burden of demonstrating the existence of a risk assessment since it referred to several scientific reports which appear to meet the minimum requirements of a risk assessment.

8.255 With respect to MGA, we note, however, that the European Communities has not submitted any scientific evidence in which the potential for adverse effects on human health of MGA residues is evaluated. Moreover, the scientists advising the Panel have at several occasions stated that they are not aware of any publicly available scientific study which evaluates the safety of MGA[456]; the studies carried out by the United States are proprietary studies which remain confidential.

8.256 The European Communities argues that the EC measures in dispute regulate hormones on the basis of their physiological action, not on the basis of individual substances and that the administration of any substance having an oestrogenic, androgenic or gestagenic action is covered by the EC ban, including MGA which has a gestagenic action.[457]

8.257 We note, however, that with respect to all five other hormones in dispute, JECFA, Codex and the European Communities itself have conducted or invoked risk assessments for each individual substance. We further note that one of the basic principles of a risk assessment appears to be that it needs to be carried out for each individual substance.[458] As was stated in the 1995 EC Scientific Conference:

> "It must be emphasised that a separate risk assessment must be conducted on each growth promoting substance. It is not appropri-

---

[454] See para. 4.131 and 4.136.

[455] See paras. 8.108-8.111.

[456] See, for example, statements by Dr. Ritter and Dr. McLean, Transcripts of the joint meeting with scientific experts of 17 February 1997, paras. 352 and 354.

[457] See para. 4.93.

[458] See, for example, answer by Dr. André to Panel Question 13 (para. 6.142) and the practice in JECFA which only examines specific substances and this, mostly, when these substances are used for specific purposes. In particular, the Joint FAO/WHO Expert Consultation on Residues of Veterinary Drugs in Foods (29 October - 5 November 1984; FAO Food and Nutrition Paper No. 32) recommended that a " ... scientific body should rely on the advice of experts in veterinary medicine, animal science, toxicology, microbiology, immunology, analytical chemistry and related sciences, and establish criteria for the safety of *individual* veterinary drug residues as appropriate, taking into account their public health significance, good animal husbandry and drug use practices, the likelihood of residues and the availability of adequate analytical methodology" (p.15, emphasis added).

> ate to attempt to produce a detailed generic risk assessment for a class of growth promoters".[459]

8.258 We thus find that the European Communities has not met its burden of demonstrating the existence of a risk assessment with respect to MGA and that, therefore, the EC measures in dispute, in so far as they relate to the hormone MGA, are not based on an assessment of risks in accordance with Article 5.

8.259 We recall, in this respect, that the European Communities has explicitly stated that Article 5.7, which deals with cases where relevant scientific evidence is insufficient and allows a Member to take provisional sanitary measures, does not apply to the measures in dispute, including those relating to MGA.[460]

8.260 We further recall our reasoning and findings reached above (with respect to the five other hormones in dispute) on the procedural and substantive requirements a Member must satisfy in order to *base* its sanitary measures *on* a risk assessment in accordance with Articles 5.1[461]. We recall, in particular, that the European Communities has, from a procedural point of view, not provided any evidence that the studies it referred to have actually been taken into account by the competent EC institutions or are reflected in the EC measures in such a way that these measures could be said to be *based on* these studies. We further recall that the European Communities has not met its burden of proving that its measures in dispute, in so far as they also ban the use of the five hormones at issue for growth promotion purposes in accordance with good practice, are, from a substantive point of view, based on a risk assessment.

8.261 The same reasoning applies *a priori* to the EC measures with respect to MGA since the European Communities has not submitted any study in which the risks related to MGA are assessed. We thus find that the European Communities has not met its burden of providing evidence to the Panel that its measures in dispute, in so far as they relate to the hormone MGA, are, either from a procedural or a substantial point of view, *based on* a risk assessment and that, therefore, these measures are inconsistent with the requirements of Article 5.1.

(c) Article 5.5: Distinctions in Levels of Protection

8.262 Even if we had found that the European Communities met its burden of proving that its measures relating to MGA are based on an assessment of risks in accordance with Articles 5.1 and 5.2 and even if, for that reason, the European Communities could have adopted an appropriate level of protection against these risks, there would still be a need to examine whether the determination and application of this level of protection is consistent with Article 5.5.[462] In this respect,

---

[459] *1995 EC Scientific Conference Proceedings*, p.250.
[460] See para. 8.249.
[461] See paras. 8.112 ff.
[462] See para. 8.163.

the United States argues that the European Communities fails to justify the following differences in regulatory treatment: (i) a ban on MGA when used for growth promotion purposes as opposed to not setting any limit for residues of the natural hormones present endogenously in untreated meat and other foods (such as milk, cabbage, broccoli or eggs) or used for therapeutic or zootechnical purposes; and (ii) a ban on MGA when used for growth promotion purposes as opposed to allowing the use of carbadox as a growth promoter in swine production. Only with respect to the last mentioned difference in treatment does the United States explicitly invoke Article 5.5.

8.263 We refer to paragraphs 4.209-4.211 for the arguments submitted by the United States with respect to these distinctions in light of the three elements contained in Article 5.5 and find that the United States meets its burden of presenting a *prima facie* case of inconsistency with Article 5.5.

(i) MGA for Growth Promotion Compared to the Natural Hormones Occurring Endogenously in Meat and Other Foods

8.264 We recall our reasoning and findings reached above with respect to the EC measures in dispute relating to the hormones at issue other than MGA, in particular our finding that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for residues of zeranol and trenbolone (two of the synthetic hormones in dispute) and residues of the natural hormones in dispute which occur endogenously in meat and other foods, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, in so far as they relate to zeranol and trenbolone, are inconsistent with the requirements imposed in Article 5.5.[463]

8.265 We consider that this reasoning and these findings equally apply to the EC measures in dispute relating to MGA (the third synthetic hormone in dispute). Firstly, the European Communities has adopted different levels of protection (a "no residue" limit[464] as opposed to an unlimited residue level) for comparable situations, *in casu* situations posing the same adverse health effect (*i.e.*, carcinogenicity), namely for MGA used as a growth promoter and the natural hormones in dispute which occur endogenously in meat and other foods in the sense of the first element of Article 5.5. Secondly, the European Communities has not submitted evidence that this difference in levels of protection is justified and has thus not met its burden of proving that this difference is not "arbitrary or unjustifiable" in the sense of the second element of Article 5.5. Thirdly, the European Communities has not met its burden of rebutting the arguments and evidence submitted by the United States that this difference in levels of protection results

[463] See para. 8.218.
[464] See para. 4.104.

in "discrimination or a disguised restriction on international trade" in the sense of the third element of Article 5.5.

8.266 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for MGA used as a growth promoter and the natural hormones in dispute which occur endogenously in meat and other foods, in light of the three elements contained in Article 5.5, and that, therefore, the EC measures in dispute, also in so far as they relate to MGA, are inconsistent with the requirements imposed by Article 5.5.

(ii) MGA for Growth Promotion Compared to Carbadox

8.267 We further recall our reasoning and findings reached above with respect to the EC measures in dispute relating to the hormones at issue other than MGA, in particular our finding that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for residues of the hormones at issue (other than MGA) when used for growth promotion purposes and residues of carbadox in light of the three elements contained in Article 5.5 and that, therefore, the EC measures in dispute, in so far as they relate to the hormones in dispute (other than MGA), are inconsistent with the requirements imposed by Article 5.5.[465]

8.268 We consider that this reasoning and these findings equally apply to the EC measures in dispute relating to MGA. Firstly, the European Communities has adopted different levels of protection (a "no residue" limit[466] as opposed to an unlimited residue level) for comparable situations, *in casu* situations posing the same adverse health effect (*i.e.*, carcinogenicity)[467], namely for MGA used as a growth promoter and carbadox in the sense of the first element of Article 5.5. Secondly, the European Communities has not submitted any evidence that this difference in levels of protection is justified and has thus not met its burden of proving that this difference is not "arbitrary or unjustifiable" in the sense of the second element of Article 5.5. Thirdly, the European Communities has not met its burden of rebutting the arguments and evidence submitted by the United States that this difference in levels of protection results in "discrimination or a disguised restriction on international trade" in the sense of the third element of Article 5.5.

8.269 We thus find that the European Communities has not met its burden of justifying the distinction it makes in levels of protection for MGA used as a growth promoter and carbadox, in light of the three elements contained in Arti-

[465] See para. 8.244.
[466] See para. 4.104.
[467] See para. 4.108.

cle 5.5, and that, for this reason, also the EC measures in dispute which relate to MGA are inconsistent with the requirements imposed by Article 5.5.

8.270 *In summary*, in this section we have found that the EC measures in dispute relating to MGA are inconsistent with the requirements contained in Articles 5.1 and 5.5.

7. Article 2: "Basic Rights and Obligations

8.271 Since we have found that the EC measures in dispute are inconsistent with the requirements of Articles 3 and 5 of the SPS Agreement and considering that Articles 3 and 5 provide for more specific rights and obligations than the "basic rights and obligations" set out in Article 2, we see no need to further examine whether the EC measures in dispute also violate Article 2.

E. Articles I and III of GATT

8.272 Since we have found that the EC measures in dispute are inconsistent with the requirements of the SPS Agreement, we see no need to further examine whether the EC measures in dispute are also inconsistent with Article I or III of GATT.

8.273 As noted above in paragraph 8.42, if we were to find an inconsistency with Article I or III of GATT, we would then need to examine whether this inconsistency could be justified, as argued by the European Communities, under Article XX(b) of GATT and would thus necessarily need to revert to the SPS Agreement under which we have already found inconsistencies. Since the European Communities has not invoked any defence under GATT other than Article XX(b), an inconsistency with Article I or III of GATT would, therefore, in any event, not be justifiable.

F. Concluding Remarks

8.274 In order to avoid any misunderstanding as to the scope and implications of the findings above, we would like to stress that it was not our task to examine generally the desirability or necessity of the EC Council Directives in dispute. The ability of any Member to take sanitary measures which do not affect international trade was not at issue in the present case. Our examination was confined to those aspects of the EC measures that have been raised by the United States, namely the EC import ban on meat and meat products of bovine origin treated with any of six specific hormones for growth promotion purposes. It was further limited to the specific provisions of GATT and the SPS Agreement which have been invoked by the European Communities in support of this import ban. That is the necessity of the import ban, which the European Communities strictly construed as a sanitary measure, for the protection of human life or health. Likewise, the ability of any Member to enact measures which are intended to protect not consumer health but other consumer concerns was not addressed. In this regard,

we are aware that in some countries where the use of growth promoting hormones is permitted in beef production, voluntary labelling schemes operate whereby beef from animals which have not received such treatment may be so labelled.

IX. CONCLUSIONS

9.10 In light of the findings above, we reach the following conclusions:

(i) The European Communities, by maintaining sanitary measures which are not based on a risk assessment, has acted inconsistently with the requirements contained in Article 5.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

(ii) The European Communities, by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers to be appropriate in different situations which result in discrimination or a disguised restriction on international trade, has acted inconsistently with the requirements contained in Article 5.5 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

(iii) The European Communities, by maintaining sanitary measures which are not based on existing international standards without justification under Article 3.3 of the Agreement on the Application of Sanitary and Phytosanitary Measures, has acted inconsistently with the requirements contained in Article 3.1 of that Agreement.

9.11 We *recommend* that the Dispute Settlement Body requests the European Communities to bring its measures in dispute into conformity with its obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures.

ARGENTINA - MEASURES AFFECTING IMPORTS OF FOOTWEAR, TEXTILES, APPAREL AND OTHER ITEMS

Report of the Appellate Body
WT/DS56/AB/R, WT/DS56/AB/R/Corr.1

Adopted by the Dispute Settlement Body on 22 April 1998

Argentina, *Appellant*	Present:
United States, *Appellee*	El-Naggar, Presiding Member
European Communities, *Third Participant*	Feliciano, Member
	Matsushita, Member

I. INTRODUCTION: STATEMENT OF THE APPEAL

1. Argentina appeals from certain issues of law covered and legal interpretations developed in the Panel Report, *Argentina - Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items*[1] (the "Panel Report"). The Panel was established to consider a complaint by the United States against Argentina concerning certain measures maintained by Argentina affecting imports of textiles, apparel, footwear and other items, in particular, measures imposing specific duties on various textile, apparel or footwear items allegedly in excess of the bound rate of 35 per cent *ad valorem* provided in Argentina's Schedule LXIV[2] and measures imposing a statistical tax of 3 per cent *ad valorem* on imports from all sources other than MERCOSUR countries. The relevant factual aspects of Argentina's import regime for textiles, apparel and footwear are described in the Panel Report, in particular, at paragraphs 2.1 to 2.21.

2. Argentina approved the results of the Uruguay Round of multilateral trade negotiations through Law No. 24.425, promulgated on 23 December 1994, and the bound rate of 35 per cent *ad valorem* included in its Schedule LXIV became effective on 1 January 1995. This binding was generally applicable to imports, with a number of exceptions that are not relevant in this case. In parallel, Argentina maintained a regime of Minimum Specific Import Duties ("DIEM")[3] as from 1993 in respect of textiles, clothing and footwear through a series of resolutions

[1] WT/DS56/R, 25 November 1997.
[2] See Argentina's Schedule LXIV, *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, done at Marrakesh, 15 April 1994.
[3] In Spanish, *Derechos de Importación Específicos Mínimos*.

and decrees commencing with Resolution No. 811/93 of 29 July 1993[4] (concerning textiles and apparel) and Resolution No. 1696/93 of 28 December 1993[5] (concerning footwear), with subsequent extensions and modifications.[6] The DIEM were revoked in respect of footwear on 14 February 1997 through Resolution No. 225/97 of the Argentine Ministry of Economy and Public Works and Services, and the Panel decided not to review the consistency with the *WTO Agreement* of the DIEM with respect to footwear.[7] In addition, Argentina imposed, from 1989 to 1994, a 3 per cent *ad valorem* tax which related to the collection of statistical information by the Argentine customs service regarding imports and exports.[8] Through Presidential Decree No. 2277/94 adopted on 23 December 1994[9], the tax was reduced to zero per cent, but was set again at 3 per cent on 22 March 1995 pursuant to Presidential Decree No. 389/95 in respect of certain import transactions. The tax is set out in Argentina's Schedule LXIV, under the heading "other duties and charges", at 3 per cent *ad valorem*.

3. The Panel Report was circulated to the Members of the World Trade Organization (the "WTO") on 25 November 1997. The Panel reached the following conclusions:

> (a) the minimum specific duties imposed by Argentina on textiles and apparel are inconsistent with the requirements of Article II of GATT;
>
> (b) the statistical tax of three per cent *ad valorem* imposed by Argentina on imports is inconsistent with the requirements of Article VIII of GATT.[10]
>
> The Panel made the following recommendation:
>
> The Panel *recommends* that the Dispute Settlement Body request Argentina to bring its measures into conformity with its obligations under the WTO Agreement.[11]

---

4 *Boletín Oficial de la República Argentina*, No. 27.692 of 2 August 1993.

5 *Boletín Oficial de la República Argentina*, No. 27.797 of 30 December 1993.

6 As further described in Panel Report, paras. 2.7-2.18, these extensions and modifications are found in: Presidential Decree No. 2275/94 of 23 December 1994, *Boletín Oficial de la República Argentina*, No. 28.050 of 30 December 1994; Resolution No. 304/95 (textiles and apparel) and 305/95 (footwear) of the Ministry of Economy and Public Works and Services of 22 September 1995; Presidential Decree No. 998/95 of 28 December 1995, *Boletín Oficial de la República Argentina*, No. 28.301 of 29 December 1995; Resolution Nos. 103/96 of 6 September 1996 and 23/97 of 7 January 1997 of the Ministry of Economy and Public Works and Services, *Boletín Oficial de la República Argentina*, No. 28.561 of 10 January 1997 (footwear); and Resolution Nos. 299/96 of 20 February 1996, 22/97 of 7 January 1997, *Boletín Oficial de la República Argentina*, No. 28.561 of 10 January 1997 and 597/97 of 14 May 1997 of the Ministry of Economy and Public Works and Services, *Boletín Oficial de la República Argentina*, No. 28.650 of 20 May 1997 (textiles and apparel).

7 Panel Report, para. 6.15.

8 *Boletín Oficial de la República Argentina*, No. 26.652 of 12 June 1989.

9 *Boletín Oficial de la República Argentina*, No. 28.050 of 30 December 1994.

10 Panel Report, para. 7.1.

4. On 21 January 1998, Argentina notified the Dispute Settlement Body[12] (the "DSB") of its intention to appeal certain issues of law covered in the Panel Report and legal interpretations developed by the Panel, pursuant to paragraph 4 of Article 16 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU"), and filed a Notice of Appeal with the Appellate Body, pursuant to Rule 20 of the *Working Procedures for Appellate Review*. On 2 February 1998, Argentina filed an appellant's submission.[13] On 16 February 1998, the United States filed an appellee's submission pursuant to Rule 22 of the *Working Procedures for Appellate Review*. That same day, the European Communities filed a third participant's submission pursuant to Rule 24 of the *Working Procedures for Appellate Review*. The oral hearing, provided for in Rule 27 of the *Working Procedures for Appellate Review*, was held on 23 February 1998. At the oral hearing, the participants and the third participant presented their arguments and answered questions from the Division of the Appellate Body hearing the appeal.

II. ARGUMENTS OF THE PARTICIPANTS AND THE THIRD PARTICIPANT

A. Claims of Error by Argentina - Appellant

5. Argentina appeals certain aspects of the legal findings and conclusions of the Panel. With respect to Article II of the GATT 1994, Argentina requests that we reverse the Panel's findings in paragraph 6.32 and declare that the Panel erred in concluding that Argentina had acted inconsistently with Article II "in all cases" in which Argentina applied the DIEM. With respect to the statistical tax, Argentina asks us to reverse the Panel's findings in paragraph 6.80 of the Panel Report. Finally, Argentina makes certain procedural claims under Article 11 of the DSU.

6. With respect to the Panel's finding in paragraph 6.32 of the Panel Report concerning Article II of the GATT 1994, Argentina submits that the Panel erred in law in interpreting the obligation set out in Article II:1(a) and II:1(b) of the GATT 1994 and the *Understanding on the Interpretation of Article II:1(b) of the GATT 1994* as prohibiting a Member from applying a type of duty other than that which is bound, without taking into account whether the level of protection ensuing from the application of that duty is, or is not, higher than the bound level of protection.

7. According to Argentina, an international legal obligation may be derived only from a formal source creating international law. As regards the WTO, the

---

[11] Panel Report, para. 7.2.
[12] WT/DS56/8, 21 January 1998.
[13] Pursuant to Rule 21(1) of the *Working Procedures for Appellate Review*.

only obligations by which Members are bound are those which flow from the *Marrakesh Agreement Establishing the World Trade Organization*[14] (the "*WTO Agreement*") and instruments agreed upon under its provisions, as well as amendments under Article X and authoritative interpretations under Article IX. There have been no amendments under Article X nor any authoritative interpretations under Article IX. The relevant provision in the *WTO Agreement* is Article II of the GATT 1994 and the *Understanding on the Interpretation of Article II:1(b) of the GATT 1994*.

8. Argentina asserts that Article II of the GATT 1994 must be interpreted in conformity with Articles 31 and 32 of the *Vienna Convention on the Law of Treaties*[15] (the "*Vienna Convention*"). The correct interpretation of Article II of the GATT 1994 should be based on the actual text of Article II, in particular paragraphs 1(a) and 1(b), and on the *Understanding on the Interpretation of Article II:1(b) of the GATT 1994*, as well as on GATT practice. The texts of Article II:1(a) and II:1(b) should be read in conjunction with each other. Article II:1(a) lays down a general obligation, and Article II:1(b) defines the scope of that obligation.

9. In Argentina's view, the Panel goes beyond the GATT 1994 in giving an "extensive" interpretation of the scope of the obligation, thereby adding requirements that are not provided for in the GATT 1994 itself. The commitment to accord "treatment no less favourable" does not automatically imply an obligation to apply a "specific type of duty". To assimilate the interpretation of the "duty set forth and provided in the Schedule" with the notion of "bound only *ad valorem*" and to infer that changing this results in "less favourable" treatment not only finds no support in the text of the provisions, but is also not supported by the *Understanding on the Interpretation of Article II:1(b) of the GATT 1994*. The object and purpose of Article II:1(a) and (b) can only be to accord treatment no less favourable than that provided for in the National Schedule. Less favourable treatment is accorded when a duty exceeding that set forth in the National Schedule is applied.

10. It is further argued by Argentina that in Article II of the GATT 1994, the bound duty represents a ceiling on the level of protection; the legal obligation deriving from this Article is not to exceed the said ceiling or bound maximum level of protection; and Members are free to choose the form or type of duty applied provided the maximum *level* of protection of the said binding is not exceeded. Thus, a difference in the form of duty applied does *not* necessarily constitute a violation of the bound level.

11. Argentina submits that the Panel has sourced the alleged obligation to apply a type of duty identical to that recorded in the National Schedule in "past GATT practice" and not in a rule or provision contained in Article II of the

[14] Done at Marrakesh, Morocco, 15 April 1994.
[15] Done at Vienna, 23 May 1969, 1155 U.N.T.S. 331; 8 International Legal Materials 679.

GATT 1994 or the *Understanding on the Interpretation of Article II:1(b) of the GATT 1994*. The Panel erred in law in interpreting the "legal history and experience" as mandatory "practice", and this subsequently led to the error of placing it on the same footing as "other decisions of the CONTRACTING PARTIES of the GATT 1947".[16] The Panel can only have arrived at its conclusion that there is an obligation beyond the literal meaning of the text by means of interpretation. In terms of "uniformity", "undisputed nature", "repetition" and "continuity", Argentina stresses that "GATT practice" is deficient. Certain GATT working party reports and panel reports, including those cited by the Panel, are contradictory precedents which, in certain cases, lead to an interpretation different from that adopted by the Panel itself.

12. Argentina submits that the Panel concluded that Argentina had violated Article II by applying the DIEM after examining only 124[17] tariff lines out of 940 tariff lines relevant to this dispute. The Panel, therefore, erred in law in considering that Argentina infringed its obligations under Article II of the GATT 1994 *in all cases* in which it applied the DIEM.

13. We are also asked to reverse the Panel's finding in paragraph 6.80 of the Panel Report that the statistical tax of 3 per cent *ad valorem* is in violation of Article VIII:1(a) of the GATT 1994. The Panel is said to have erred in failing to take into account Argentina's obligations to the International Monetary Fund (the "IMF") in its interpretation of Article VIII of the GATT 1994. Argentina contends that its agreement with the IMF includes an undertaking to impose a tax in the form of a statistical tax. This undertaking is contained in a document entitled "Memorandum on Economic Policy"[18], referred to by Argentina as a "Memorandum of Understanding" between Argentina and the IMF. Argentina asserts that, by its acquiescence, the United States helped to create Argentina's obligation with the IMF, and the United States cannot now deny the binding nature, i.e. its legal effects with regard to Article VIII of the GATT 1994, of that obligation.

14. It is also submitted by Argentina that the Panel disregarded its duty under Article 11 of the DSU by not making an objective assessment of the matter before it. Paragraph 5.3 of the Panel Report ignores an obvious fact and appears to contradict all the reasons given by the Panel regarding burden of proof when dealing with the matter of the DIEM. The Panel's conclusion that the statistical tax was inconsistent with Article VIII of the GATT 1994 does not meet the requirement laid down in Article 12.7 of the DSU that a panel report shall set out "the findings of fact, the applicability of relevant provisions and the basic rationale behind any findings and recommendations that it makes." The Panel's failure

---

[16] Paragraph 1(b)(iv) of the language of Annex 1A incorporating the GATT 1994 into the *WTO Agreement*.

[17] This includes evidence with regard to six tariff lines in the documentation submitted by the United States prior to the second meeting with the Panel. We note that Argentina challenges the Panel's acceptance of this evidence under Article 11 of the DSU. See Part VI of this Report.

[18] Exhibit S to the United States' first written submission to the Panel.

to accede to the request by the United States to consult the IMF regarding the existence of this obligation led to another error in law because the Panel, in effect, ignored relevant opinions that could have helped to form a more complete judgement.

15. In Argentina's view, the Panel also erred in law by excluding from its consideration subsequent legislative developments - namely, the *Agreement Between the International Monetary Fund and the World Trade Organization* (the "*Agreement Between the IMF and the WTO*") drawn up on the basis of the *Declaration on the Contribution of the World Trade Organization to Achieving Greater Coherence in Global Economic Policymaking* (the "*Declaration on Coherence*") - and by reaching its conclusion on the statistical tax solely on the basis of Article VIII of the GATT 1994. Argentina argues that the interpretation of the *Agreement Between the IMF and the WTO* is covered by the DSU as it is a legislative development in the terms of Article V.1 of the *WTO Agreement*, and the *WTO Agreement* is included in Appendix 1 of the DSU. Argentina asserts that under paragraph 5 of the *Declaration on Coherence*, the WTO is to cooperate with the IMF and should avoid "the imposition on governments of cross-conditionality or additional conditions". If the *Declaration on Coherence* had been taken into account, the Panel would have had to consider the existence of a cross-obligation within the meaning of paragraph 5 of that Declaration. According to Argentina, this is made even more explicit in paragraph 10 of the *WTO-IMF Agreement*. Thus, the issue at stake is not one of making exceptions, but of interpreting the *WTO Agreement* in the light of its content.

16. Argentina states that the Panel has placed Article VIII of the GATT 1994 in a "legal limbo", isolated from related agreements and other relevant rules and principles of public international law. The Panel undertook only a partial analysis of the arguments put forward by Argentina, disregarded subsequent legislative developments, and did not take into account previous practice. Referring to the Director-General's Report on implementation of the agreements between the WTO and the IMF and the World Bank[19] and the discussions on this Report at the General Council meeting of 10 December 1997, Argentina argues that the Panel should have considered the need to ensure that the decisions adopted by these bodies are mutually supportive in the context of the provisions endorsed in the *Declaration on Coherence*.

17. It is further claimed by Argentina that the Panel did not comply with its obligation under Article 11 of the DSU on two counts. First, the Panel accepted certain evidence submitted by the United States to the Panel on 21 July 1997, two days before the second meeting of the parties (ten days after the expiry of the time-limit for submitting the respective rebuttals). Argentina states that it ob-

[19] Agreements between the WTO and the IMF and the World Bank, Report by the Director-General on Implementation of the Agreements, WT/GC/W/68, 13 November 1997. Annex I to Argentina's appellant's submission.

jected to the admission of such evidence into the record and drew attention to the impossibility of responding to the evidence within the two-week period granted by the Panel. This evidence related to transactions carried out using the manual customs clearance system and not the MARIA computerized system. The names of the importers, customs identification numbers and, sometimes, the description of the items imported were deleted, thereby making it impossible to verify any of the information submitted within the period granted by the Panel. For Argentina, the Panel's position is difficult to reconcile with "due process", considering that the submission of evidence after the time-limit has expired alters the balance of rights and obligations during examination of the case and, combined with the impossibility of rebuttal within a tight time-limit, disadvantages one party, in this case Argentina. Second, the Panel failed to fulfil its obligation to render an objective assessment of the matter by not acceding to the request of both parties to the dispute to seek information and consult with the IMF so as to obtain its opinion on specific aspects of the statistical tax. The DSU gives panels different tools to fulfil the obligation under Article 11, and one of these is the right to "seek information" provided in Article 13 of the DSU. The Panel did not make use of this means, which would have allowed it to verify the information provided by the parties, which information could have altered the Panel's conclusion regarding the statistical tax. Argentina further argues that the Panel failed to fulfil a general obligation governing procedure in any international dispute, namely to elucidate a fact or investigate an objective claim that both parties to the dispute have expressed as a concern, in order to establish the truth regarding the point raised.

B. Arguments by the United States - Appellee

18. The United States endorses the findings and conclusions of the Panel in paragraph 6.32 and argues that the Panel correctly concluded, on the basis of the evidence before it, that the application of the DIEM violated Article II of the GATT 1994. The United States also endorses paragraph 6.80 of the Panel Report and argues that the Panel acted consistently with Article 11 of the DSU.

19. With respect to Article II of the GATT 1994, the United States believes that the Panel correctly found that Argentina’s specific duties are inconsistent with its *ad valorem* binding, and that the Panel's interpretation of Article II is consistent with principles of public international law, previous decisions of the Appellate Body and prior GATT practice, and gives full meaning to the text of this provision.

20. The United States contends that one of the fundamental objectives of the GATT 1994, expressed in the preamble, is to achieve "the substantial reduction of tariffs". To ensure that tariff concessions, once made, have the full force and effect intended, Article II provides that duty rates identified in a WTO Member’s Schedule are maximum limits that may not be exceeded. This is made clear in Article II:1(b) of the GATT 1994. Article II:1(a) goes further; it obligates WTO Members to provide the *quality* of "treatment" provided for in its Schedule.

Paragraphs (a) and (b) of Article II:1 together guarantee WTO Members that their exports will not be subjected to duties greater than the amount established in relevant Schedules. They also guarantee that WTO Members will not be able to manipulate the administration of duties so as to collect excessive tariffs. In this way, Article II ensures the security and predictability of tariff concessions.

21. A basic submission of the United States is that Argentina's DIEM afford "treatment less favourable" in violation of Article II because they impair the value of the concessions Argentina made during the Uruguay Round. The DIEM necessarily have the potential to exceed Argentina's bound rate of 35 percent *ad valorem* for some covered items in the future, in view of the fundamental difference between *ad valorem* and specific duties, the disparate ways each affects imported merchandise and the manner in which Argentina fixes the rates of its specific duties.

22. According to the United States, Argentina incorrectly equates the restriction against imposing duties in excess of a bound rate under Article II:1(b) with the broader requirement of Article II:1(a) to afford WTO Members "treatment no less favourable" in respect of goods bound in a Schedule. If Argentina's view were to be accepted, the "treatment no less favourable" requirement of Article II:1(a) would mean nothing more than a commitment to refrain from imposing duties in excess of a bound rate. In the view of the United States, such a reading would reduce Article II:1(a) to "redundancy or inutility" contrary to the Appellate Body's statements in *United States - Standards for Reformulated and Conventional Gasoline*.[20] In advancing its interpretation of its Schedule, Argentina essentially seeks to achieve what other WTO Members were required to negotiate for during the Uruguay Round.

23. In contrast, the Panel's interpretation gives effect to all relevant parts of the GATT 1994. It gives effect not only to Article II:1(b) - i.e., by determining that Argentina's specific duties, as applied, exceed Argentina's bound rate - but also to Article II:1(a), by acknowledging that the inevitable potential to exceed the bound rate inherent in Argentina's tariff regime affords less favourable treatment to low-price future imports. It also preserves the value of Schedules of other WTO Members that reserved the right to apply both *ad valorem* and specific duties. The Panel's decision thus assures the "security and predictability" that Article 3.2 of the DSU demands. The Panel gave proper weight to prior GATT practice. In the view of the United States, the principles established in a number of GATT decisions clearly support the Panel's decision.

24. The United States contends that the Panel correctly concluded that Argentina failed to meet its burden of rebutting the presumption raised by the United States that all of Argentina's specific duties on textiles and apparel violate Article II of the GATT 1994 and that Argentina should conform the measures imposing them to the requirements of Article II.

---

[20] Adopted 20 May 1996, WT/DS2/AB/R, DSR 1996:I, 3 at 21.

25. The United States sees no merit in Argentina's argument that the Panel did not adequately consider its contention that the IMF requires Argentina to levy the statistical tax and that this purported requirement establishes an exception to the prohibition contained in Article VIII of the GATT 1994. Argentina failed to establish that the IMF ever imposed or approved such a requirement, and this failure to present the requisite evidence cannot be remedied by Argentina on appeal. Moreover, there is no provision in the *WTO Agreement* that would create the exception to Article VIII that Argentina seeks. The fiscal character of the statistical tax runs counter to Article VIII, which prohibits the "taxation of imports ... for fiscal purposes." This prohibition is unqualified. Argentina's statistical tax is not an exchange action and is thus outside the scope of Article XV of the GATT 1994. The *Agreement between the IMF and the WTO* does not address, and does not affect, the substantive obligations of Members under the *WTO Agreement*, or the extent to which the IMF may authorize an exchange control action that is inconsistent with a provision of the GATT 1994. Furthermore, the *Declaration on the Relationship of the World Trade Organization with the International Monetary Fund* (the "*Declaration on the Relationship of the WTO with the IMF*") does not establish any exception to Article VIII of the GATT 1994. The same is true for the *Declaration on Coherence*.

26. With respect to Article 11 of the DSU, the United States submits that the real question Argentina raises is not whether the Panel has failed to discharge its duty under Article 11, but whether the Panel abused its discretion in accepting the additional examples from the United States by causing such significant prejudice as to deny Argentina fundamental fairness or due process. The United States believes that the Panel did not abuse its discretion in admitting such additional examples which were submitted as part of a claim within the Panel's terms of reference and as part of the natural process of progressively clarifying the parties' positions. Furthermore, Argentina did not demonstrate that it has suffered prejudice from the Panel's acceptance of the evidence in question. At any rate, exclusion of the evidence Argentina now challenges would not alter the outcome of the dispute.

27. The United States also contends that the Panel did not abuse its discretion in not consulting with the IMF. Given that Argentina did not have plausible arguments on the law or facts, the Panel was under no obligation to inquire with the IMF. Furthermore, panels have considerable discretion in determining how they would proceed, and the WTO has not established guidelines regarding factual discovery.

C. Arguments by the European Communities - Third Participant

28. With respect to Article II of the GATT 1994, the European Communities submits that it was not necessary, in order to resolve the case before it, for the Panel to have made the finding in paragraph 6.32 of the Panel Report and that violation of Article II of the GATT 1994 exists in respect of all import transactions where duties are imposed which exceed the binding. Argentina's admitted

methodology used to establish the DIEM leads to duties in excess of the bindings for all products priced below the "representative price". With respect to Argentina's statistical tax, the European Communities endorses the Panel's finding in paragraph 6.80 of the Panel Report. The European Communities also makes certain comments with respect to Argentina's claims under Article 11 of the DSU.

29. In coming to the conclusion that the Argentine system of DIEM must violate Article II of the GATT 1994 in all cases, the Panel acknowledged that the wording of Article II does not explicitly address the question of whether there is an obligation to use the particular type of duty referred to in the Schedule. The Panel relied instead on past GATT practice. In the view of the European Communities, GATT practice is only relevant for the purpose of interpreting WTO obligations and cannot constitute a source of obligations in itself. The Panel appears to have treated the past GATT practice to which it refers as a source of law. The past practice referred to by the Panel, according to the European Communities, is far from persuasive.

30. The European Communities believes that the Panel should have taken the wording and context of Article II of the GATT 1994 as its starting point. Article II:1(a) may fulfil a role similar to that of Article III:1. Article II:1(a) "articulates a general principle" which "informs" the rest of Article II. The relevant obligation in Article II:1(a) and II:1(b) is to give treatment "no less favourable" than that provided for in the Schedule and to exempt products of other contracting parties from duties "in excess of those" in the Schedule. The Schedules set out the rates of duty and a duty type. The reference to a type of duty can be explained by the fact that it is necessary to establish a basis for calculation of the amount of duty which can be imposed in each case and not as a commitment to impose duties in that form only.

31. The European Communities contends that no provision of Article II contains obligations relating to the type as opposed to the amount of the duty. Accordingly, the Schedules only bind the amount of the duty which may be imposed in any case, not the type of duty. The European Communities knows of no case where a Member has reserved, in its Schedule, the right to impose a different type of duty even though an overall limit on the amount of duty payable under the other type of duty would not be exceeded. Even if it were considered that the type of duty was also bound independently of the binding of the amount, it would still be necessary to show that the change in the type of duty led to "treatment less favourable" than that resulting from the type of duty referred to in the Schedule.

32. Paragraph 6.31 of the Panel Report suggests that a change in the type of duty "undermines the stability and predictability of Members' Schedules." The European Communities does not consider that this is a matter covered by Article II of the GATT 1994. Another possible basis for a conclusion that the change in the type of the duty leads to "treatment less favourable" than that resulting from the type of duty provided for in the Schedule is suggested in paragraphs 6.46 and 6.47 of the Panel Report. The European Communities does not believe that change in competitive relationships is a correct test to apply in this case. The

wording of Article II:1(a) of the GATT 1994 makes it clear that the obligation not to exceed the tariff binding applies to each individual import transaction and that it is not possible for a Member to compensate higher duties on some transactions, or on some tariff lines, with lower duties elsewhere.

33. In respect of the statistical tax, the European Communities agrees with Argentina that it is not sufficient for the Panel to state that "there is no evidence that Argentina was requested by the International Monetary Fund ("IMF") to impose an import tax that would violate the provisions of the WTO Agreement" in order to conclude that there can be no question of conflicting obligations. An obligation can also arise if Argentina made the commitment without it having been requested. However, the only document on which Argentina relies, in arguing that it is under an obligation to the IMF to maintain a 3 per cent statistical tax, is the Memorandum on Economic Policy. In the view of the European Communities, this is a unilateral communication to the IMF, not an agreement, which mentions only a 3 per cent temporary import surcharge on certain imports. That this document did not create an obligation to maintain the 3 per cent statistical tax is also indicated by the fact that Argentina reduced the tax to 0.5 per cent and replaced it with a general increase in tariffs of 3 per cent.

34. The European Communities agrees with the Panel that Argentina's argument that it was under a conflicting obligation to the IMF should be rejected. An obligation of Argentina to the IMF in relation to a statistical or import tax, assuming it to exist, will, in accordance with the principle of *pacta tertiis nec nocent nec prosunt*, not in itself be of any consequence to the WTO, the United States or the European Communities. The conditions for the operation of the principle of acquiescence in international law are not met in the present case. A legal basis within the *WTO Agreement* itself is necessary for the alleged obligation to have the effect of excusing the violation of Article VIII of the GATT 1994.

35. According to the European Communities, the *Declaration on Coherence* may be relevant for the purpose of interpreting the procedural provisions of the *WTO Agreement*, but cannot provide an exception to any of the substantive WTO obligations invoked in this case. The *Declaration on the Relationship of the WTO with the IMF* forms part of the context of the *WTO Agreement* to be taken into account in its interpretation. The *Agreement Between the IMF and the WTO* is not a covered agreement for the purpose of the DSU. In any event, it does not contain any provision relevant to this dispute. In the view of the European Communities, the arguments of Argentina in respect of this Agreement amount to an allegation that the Panel failed to fulfil a procedural obligation to consult the IMF.

36. If Argentina were to seek to justify the 3 per cent statistical tax/import surcharge as a balance of payments measure, it would need to invoke Articles XII and XVIII of the GATT 1994 and notify the Committee on Balance-of-Payments Restrictions under Articles XII:4 or XVIII:12 of the GATT 1994. There is no indication that any of this has been done and there is, therefore, no basis to re-

view the Panel's finding that the measure is inconsistent with Article VIII of the GATT 1994.

37. With regard to Article 11 of the DSU, the European Communities contends that it was not necessary for the Panel to have evidence based on invoices that duties exceeding the bound levels were imposed. The European Communities stresses the importance of respecting the principles of due process in panel proceedings, but does not consider it necessary or appropriate to comment on the submission and use of the evidence submitted by the United States prior to the second meeting of the Panel. Article 13 of the DSU entitles a panel to seek information from any body, including the IMF, if it considers this necessary. There was no need for the Panel to seek the opinion of the IMF on the existence of an obligation toward it by Argentina to maintain the 3 per cent statistical duty since that would not have been relevant for deciding whether or not there was a violation of Article VIII of the GATT 1994.

III. ISSUES RAISED IN THIS APPEAL

38. The appellant, Argentina, raises the following issues in this appeal:

(a) Whether the application by a Member of a type of duty other than the type provided for in that Member's Schedule is, in itself, inconsistent with Article II of the GATT 1994;

(b) Whether the Panel erred in concluding that Argentina had acted inconsistently with its obligations under Article II of the GATT 1994 "in all cases" in which Argentina applied the DIEM;

(c) Whether the Panel erred in its application of Article VIII of the GATT 1994 to the 3 per cent *ad valorem* statistical tax by not taking into account commitments that Argentina states it made to the IMF; and

(d) Whether the Panel acted inconsistently with Article 11 of the DSU in: (i) admitting certain evidence submitted by the United States two days prior to the second substantive meeting of the Panel with the parties, and granting Argentina only two weeks to respond; and (ii) not seeking information from, and consulting with, the IMF so as to obtain its opinion on specific aspects of the matter concerning the statistical tax imposed by Argentina.

IV. INTERPRETATION OF ARTICLE II OF THE GATT 1994

A. The Type of Duty

39. Article II:1 of the GATT 1994 states, in pertinent part:

(a) Each Member shall accord to the commerce of the other Members treatment no less favourable than that provided for in the appropriate Part of the appropriate Schedule annexed to this Agreement.

(b) The products described in Part I of the Schedule relating to any Member, which are the products of territories of other Members, shall, on their importation into the territory to which the Schedule relates, and subject to the terms, conditions or qualifications set forth in that Schedule, be exempt from ordinary customs duties in excess of those set forth and provided therein.

40. With respect to Article II, the Panel found, *inter alia*:

> 6.31 We note that the past GATT practice is clear: a situation whereby a contracting party applies one type of duties while its Schedule refers to bindings of another type of duties constitutes a violation of Article II of GATT, without any obligation for the complaining party to submit further evidence that such variance leads to an effective breach of bindings. ... As a guarantee for predictability and to ensure the full respect of the negotiations under Article II, GATT practice has generally required that once a Member has indicated the type(s) of duties in specifying its bound rate, it must apply such type(s) of duties. Accordingly, faced with such a variance in the type [of] duties applied by Argentina from that reflected in its Schedule, we consider that we do not have to examine the effects of that variance on possible future imports. Indeed, such a variance undermines the stability and predictability of Members' Schedules.
>
> 6.32 We, therefore, find that Argentina, in using a system of specific minimum tariffs although it has bound its tariffs at *ad valorem* rates only, is violating the provisions of Article II of GATT and that the United States does not have to provide further evidence that the resultant duties exceed the bound tariff rate. Such a variance between Argentina's Schedule and its applied tariffs constitutes a less favourable treatment to the commerce of the other Members than that provided for in Argentina's Schedule, contrary to the provisions of Article II of GATT.[21]

41. Argentina appeals from paragraphs 6.31 and 6.32 of the Panel Report, arguing that the Panel erred in its interpretation that Article II of the GATT 1994 does not permit a Member to apply a type of duty other than that provided for in that Member's Schedule. Argentina maintains that the Panel should have taken into account whether the level of protection to domestic products ensuing from the application of the actual duty imposed is, or is not, higher than the level of protection resulting from the duty bound in the Member's Schedule. In Argentina's view, a Member is free to choose the type of duty applied, provided that the

[21] Panel Report, paras. 6.31-6.32.

maximum level of protection specified in that Member's Schedule is not exceeded.

42. In paragraphs 6.31 and 6.32 of the Panel Report, the Panel holds that any variance between the type of duty provided for in a Member's Schedule and the type of duty actually applied by that Member "constitutes a less favourable treatment to the commerce of the other Members"[22] than that provided for in the Member's Schedule, and therefore is inconsistent with Article II of the GATT 1994. Furthermore, the Panel asserts that the complaining party "does not have to provide further evidence that the resultant duties exceed the bound tariff rate."[23] We note that the Panel did not base its finding on a textual analysis of either paragraph (a) or (b) of Article II:1 of the GATT 1994. It observes that "[t]he wording of Article II does not seem to address explicitly whether WTO Members have an obligation to use a particular type of duty"[24], and then asserts that "the wording of Article II must be interpreted in the light of past GATT practice ...".[25] The Panel relies heavily on what it characterizes as "past GATT practice", without undertaking any analysis of the ordinary meaning of the terms of Article II in their context and in the light of the object and purpose of the GATT 1994, in accordance with the general rules of treaty interpretation set out in Article 31 of the *Vienna Convention*. After citing three working party reports[26], the adopted report of the *Panel on Newsprint*[27] and the unadopted panel report in *EEC - Import Regime for Bananas*[28] ("*Bananas II*"), the Panel declared that "... the past GATT practice is clear: a situation whereby a contracting party applies one type of duties while its Schedule refers to bindings of another type of duties constitutes a violation of Article II of GATT ...".[29]

43. We are not persuaded that "the past GATT practice is clear". The three working party reports cited by the Panel did not arise in the context of dispute settlement cases brought pursuant to Article XXIII of the GATT 1947, unlike some working party reports in GATT history that resulted from complaints made under Article XXIII.[30] We also note that these three working party reports did not result in the CONTRACTING PARTIES giving a ruling or making recommendations, pursuant to Article XXIII:2 of the GATT 1994, on whether a variance in the type of duty applied by a contracting party from the type of duty provided for

---

22 Panel Report, para. 6.32.
23 *Ibid.*
24 Panel Report, para. 6.24.
25 *Ibid.*
26 Working Party Report, *Rectifications and Modifications of Schedules*, adopted 24 October 1953, BISD 2S/63, para. 8; Working Party Report, *Transposition of the Schedule XXXVII - Turkey*, adopted 20 December 1954, BISD 3S/127; and Working Party Report, *Fourth Protocol on Rectifications and Modifications*, adopted 3 March 1955, BISD 3S/130.
27 Adopted 20 November 1984, BISD 31S/114.
28 DS38/R, 11 February 1994, unadopted.
29 Panel Report, para. 6.31.
30 See, for example, *Australian Subsidy on Ammonium Sulphate*, adopted 3 April 1950, BISD II/188.

in its Schedule constituted an infringement of Article II:1 of the GATT 1947.[31] The Panel also referred to the report of the *Panel on Newsprint* that did not, on its facts, deal with the application by a contracting party of a specific duty rather than an *ad valorem* duty provided for in its Schedule.[32] Finally, the Panel relied extensively on the *unadopted* panel report in *Bananas II*. In our Report in *Japan - Taxes on Alcoholic Beverages*[33], we agreed with that panel that "*unadopted* panel reports 'have no legal status in the GATT or WTO system ...'", although we believe that "'a panel could nevertheless find useful guidance in the reasoning of an unadopted panel report that it considered to be relevant'". In the case before us, the Panel's use of the *Bananas II* panel report appears to have gone beyond deriving "useful guidance" from the reasoning employed in that unadopted panel report. The Panel, in fact, *relies* upon the *Bananas II* panel report.

44. The legal issue before us here is whether the application by a Member of a type of duty other than that provided for in its Schedule is, in itself, inconsistent with Article II of the GATT 1994. We now turn to an examination of this question, first, in the light of the terms of Article II:1 of the GATT 1994 and, second, in the context of Argentina's DIEM system at issue in this case.

45. The terms of Article II:1(a) require that a Member "accord to the commerce of the other Members treatment no less favourable than that provided for" in that Member's Schedule. Article II:1(b), first sentence, states, in part: "The products described in Part I of the Schedule ... shall, on their importation into the territory to which the Schedule relates, ... be exempt from ordinary customs du-

---

[31] As the Panel observed in paragraph 6.26 of the Panel Report, we note that the working party report in *Transposition of Schedule XXXVII - Turkey*, adopted 20 December 1954, BISD 3S/127, stated in paragraph 4:

> The obligations of contracting parties are established by the rates of duty appearing in the schedules and any change in the rate such as a change from a specific to an ad valorem duty could in some circumstances adversely affect the value of the concessions to other contracting parties. Consequently, any conversion of specific into ad valorem rates of duty can be made only under some procedure for the modification of concessions.

This working party report, which examined a proposal by Turkey to change into *ad valorem* duties the specific duties provided for in its Schedule, did not address whether or not such a modification would be inconsistent with Article II of the GATT 1947.

[32] We note that the *Panel on Newsprint*, adopted 20 November 1984, BISD 31S/114, stated in paragraph 50:

> ... under long-standing GATT practice, even purely formal changes in the tariff schedule of a contracting party, which may not affect the GATT rights of other countries, such as the conversion of a specific to an *ad valorem* duty without an increase in the protective effect of the tariff rate in question, have been considered to require renegotiations.

It should be noted that the issue before the *Panel on Newsprint* was *not* whether a change in the type of customs duty applied by a contracting party from a specific duty to an *ad valorem* duty was consistent with Article II of the GATT 1947, but whether a reduction in a tariff-rate quota from 1.5 million tonnes to 0.5 million tonnes was consistent with Article II of the GATT 1947. For this reason, we consider the above statement to be *obiter*.

[33] Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, DSR 1996:I, 97 at 108.

ties in excess of those set forth and provided therein." Paragraph (a) of Article II:1 contains a general prohibition against according treatment less favourable to imports than that provided for in a Member's Schedule. Paragraph (b) prohibits a specific kind of practice that will always be inconsistent with paragraph (a): that is, the application of ordinary customs duties in excess of those provided for in the Schedule. Because the language of Article II:1(b), first sentence, is more specific and germane to the case at hand, our interpretative analysis begins with, and focuses on, that provision.

46. A tariff binding in a Member's Schedule provides an upper limit on the amount of duty that may be imposed, and a Member is permitted to impose a duty that is less than that provided for in its Schedule. The principal obligation in the first sentence of Article II:1(b), as we have noted above, requires a Member to refrain from imposing ordinary customs duties *in excess of* those provided for in that Member's Schedule. However, the text of Article II:1(b), first sentence, does not address whether applying a *type* of duty different from the *type* provided for in a Member's Schedule is inconsistent, in itself, with that provision.

47. In accordance with the general rules of treaty interpretation set out in Article 31 of the *Vienna Convention*, Article II:1(b), first sentence, must be read in its context and in light of the object and purpose of the GATT 1994. Article II:1(a) is part of the context of Article II:1(b); it requires that a Member must accord to the commerce of the other Members "treatment no less favourable than that provided for" in its Schedule. It is evident to us that the application of customs duties *in excess of* those provided for in a Member's Schedule, inconsistent with the first sentence of Article II:1(b), constitutes "less favourable" treatment under the provisions of Article II:1(a). A basic object and purpose of the GATT 1994, as reflected in Article II, is to preserve the value of tariff concessions negotiated by a Member with its trading partners, and bound in that Member's Schedule. Once a tariff concession is agreed and bound in a Member's Schedule, a reduction in its value by the imposition of duties in excess of the bound tariff rate would upset the balance of concessions among Members.

48. We turn next to examine whether, by applying the DIEM instead of the *ad valorem* duties provided for in its Schedule, Argentina has acted inconsistently with Article II:1(b), first sentence, of the GATT 1994.

49. As we understand it, the Argentine methodology of determining the DIEM is, first, to identify a representative international price for each relevant tariff category of textile and apparel products. Once this representative international price has been established, Argentina then multiplies that price by the bound rate of 35 per cent, or by the actually applied rate of less than 35 per cent[34], to arrive at the DIEM for the products in that category. Customs officials are directed, in a

[34] Argentina's response to questioning at the oral hearing.

specific transaction, to collect the higher of the two values: the applied *ad valorem* rate or the DIEM.[35]

50. To grasp the meaning and implications of the Argentine system, it is important to keep in mind that for any specific duty, there is an *ad valorem* equivalent deduced from the ratio of the absolute amount collected to the price of the imported product. Thus, the *ad valorem* equivalent of a specific duty varies with the variation in the price of imports. It is higher for low-priced products than for high-priced products. To illustrate, a specific duty of $10 collected on all imported products in a certain tariff category, is equivalent to 10 per cent *ad valorem* if the price of the imported product is $100; however, it is equivalent to 20 per cent *ad valorem* if the price is only $50.

51. Thus, under the Argentine system, whenever the amount of the specific duty is determined by applying the bound rate of 35 per cent to the representative international price in a certain tariff category, the *ad valorem* equivalent of the specific duty is greater than 35 per cent for all imports at prices below the representative international price; it is less than 35 per cent for all imports at prices above the representative international price. Therefore, collecting the higher of the two values means applying the bound tariff rate of 35 per cent *ad valorem* to the range of prices above the representative international price, and applying the minimum specific import duty with an *ad valorem* equivalent of more than 35 per cent to the range of prices below the representative international price.

52. In cases where the amount of the DIEM is determined by applying a rate of *less than* 35 per cent - for example, 20 per cent - to the representative international price in a certain tariff category, the result would be as follows. For the range of prices *above* the representative international price, the *ad valorem* equivalent of the specific duty would be less than 20 per cent. With respect to the range of prices *below* the representative international price, a distinction should be made between two zones. As to a certain zone of prices immediately below the representative international price, the *ad valorem* equivalent of the specific duty would be greater than 20 per cent but less than 35 per cent. However, for products at prices below that zone, the *ad valorem* equivalent of the specific duty would be greater than 35 per cent.[36]

53. In the light of this analysis, we may generalize that under the Argentine system, whether the amount of the DIEM is determined by applying 35 per cent, or a rate less than 35 per cent, to the representative international price, there will remain the possibility of a price that is sufficiently low to produce an *ad valorem* equivalent of the DIEM that is greater than 35 per cent. In other words, the structure and design of the Argentine system is such that for any DIEM, no mat-

[35] As the Panel observed, Resolution No. 811/93 of 29 July 1993, expressly stated in Article 3 that "the specific import duties established by Article 1 of this decision shall operate as a minimum of the corresponding *ad valorem* import duty". See Panel Report, para. 6.19 and footnote 171.

[36] See Panel Report, para. 3.125.

ter what *ad valorem* rate is used as the multiplier of the representative international price, the possibility remains that there is a "break-even" price below which the *ad valorem* equivalent of the customs duty collected is in excess of the bound *ad valorem* rate of 35 per cent.

54. We note that it is possible, under certain circumstances, for a Member to design a legislative "ceiling" or "cap" on the level of duty applied which would ensure that, even if the type of duty applied differs from the type provided for in that Member's Schedule, the *ad valorem* equivalents of the duties actually applied would not exceed the *ad valorem* duties provided for in the Member's Schedule. However, no such "ceiling" exists in this case. The measures at issue here, as we have already noted, specifically and expressly require Argentine customs officials to collect the *greater* of the *ad valorem* or the specific duties applicable, with no upper limit on the level of the *ad valorem* equivalent of the specific duty that may be imposed. Before the Panel, Argentina argued that its domestic challenge procedure (*recurso de impugnación*), in combination with the precedence and direct effect of international treaty obligations in the Argentine national legal system, operated as an effective legislative "ceiling" to ensure that a duty in excess of the bound rate of 35 per cent *ad valorem* could never actually be imposed. The Panel did not accept this argument[37], and Argentina has not appealed from that finding of the Panel. In this case, therefore, there is no effective legislative "ceiling" in the Argentine system which ensures that duties in excess of the bound rate of 35 per cent *ad valorem* will not be applied.

55. We conclude that the application of a type of duty different from the type provided for in a Member's Schedule is inconsistent with Article II:1(b), first sentence, of the GATT 1994 to the extent that it results in ordinary customs duties being levied in excess of those provided for in that Member's Schedule. In this case, we find that Argentina has acted inconsistently with its obligations under Article II:1(b), first sentence, of the GATT 1994, because the DIEM regime, by its structure and design, results, with respect to a certain range of import prices in any relevant tariff category to which it applies, in the levying of customs duties in excess of the bound rate of 35 per cent *ad valorem* in Argentina's Schedule.

56. We modify the Panel's findings in paragraphs 6.31 and 6.32 of the Panel Report accordingly.

B. Violation of Article II "In All Cases"

57. Argentina claims that the Panel erred in finding that it had infringed its obligations under Article II of the GATT 1994 "in all cases" in which it applied the DIEM. Argentina argues that the United States submitted evidence with respect to only 118 out of the approximately 940 relevant tariff categories in the

[37] Panel Report, para. 6.69.

Nomenclatura Común MERCOSUR ("N.C.M.").[38] Argentina further asserts that, had evidence in respect of the remaining tariff categories been examined, it would have shown that the application of the DIEM, on average over all tariff categories, had not exceeded the maximum level of binding in Argentina's Schedule.[39] On another ground, Argentina appeals the Panel's late admission into evidence of certain invoices and customs documents submitted by the United States relating to specific import transactions in six additional tariff categories.[40] We examine this separate ground of appeal in Part VI of this Report.

58. The Panel concluded that:

> In the light of the foregoing, we find that the United States has provided sufficient evidence that Argentina has effectively imposed duties on imports of textiles and apparel above 35 per cent *ad valorem*, that indeed the total amount of duties collected annually on these items leads to the conclusion that duties above 35 per cent *ad valorem* on the average transaction value have been imposed on the same items, and that in any case, as we found in paragraph 6.47 above, the very nature of the minimum specific duty system imposed in Argentina on the items at issue will inevitably lead, in certain instances, to the imposition of duties above 35 per cent *ad valorem*.[41]

59. We note that the Panel did *not* make a finding that Argentina had infringed its obligations under Article II of the GATT 1994 "in all cases" in which it applied the DIEM. In fact, the Panel stated that:

> As Argentina did not provide any affirmative evidence to the contrary, we consider that this US evidence provides reliable information that, on a tariff line basis, duties above the bound rate of 35 per cent *ad valorem* have been imposed. We agree that, if an average calculation shows duties above 35 per cent, this is evidence of a sufficient number of transactions which were subject to duties imposed above the 35 per cent *ad valorem*. The United States was able to demonstrate that Argentina had imposed and collected du-

---

[38] We note that the Panel appears to use the terms "category", "HS category", "line-item" and "tariff line" interchangeably. (See e.g. Panel Report, paras. 6.48, 6.52 and 6.54.) We also note that the parties, in their submissions to the Panel, sometimes used these terms interchangeably. (See e.g. pp. 8-10 of the United States' second written submission to the Panel.) In this Report, we use the term "tariff category" to refer to the relevant 6 or 8-digit subheading in the *Nomenclatura Común MERCOSUR* ("N.C.M.") applied by Argentina through Decree No. 2275/94 of 23 December 1994, as subsequently modified.

[39] Argentina's appellant's submission, paras. 70-72.

[40] Argentina's appellant's submission, paras. 106-110.

[41] Panel Report, para. 6.65.

> ties on the effective price of the import transactions at levels well above the bound rate of 35 per cent *ad valorem*.[42]

60. It is our understanding that Argentina is objecting to the Panel's conclusion that the application of the DIEM is inconsistent with Argentina's obligations under Article II of the GATT 1994 to the extent that this conclusion was based on the Panel's examination of evidence relating to only 118, or at most 124, tariff categories out of approximately 940 relevant tariff categories for textile and apparel products. We note that Argentina did not challenge the methodology employed by the Panel in examining the evidence submitted by the United States identifying 118 tariff categories which led it to conclude, on the basis of statistical data relating to the average value of transactions, that the *ad valorem* equivalents of Argentina's specific duties exceeded 35 per cent *ad valorem* in a "sufficient number of transactions".[43]

61. The real issue posed here by Argentina is whether the United States had adduced sufficient evidence to establish a *prima facie* case of inconsistency with Article II:1 of the GATT 1994 for all tariff categories covered by Chapters 51 to 63 of the N.C.M.. As we have noted above, the Panel stated that the statistical data submitted by the United States on the average import price of certain products in relation to the total amount of duties collected, "... provides *reliable information* that, on a tariff line basis, duties above the bound rate of 35 per cent *ad valorem* have been imposed."[44] (emphasis added) Furthermore, the Panel agreed with the United States that, "... if an average calculation shows duties above 35 per cent, this is *evidence of a sufficient number of transactions* which were subject to duties imposed above the 35 per cent *ad valorem*."[45] (emphasis added) The Panel also noted that Argentina had not submitted "any affirmative evidence to the contrary".[46] Argentina, in other words, did not successfully overcome the *prima facie* case established by the United States. We cannot find any error of law in the findings of the Panel based on the evidence submitted by the United States on average calculations relating to 118 tariff categories out of approximately 940 tariff categories for textile and apparel products.

62. As noted above, the Panel stated that "... the very nature of the minimum specific duty system imposed in Argentina on the items at issue will inevitably lead, *in certain instances*, to the imposition of duties above 35 per cent *ad valorem*."[47] (emphasis added) This reference to "in certain instances" indicates that the Panel did not conclude that there was infringement "in all cases". We recall our finding that the DIEM regime, by its structure and design, results in the application of specific duties with *ad valorem* equivalents exceeding 35 per cent for

---

42 Panel Report, para. 6.51.
43 *Ibid.*
44 *Ibid.*
45 *Ibid.*
46 *Ibid.*
47 *Ibid.*, para. 6.65.

all textile and apparel products imported at prices below the relevant "break-even" prices in the relevant tariff categories.[48] At the same time, products imported at prices above such "break-even" prices will be subject to a duty equivalent to 35 per cent or less *ad valorem*. This proposition holds for all relevant tariff categories relating to textile and apparel products to which the DIEM are applied. It is the result of Argentina requiring its customs officials to collect the higher of two values: the applicable *ad valorem* duty or the DIEM. It follows that, under such a system, the rate of duty applicable to any import transaction depends on the position of the imported product within the prevailing price range in any relevant tariff category. Thus, some transactions will fall within a price range where the application of the DIEM results in *ad valorem* equivalents exceeding 35 per cent. Other transactions, on the other hand, will fall within a price range where the application of the DIEM results in *ad valorem* equivalents less than, or equal to, 35 per cent. We agree with Argentina, therefore, that the application of the DIEM does not result in a breach of Article II for *each and every* import transaction in a given tariff category. At the same time, however, we agree with the Panel that there are sufficient reasons to conclude that the structure and design of the DIEM will result, with respect to a certain range of import prices within a relevant tariff category, in an infringement of Argentina's obligations under Article II:1 for all tariff categories in Chapters 51 to 63 of the N.C.M..

63. For these reasons, we find no legal basis on which to reverse the Panel's findings in paragraph 6.65 of the Panel Report.

V. THE STATISTICAL TAX AND ARGENTINA'S STATED COMMITMENTS TO THE IMF

64. At the time the Panel proceeding commenced, there was in effect in Argentina an *ad valorem* tax of 3 per cent on imports, without a minimum or a maximum charge, which was called a "statistical tax" and was described as designed to cover the cost of providing a statistical service intended to provide a reliable data base for foreign trade operators.[49] In respect of this statistical tax, the Panel found as follows:

> Consequently, following the GATT practice on the subject matter, we conclude that Argentina's statistical tax of three per cent *ad valorem*, in its present form, is in violation of Article VIII:1(a) of GATT to the extent it results in charges being levied in excess of

[48] See paras. 51-53 of this Report. We note that this "break-even" price will be the representative international price when the DIEM are calculated on the basis of the 35 per cent bound *ad valorem* rate. However, when the DIEM are calculated on the basis of a lower, applied rate, the "break-even" price will be lower than the representative international price.

[49] According to Argentina's statement at the oral hearing on 23 February 1998, this *ad valorem* statistical tax was modified to 0.5 per cent in December 1997.

> the approximate costs of the services rendered as well as being a measure designated for fiscal purposes.[50]

65. Argentina does not appeal the Panel's finding that the statistical tax is inconsistent with the substantive requirements of Article VIII of the GATT 1994. Rather, Argentina submits that the Panel erred in law in failing to take into account Argentina's obligations to the IMF in the Panel's interpretation of Article VIII. Argentina refers to the Memorandum on Economic Policy[51], that forms part of the panel record in this case, as a "Memorandum of Understanding" between Argentina and the IMF. Argentina states that this "Memorandum of Understanding" is a "simplified agreement" which includes an "undertaking" or an "obligation" on its part to collect a specified amount in the form of a statistical tax.[52] This obligation is said to be set out or reflected in the statement on page 7 of the Memorandum on Economic Policy that the fiscal measures to be adopted by Argentina include "... increases in import duties, including a temporary 3 per cent surcharge on imports".[53]

66. Argentina argues that in failing to consider its arguments about its obligations to the IMF and in failing to provide any reasons for not taking these arguments into account, the Panel disregarded its duty to make "an objective assessment of the matter" under Article 11 of the DSU. It is furthermore contended that the Panel, in ruling that the statistical tax is not consistent with Article VIII of the GATT 1994, failed to comply with the requirement in Article 12.7 of the DSU that "a panel shall set out ... the basic rationale behind any findings and recommendations that it makes."[54] Argentina argues still further that the Panel erred in law in failing to consider certain "subsequent legislative developments" - namely, the *Agreement Between the IMF and the WTO* and the *Declaration on Coherence*.[55] Paragraph 10 of the *Agreement Between the IMF and the WTO* and paragraph 5 of the *Declaration on Coherence* require, in the view of Argentina, that "the imposition on governments of cross-conditionality or additional conditions"[56] must be avoided.[57]

67. In the "Findings" section of the Panel Report, the Panel said:

> We find no exception in the WTO Agreement that would excuse Argentina's compliance with the requirements of Article VIII of GATT. Moreover, we see nothing in the Agreement Between the IMF and the WTO, the Declaration on the Relationship of the

---

50 Panel Report, para. 6.80.
51 Exhibit S to the United States' first written submission to the Panel.
52 Argentina's appellant's submission, para. 76.
53 Argentina's appellant's submission, para. 82, and response of Argentina to questioning at the oral hearing.
54 Argentina's appellant's submission, paras. 80-87.
55 Argentina's appellant's submission, para. 91.
56 *Declaration on Coherence*, para. 5.
57 Argentina's appellant's submission, paras. 95-96.

> World Trade Organization with the International Monetary Fund and the Declaration on the Contribution of the World Trade Organization to Achieving Greater Coherence in Global Economic Policymaking that suggests that we should interpret Article VIII as argued by Argentina.[58]

68. In Part V of its Report, under the heading "Interim Review", although not in its "Findings" section, the Panel offers some explanation as to why it did not address Argentina's arguments concerning cross-conditionalities or conflicts between Argentina's commitments to the IMF and its obligations under the *WTO Agreement*. The Panel stated:

> We see no reason to address this wider issue since, in the situation before the Panel, *there is no evidence that Argentina was requested by the International Monetary Fund* ("IMF") to impose an import tax that would violate the provisions of the WTO Agreement. Moreover, we see nothing in the Agreement Between the IMF and the WTO, the Declaration on the Relationship of the World Trade Organization with the International Monetary Fund and the Declaration on the Contribution of the World Trade Organization to Achieving Greater Coherence in Global Economic Policymaking that suggests that we should change our approach.[59] (emphasis added)

69. Implicit in the above statement is the Panel's belief that Argentina had not successfully shown that it was required under an agreement with the IMF to impose the statistical tax.[60] Indeed, the Panel does not appear to have been convinced that Argentina had a legally binding agreement with the IMF at all. From the panel record in this case, it does not appear possible to determine the precise legal nature of this Memorandum on Economic Policy, nor the extent to which commitments undertaken by Argentina in this Memorandum constitute legally binding obligations. We note that page 7 of the Memorandum on Economic Policy refers to "a temporary 3 percent surcharge on imports", which is not necessarily the same thing as the 3 per cent statistical tax levied on imports. Argentina did not show an irreconcilable conflict between the provisions of its "Memorandum of Understanding" with the IMF and the provisions of Article VIII of the GATT 1994. We thus agree with the Panel's implicit finding that Argentina failed to demonstrate that it had a legally binding commitment to the IMF that would

---

58 Panel Report, para. 6.79.

59 *Ibid.*, para. 5.3.

60 We note that the Panel's statement in paragraph 6.79 of the Panel Report that Argentina "... does not argue that it is required to impose this specific tax in order to meet its commitments to the IMF" is not, strictly speaking, accurate, as it does not reflect Argentina's arguments before the Panel or before the Appellate Body in this appeal. See Panel Report, para. 3.276, and Argentina's appellant's submission, paras. 73-105.

somehow supersede Argentina's obligations under Article VIII of the GATT 1994.

70. We also agree with the Panel that there is nothing in the *Agreement Between the IMF and the WTO*, the *Declaration on the Relationship of the WTO with the IMF* or the *Declaration on Coherence* which justifies a conclusion that a Member's commitments to the IMF shall prevail over its obligations under Article VIII of the GATT 1994. The 1994 *Declaration on Coherence* is a Ministerial decision that articulates the objective of promoting increased cooperation between the WTO and the IMF in order to encourage greater coherence in global economic policy-making. This objective is more explicitly recognized in the treaty language of the *WTO Agreement* in Article III:5, which states:

> With a view to achieving greater coherence in global economic policy-making, *the WTO shall cooperate, as appropriate*, with the International Monetary Fund and with the International Bank for Reconstruction and Development and its affiliated agencies. (emphasis added)

71. In furtherance of the WTO's mandate to "cooperate, as appropriate" with the IMF, the *Agreement Between the IMF and the WTO* was concluded in 1996.[61] This Agreement provides for specific means of administrative cooperation between the two organizations. It provides for consultations and the exchange of information between the WTO Secretariat and the staff of the IMF in certain specified circumstances, and grants to each organization observer status in certain of the other's meetings.[62]

72. The *Agreement Between the IMF and the WTO*, however, does *not* modify, add to or diminish the rights and obligations of Members under the *WTO Agreement*, nor does it modify individual States' commitments to the IMF. It does not provide any substantive rules concerning the resolution of possible conflicts between obligations of a Member under the *WTO Agreement* and obligations under the Articles of Agreement of the IMF or any agreement with the IMF. However, paragraph 10 of the *Agreement Between the IMF and the WTO* contains a direction to the staff of the IMF and the WTO Secretariat to *consult* on "issues of *possible inconsistency* between *measures under discussion*".

73. In the 1994 *Declaration on the Relationship of the WTO with the IMF*, Ministers reaffirmed that, unless otherwise provided for in the *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, "the relationship of the WTO with the International Monetary Fund, with regard

---

[61] Done at Singapore, 9 December 1996.

[62] Excluding the DSB and dispute settlement panels, except where "matters of jurisdictional relevance to the Fund are to be considered". The WTO may invite a member of the staff of the Fund to attend a meeting of DSB "when the WTO, after consultation between the WTO Secretariat and the staff of the Fund, finds that such a presence would be of particular common interest to both organizations." *Agreement Between the IMF and the WTO*, para. 6.

to the areas covered by the Multilateral Trade Agreements in Annex 1A of the WTO Agreement, will be based on the provisions that have governed the relationship of the CONTRACTING PARTIES to the GATT 1947 with the International Monetary Fund." We note that certain provisions of the GATT 1994, such as Articles XII, XIV, XV and XVIII, permit a WTO Member, in certain specified circumstances relating to exchange matters and/or balance of payments, to be excused from certain of its obligations under the GATT 1994. However, Article VIII contains no such exception or permission.

74. We agree, therefore, with the Panel that there is "nothing in the Agreement Between the IMF and the WTO, the Declaration on the Relationship of the World Trade Organization with the International Monetary Fund and the Declaration on the Contribution of the World Trade Organization to Achieving Greater Coherence in Global Economic Policymaking"[63] that modifies Argentina's obligations under Article VIII of the GATT 1994. We also agree with the Panel that there is "... no exception in the WTO Agreement that would excuse Argentina's compliance with the requirements of Article VIII of GATT."[64] There does not appear to be anything in the *WTO Agreement* or in the other legal instruments cited by Argentina that would relieve a Member from its obligations under Article VIII of the GATT 1994. For these reasons, we uphold the Panel's findings in paragraphs 6.79 and 6.80 of the Panel Report.

VI. OBJECTIVE ASSESSMENT OF THE MATTER UNDER ARTICLE 11 OF THE DSU

75. Argentina makes two claims under Article 11 of the DSU. It submits that the Panel acted inconsistently with Article 11 in: (i) admitting certain evidence submitted by the United States two days before the second substantive meeting of the Panel with the parties, and granting Argentina only two weeks to respond; and (ii) not seeking information from, and consulting with, the IMF to obtain its opinion on specific aspects of the matter relating to the statistical tax imposed by Argentina.[65] We examine each of these arguments in turn.

76. Article 11 of the DSU states in part:

> The function of panels is to assist the DSB in discharging its responsibilities under this Understanding and the covered agreements. Accordingly, a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements, and make such other findings as will

[63] Panel Report, para. 6.79.
[64] *Ibid.*
[65] Argentina's appellant's submission, paras. 106-114.

> assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements. ...

A. Admission of Certain Evidence

77. Argentina submits that the Panel acted inconsistently with Article 11 of the DSU by admitting certain evidence offered by the United States two days before the second substantive meeting of the Panel with the parties. This evidence consisted of approximately 90 invoices and customs documents purporting to show specific cases in which Argentina had applied duties in excess of its 35 per cent *ad valorem* tariff binding.[66] At the second substantive meeting of the Panel with the parties, Argentina requested the Panel to reject this evidence on the grounds that it had been submitted too late in the panel process and that, because of the blacking-out of certain information from these documents, it would be impossible for Argentina to respond to this evidence. These documents related to customs operations or transactions carried out using the manual customs clearance system rather than the MARIA computerized system which, Argentina states, made it impossible to verify the information within the time period granted by the Panel.[67] The Panel ruled that it would admit this evidence, but allowed Argentina two weeks to respond to it.

78. Paragraph 6.55 of the Panel Report reads, in part, as follows:

> We note that the rules of procedures of panels do not prohibit the practice of submitting additional evidence after the first hearing of the Panel. Until the WTO Members agree on different and more specific rules on this regard, our main concern is to ensure that "due process" is respected and that all parties to a dispute are given all the opportunities to defend their position to the fullest extent possible. In light of the difficulties faced by Argentina in responding to this evidence on such a short notice, we decided to accept this additional evidence on the understanding that Argentina would have a period of two weeks to provide further comments on these additional invoices and customs documents. Argentina informed the Panel that it would not be submitting any further comment.

79. Article 11 of the DSU does not establish time limits for the submission of evidence to a panel. Article 12.1 of the DSU directs a panel to follow the Working Procedures set out in Appendix 3 of the DSU, but at the same time authorizes a panel to do otherwise after consulting the parties to the dispute. The Working Procedures in Appendix 3 also do not establish precise deadlines for the presen-

---

[66] See Panel Report, paras. 3.179 and 6.55.
[67] Argentina's appellant's submission, paras. 107-108.

tation of evidence by a party to the dispute.[68] It is true that the Working Procedures "do not prohibit" submission of additional evidence after the first substantive meeting of a panel with the parties. It is also true, however, that the Working Procedures in Appendix 3 do contemplate two distinguishable stages in a proceeding before a panel. Paragraphs 4 and 5 of the Working Procedures address the first stage in the following terms:

> 4. Before the first substantive meeting of the panel with the parties, the parties to the dispute shall transmit to the panel written submissions in which they present the facts of the case and their arguments.
>
> 5. At its first substantive meeting with the parties, the panel shall ask the party which has brought the complaint to present its case. Subsequently, and still at the same meeting, the party against which the complaint has been brought shall be asked to present its point of view.

The second stage of a panel proceeding is dealt with in paragraph 7 which states:

> 7. Formal rebuttals shall be made at a second substantive meeting of the panel. The party complained against shall have the right to take the floor first to be followed by the complaining party. The parties shall submit, prior to that meeting, written rebuttals to the panel.

Under the Working Procedures in Appendix 3, the complaining party should set out its case in chief, including a full presentation of the facts on the basis of submission of supporting evidence, during the first stage. The second stage is generally designed to permit "rebuttals" by each party of the arguments and evidence submitted by the other parties.

80. As noted above, however, the Working Procedures in their present form do not constrain panels with hard and fast rules on deadlines for submitting evidence. The Panel could have refused to admit the additional documentary evidence of the United States as unseasonably submitted. The Panel chose, instead, to admit that evidence, at the same time allowing Argentina two weeks to respond to it. Argentina drew attention to the difficulties it would face in tracing and verifying the manually processed customs documents and in responding to them, since identifying names, customs identification numbers and, in some cases, descriptions of the products had been blacked out. The Panel could well have granted Argentina more than two weeks to respond to the additional evidence. However, there is no indication in the panel record that Argentina explicitly re-

---

[68] As we have observed in two previous Appellate Body Reports, we believe that detailed, standard working procedures for panels would help to ensure due process and fairness in panel proceedings. See *European Communities - Regime for the Importation, Sale and Distribution of Bananas*, adopted 25 September 1997, WT/DS27/AB/R, para. 144; *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, adopted 16 January 1998, WT/DS50/AB/R, para. 95.

quested from the Panel, at that time or at any later time, a longer period within which to respond to the additional documentary evidence of the United States. Argentina also did not submit any countering documents or comments in respect of any of the additional documents of the United States.

81. Accordingly, while another panel could well have exercised its discretion differently, we do not believe that the Panel here committed an abuse of discretion amounting to a failure to render an objective assessment of the matter as mandated by Article 11 of the DSU.

B. *Consultation with the IMF*

82. Argentina also argues that the Panel failed to make "an objective assessment of the matter", as required by Article 11 of the DSU, by not acceding to the request of the parties to seek information from, and consult with, the IMF so as to obtain its opinion on specific aspects of the matter concerning the statistical tax.[69] The DSU gives panels different means or instruments for complying with Article 11; among these is the right to "seek information and technical advice" provided in Article 13 of the DSU. Argentina maintains that the Panel did not make use of this right, which would have allowed it to verify the information provided by the parties, and which might have altered the Panel's findings regarding the statistical tax.[70]

83. During the panel proceedings, the United States argued that Argentina had not demonstrated that the imposition of a 3 per cent statistical tax was required, or even requested, by the IMF, and invited the Panel to consult with the IMF to ascertain whether it had asked Argentina to impose the tax.[71] In its appellant's submission, Argentina states that it too requested "consultations" with the IMF by the Panel.[72]

84. The only provision of the *WTO Agreement* that *requires* consultations with the IMF is Article XV:2 of the GATT 1994. This provision *requires* the WTO to consult with the IMF when dealing with "problems concerning monetary reserves, balances of payments or foreign exchange arrangements".[73] However, this case does not relate to these matters. Article 13.1 of the DSU gives a panel "... the right to seek information and technical advice from any individual or body which *it deems appropriate*." (emphasis added) Pursuant to Article 13.2 of the DSU, a panel may seek information from any relevant source and may consult

---

[69] Argentina's appellant's submission, para. 111.

[70] *Ibid.*, paras. 111-112.

[71] Opening statement of the United States at the first meeting of the Panel with the parties, p. 8 and second submission of the United States to the Panel, pp. 25-26. Also see Panel Report, para. 3.281.

[72] Argentina's appellant's submission, para. 90, referring to Panel Report, para. 3.294.

[73] Furthermore, Article XV:2 states that, in such consultations, the WTO "... shall accept all findings of statistical and other facts presented by the Fund relating to foreign exchange, monetary reserves and balances of payments, and shall accept the determination of the Fund as to whether action by a Member in exchange matters is in accordance with the Articles of Agreement of the International Monetary Fund ...".

experts to obtain their opinions on certain aspects of the matter at issue. This is a grant of discretionary authority: a panel is not duty-bound to seek information in each and every case or to consult particular experts under this provision. We recall our statement in *EC Measures Concerning Meat and Meat Products (Hormones)* that Article 13 of the DSU enables a panel to seek information and technical advice as it deems appropriate in a particular case, and that the DSU leaves "to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate."[74] Just as a panel has the discretion to determine how to seek expert advice, so also does a panel have the discretion to determine whether to seek information or expert advice at all.

85. As in the *WTO Agreement*, there are no provisions in the *Agreement Between the IMF and the WTO* that *require* a panel to consult with the IMF in a case such as this. Under paragraph 8 of this latter Agreement, in a case involving "exchange measures within the Fund's jurisdiction", the IMF "shall inform in writing the relevant WTO body (including dispute settlement panels) ... whether such measures are consistent with the Articles of Agreement of the Fund." This case does not, however, involve "exchange measures within the Fund's jurisdiction". Paragraph 8 also provides that the IMF "may communicate its views in writing on matters of mutual interest to the [WTO] or any of its organs or bodies (*excluding the WTO's dispute settlement panels*) ..." (emphasis added). Evidently, the IMF has not been authorized to provide its views to a WTO dispute settlement panel on matters *not* relating to exchange measures within its jurisdiction, unless it is requested to do so by a panel under Article 13 of the DSU.

86. In this case, we find that the Panel acted within the bounds of its discretionary authority under Articles 11 and 13 of the DSU in deciding not to seek information from, nor to consult with, the IMF. While it might perhaps have been useful for the Panel to have consulted with the IMF on the legal character of the relationship or arrangement between Argentina and the IMF in this case, we believe that the Panel did not abuse its discretion by not seeking information or an opinion from the IMF. For these reasons, we find that the Panel did not violate Article 11 of the DSU by not seeking information from, and consulting with, the IMF so as to obtain its opinion on specific aspects of the matter concerning the statistical tax imposed by Argentina.

VII. FINDINGS AND CONCLUSIONS

87. For the reasons set out in this Report, the Appellate Body:

(a) modifies the Panel's findings in paragraphs 6.31 and 6.32 of the Panel Report by concluding that the application of a type of duty different from the type provided for in a Member's Schedule is in-

[74] Adopted 13 February 1998, WT/DS26/AB/R, WT/DS48/AB/R, para. 147.

consistent with Article II:1(b), first sentence, of the GATT 1994 to the extent that it results in ordinary customs duties being levied in excess of those provided for in that Member's Schedule. In this case, Argentina has acted inconsistently with its obligations under Article II:1(b), first sentence, of the GATT 1994, because the DIEM regime, by its structure and design, results, with respect to a certain range of import prices in any relevant tariff category to which it applies, in the levying of customs duties in excess of the bound rate of 35 per cent *ad valorem* in Argentina's Schedule;

(b) concludes that the Panel did not err in finding that Argentina had acted inconsistently with its obligations under Article II of the GATT 1994 "in all cases" in which Argentina applied the DIEM, and, therefore, upholds the findings of the Panel in paragraph 6.65 of the Panel Report;

(c) upholds the findings of the Panel in paragraphs 6.79 and 6.80 of the Panel Report; and

(d) concludes that the Panel did not violate Article 11 of the DSU in: (i) admitting certain evidence submitted by the United States two days prior to the second substantive meeting of the Panel with the parties, and granting Argentina two weeks to respond; and (ii) not seeking information from, and consulting with, the IMF so as to obtain its opinion on specific aspects of the matter concerning the statistical tax imposed by Argentina.

88. The Appellate Body *recommends* that the Dispute Settlement Body request Argentina to bring its measures found in this Report and in the Panel Report, as modified by this Report, to be inconsistent with the GATT 1994 into conformity with the obligations of Argentina under the GATT 1994.

Signed in the original at Geneva this 11th day of March 1998 by:

ARGENTINA - MEASURES AFFECTING IMPORTS OF FOOTWEAR, TEXTILES, APPAREL AND OTHER ITEMS

Report of the Panel
WT/DS56/R

Adopted by the Dispute Settlement Body on 22 April 1998
as modified by the Appellate Body Report

TABLE OF CONTENTS

Page

Page

Page

I. INTRODUCTION

1.1 On 4 October 1996, the United States requested Argentina to hold consultations pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), Article XXII:1 of the General Agreement on Tariffs and Trade 1994 ("GATT 1994"), Article 14 of the Agreement on Technical Barriers to Trade ("TBT Agreement"), Article 19 of the Agreement on Implementation of Article VII of the GATT 1994 ("Customs Valuation Agreement"), and Article 7 of the Agreement on Textiles and Clothing ("ATC"), regarding certain measures maintained by Argentina affecting imports of footwear, textiles, apparel and other items, namely, measures imposing specific duties on various footwear, textiles and apparel in excess of the bound rate of 35 per cent *ad valorem* provided in Argentina's Schedule LXIV; a statistical tax of three per cent *ad valorem* on imports of all sources other than MERCOSUR countries; and measures imposing, *inter alia*, labelling requirements related to affidavits of product components (WT/DS56/1).

1.2 Pursuant to Article 4.11 DSU, Hungary requested to be joined in these consultations on 21 October 1996 (WT/DS56/2). The European Communities ("EC") made a similar request on 25 October 1996 (WT/DS56/3). In separate communications dated 6 November 1996, Argentina accepted the request of Hungary and the request of the EC to join the consultations which the United States had requested (WT/DS56/4).

1.3 During the consultations, a mutually agreed solution was reached between the United States and Argentina regarding Argentina's labelling requirements. However, the parties failed to reach a mutually satisfactory solution on the other aspects raised during the consultations.

1.4 On 9 January 1997, the United States requested the Dispute Settlement Body ("DSB") to establish a panel (WT/DS56/5). The United States claimed that Argentina's measures were "inconsistent with the obligations of Argentina under Articles II, VII, VIII and X of the GATT 1994; Articles 1 through 8 of the Agreement on Implementation of Article VII of the GATT 1994; and Article 7 of the Agreement on Textiles and Clothing".

1.5 On 25 February 1997, the DSB established a panel pursuant to the request made by the United States, in accordance with Article 6 DSU. In document WT/DS56/6, the Secretariat reported that the parties had agreed that the Panel would have the standard terms of reference as follows:

> "to examine, in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS56/5, the matter referred to the DSB by the United States in that document and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements".

1.6 The same document WT/DS56/6 reported the constitution of the Panel on 4 April 1997 with the following composition:

Chairman:	Mr. Peter Palecka
Members:	Ms. Heather Forton
	Mr. Peter May

1.7 The EC, Hungary and India reserved their rights to participate in the Panel proceedings as third parties, and all presented arguments to the Panel.

1.8 The Panel met with the parties on 17-18 June 1997 and 23 July 1997. It met with third parties on 17 June 1997. The Panel issued its interim report to the parties on 30 September 1997. Both parties requested the panel to review parts of the interim report. None of them requested the panel to hold an additional meeting.

II. FACTUAL ASPECTS

A. Argentina's Import Regime For Textiles, Apparel and Footwear

2.1 The great majority of Argentina's import tariffs are fixed in *ad valorem* terms. Regarding textiles, clothing and footwear, Argentina maintained a regime of minimum specific import duties as from 1993. This regime was applied through *resoluciónes* (resolutions) and *decretos* (decrees) having fixed terms.

2.2 Argentina approved the results of the Uruguay Round through Law No. 24.425, promulgated on 23 December 1994. These results included a bound rate of duty of 35 per cent *ad valorem* with respect to textiles, apparel and footwear imported into Argentina. In parallel, Argentina continued to apply a system of minimum specific import duties in the footwear, textile and apparel sectors. Regarding footwear, the minimum specific duty was revoked in 1997. Provisional safeguard measures were applied in that sector on 25 February 1997.

2.3 Concurrently, since 1989, Argentina applied a tax on imported products intended to finance statistical services to importers, exporters and the general public.

2.4 The Panel procedure concerned the Argentine measures adopted in order to apply the above-mentioned regime, as established and maintained *inter alia*

through the laws, decrees and resolutions referred to below. The latest measures adopted at the time of the request for the establishment of the Panel (9 January 1997) were, for textiles and apparel, Resolution No. 22/97 of 7 January 1997, extending the validity of the minimum specific import duties for those sectors until 31 August 1997,[1] for footwear Resolution No. 23/97 of 7 January 1997, extending the validity of the minimum specific import duties for that sector until 31 August 1997[2] and, with respect to the statistical services tax, Presidential Decree No. 389/95 of 22 March 1995. On 25 February 1997, the date of establishment of the Panel by the DSB, the minimum specific import duties for the tariff headings contained in Harmonized System ("HS") Chapter 64 (footwear) and listed in Annex IX to Decree No. 998/95, as amended, had been repealed by Resolution No. 225/97, dated 14 February 1997. Further to the initiation of a safeguard investigation, provisional safeguard measures in the form of minimum specific import duties became applicable on 25 February 1997 to certain imports of footwear in application of Resolution No. 226/97.[3]

B. Minimum Specific Import Duties ("DIEM")

1. Stated Purpose and Functioning of the Minimum Specific Import Duties

2.5 The stated purpose of the minimum specific import duties, also referred to as "DIEM",[4] was to counteract injury allegedly suffered by Argentine manufacturers as a result of imports of textiles, apparel and footwear at prices lower than the production costs in the countries of origin or lower than international prices.[5]

2.6 The system operated as follows: for each relevant HS tariff line of textiles, apparels and footwear, Argentina calculated an *average import price*. Once it had determined the average import price for a particular category, Argentina multiplied that price by the bound rate of 35 per cent, resulting in a specific minimum duty for all products in that category. Upon the importation of covered textiles, apparel or footwear, depending on the customs value of the goods concerned, Argentina applied either the specific minimum duty applicable to those items or the *ad valorem* rate, whichever was higher.

---

1 *Boletín Oficial de la República Argentina*, No. 28.561 of 10 January 1997.
2 *Ibid.*
3 *Boletín Oficial de la República Argentina*, No. 28.592 of 24 February 1997.
4 For *Derechos de Importación Específicos Mínimos* (minimum specific import duties).
5 See, e.g., preambles of Resolutions No. 811/93 (textiles and apparel) and No. 1696/93 (footwear).

2. Minimum Specific Import Duties on Textiles and Apparel

2.7 Minimum specific import duties were originally applied by Argentina to approximately 200 categories of textiles and apparel by Resolution No. 811/93 of the Argentine Ministry of Economy, and Public Works and Services of 29 July 1993.[6] Article 3 of the Resolution provided that the specific import duties established by Article 1 were to operate as a minimum of the corresponding *ad valorem* import duty. The categories of products to which the minimum specific duties applied were listed, together with the duties, in Annex I to the Resolution. The minimum specific import duties established by the Resolution were to remain valid until 31 January 1995, with the possibility of a single, non-renewable extension of six months.

2.8 As a result of the Uruguay Round of multilateral trade negotiations, Argentina included in its Schedule of Concessions (Schedule LXIV) a maximum duty rate of 35 per cent *ad valorem*.[7] This bound rate became effective on 1 January 1995. It was generally applicable to imports, with certain specified exceptions for products subject to a different level of binding.

2.9 After the entry into force of the Uruguay Round results, Argentina continued to apply the minimum specific import duties. Presidential Decree No. 2275/94 of 23 December 1994 extended the application of these specific duties until 31 December 1995 and expanded the number of affected categories of merchandise.[8] Pursuant to Article 15 and Annex XII to the Decree, minimum specific import duties applied to categories of textiles and apparel (HS Chapters 51 to 63) and footwear (HS Chapter 64).

2.10 Presidential Decree No. 2275/94 was modified, on 22 September 1995, by two resolutions of the Argentine Ministry of Economy and Public Works and Services. Resolution No. 304/95 applied to textiles and apparel and modified the specific duties applicable. It increased the rate of the formerly established specific duties for a number of textiles and apparel tariff lines. Resolution No. 305/95 applied to footwear.

2.11 The application of the minimum specific import duties on textiles and apparel was extended until 31 December 1996 by Article 9 of Presidential Decree No. 998/95 of 28 December 1995.[9] This Decree was amended through Resolution No. 299/96 of the Ministry of Economy and Public Works and Services of 20 February 1996, which, *inter alia*, modified the specific duties applicable to imports of nylon carpeting, towels and undergarments.

---

6 *Boletín Oficial de la República Argentina*, No. 27.692 of 2 August 1993.

7 See Argentina's Schedule LXIV, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations done at Marrakesh on 15 April 1994. Members' schedules of concessions are hereafter referred to as their "Schedules".

8 *Boletín Oficial de la República Argentina*, No. 28.050 of 30 December 1994.

9 *Boletín Official de la República Argentina*, No. 28.301 of 29 December 1995.

2.12 As of 1 January 1997, the Ministry of Economy and Public Works and Services extended the application of the minimum specific import duties until 31 August 1997 through Resolution No. 22/97.[10]

2.13 The minimum specific import duties on textile and apparel products were finally modified by Resolution No. 597/97 of the Ministry of Economy and Public Works and Services of 14 May 1997.[11] This Resolution modified Annex IX to Decree No. 998/95 for a series of tariff positions. For some of these, minimum specific duties were progressively reduced. The Resolution called for reductions to take place on five dates between 1 June 1997 and 1 April 1998.

3. Minimum Specific Duties on Footwear

2.14 Measures similar to the specific duties applicable to textiles and apparel were applied to imports of footwear. Through Resolution No. 1696/93 of 28 December 1993,[12] the Argentine Ministry of Economy and Public Works and Services instituted minimum specific import duties on certain categories of athletic shoes. Article 5 of the Resolution provided that the specific import duties established by Article 4 were to operate as a minimum of the corresponding *ad valorem* import duty. Article 6 provided that the Resolution was to apply until 31 December 1994, with the possibility of a single, non-renewable extension of six months. As for the minimum specific import duties on textiles and apparel, the specific import duties on footwear were to be levied only in the event that they resulted in the payment of a higher tariff than the relevant *ad valorem* duty.[13] Resolution No. 1696/93 applied only to products from countries outside the Southern Common Market (MERCOSUR) or the Latin American Integration Association (LAIA).[14]

2.15 The minimum specific import duties on footwear were maintained after the entry into force of the Uruguay Round results. As for textiles and apparel, Presidential Decree No. 2275/94 of 23 December 1994 extended the application of the specific duties on footwear until 31 December 1995. Their application was further extended until 31 December 1996 by Article 9 of Presidential Decree No. 998/95. Resolution No. 305/95 of 22 September 1995 increased the specific duties for certain categories of footwear and amended the list of footwear tariff lines to which the minimum specific import duties were applicable.

2.16 Through Resolution No. 103/96 of 6 September 1996, Argentina's Ministry of Economy and Public Works and Services amended the level of specific duties applied on certain footwear categories. Reductions in the rate of duty were to occur in four phases through January 1998.

---

[10] *Boletín Oficial de la República Argentina*, No. 28.561 of 10 January 1997.
[11] *Boletín Oficial de la República Argentina*, No. 28.650 of 20 May 1997.
[12] *Boletín Official de la República Argentina*, No. 27.797 of 30 December 1993.
[13] See Resolution No. 1696/93, Article 5.
[14] *Ibid.*, Article 7.

2.17 The specific duties on footwear HS categories as set forth in Decree No. 998/95 as amended by Resolution No. 103/96 were renewed by Resolution No. 23/97 until 31 August 1997.[15]

2.18 On 14 February 1997, the Argentine Ministry of Economy and Public Works and Services adopted Resolution No. 225/97, revoking all minimum specific import duties on footwear. The same day, the Ministry of Economy and Public Works and Services, through Resolution No. 226/97,[16] initiated a safeguard investigation and imposed provisional safeguard measures. On 21 February 1997, Argentina notified the Committee on Safeguards of the World Trade Organization of the initiation of an investigation and the reasons for it as well as of its intention to adopt provisional safeguard measures.[17] The provisional safeguard duties became effective on 25 February 1997.

C. Statistical Tax

2.19 The statistical tax at issue in this case was regulated by Articles 762 to 766 of the Argentine Customs Code (Law No. 22.415). In 1961, a tax intended to finance a statistical service had been imposed through Decree No. 6123/61. In application of Law No. 23.664, adopted in 1989 and relating to Articles 762 to 766 of the Argentine Customs Code,[18] Argentina imposed, until 1994, a three per cent *ad valorem* tax which related to the collection of statistical information by the Argentine customs service regarding imports and exports. Through Presidential Decree No. 2277/94 adopted on 23 December 1994[19] pursuant to Article 764 of the Customs Code, the tax was reduced to zero per cent in order (a) "to remove all those factors that may complicate the process of economic integration and openness";[20] (b) "to eliminate those factors that can make difficult the free circulation of goods";[21] and (c) "to neutralize the effect on foreign trade that the statistical tax [...] in force in [Argentina] may cause".[22] On 22 March 1995, Presidential Decree No. 389/95 set the level of the statistical tax at three per cent. The statistical tax was applied to import transactions with a view to providing a general statistical service. According to Article 762 of the Argentine Customs Code, the tax was to be applied on an *ad valorem* basis. The tax did not apply to goods exported to any destination in suspensive or definitive form for consumption. It applied to all imports except for articles subject to a temporary import

---

15 *Boletín Oficial de la República Argentina* No. 28.561 of 10 January 1997.
16 *Boletín Oficial de la República Argentina*, No. 28.592 of 24 February 1997.
17 Document G/SG/N/6/ARG/1, G/SG/N/7/ARG/1, 25 February 1997.
18 *Boletín Oficial de la República Argentina*, No. 26.652 of 12 June 1989.
19 *Boletín Oficial de la República Argentina*, No. 28.050 of 30 December 1994.
20 Decree No. 2277/94 first preambular paragraph. The original in Spanish reads *"remover todos aquellos factores que puedan dificultar dicho proceso de apertura e integración económica"*.
21 *Ibid.*, third preambular paragraph. The original in Spanish reads: *"eliminarse todos aquellos factores que pueden dificultar la libre circulacion de bienes"*.
22 *Ibid.*, fourth preambular paragraph. The original in Spanish reads *"neutralizar los efectos que, en el comercio exterior, puede producir la tasa de estadística [...] vigente en [Argentina]"*.

regime, articles originating in MERCOSUR Member States, imported goods subject to the MERCOSUR common external tariff rate of zero percent, selected imported capital goods, goods related to data processing and telecommunications and certain other categories under the Common Nomenclature of MERCOSUR. The Ministry of Economy and Public Works and Services was authorized by Decree No. 389/95 to establish the appropriate exceptions in every case.

2.20 The purpose of Argentina's import tax was to recover the cost of the statistical service rendered in respect of Argentine import and export transactions. The first paragraph of the preamble of the Decree stated that "it was necessary to provide for the necessary tax collection to contribute to the financing of customs activities related to the registration, computing and data processing of export and import information, in order to rely upon Foreign Trade statistics in rapid and flexible form".[23] This service was not provided to importers on an individual basis, *i.e.* to the specific importer concerned by the relevant transaction on which the statistical tax was levied, but benefited foreign trade operators in general and foreign trade as an activity in itself. The service consisted in the recording of trade information, subsequent processing and publication, and distribution to the public in general. Argentina's customs administration registered the information relating to prices, quantities, description, quality and classification of the goods in the desegregated form required for purposes of control, valuation and assessment of the taxes. This information was standardized and transmitted to the National Statistical and Census Institute[24] of Argentina for purposes of analysis and subsequent processing, and a compilation of the information was published. At the same time, the basic data were also transmitted to the Departments of Agriculture, Mining, Fuel, Tourism, Transport and Industry and Trade, for analysis and processing. This exercise resulted in publications and statistical material which was made available to foreign trade operators.

2.21 The tax was bound in Argentina's Schedule LXIV under the heading "other duties and charges" at three per cent *ad valorem*.

III. CLAIMS AND MAIN ARGUMENTS

3.1 The **United States** asked the Panel to find that:

(a) Decree No. 998/95, Resolution No. 299/96, and Resolution No. 22/97, which imposed specific duties on textiles and apparel violated Articles II:1(a) and II:1(b) GATT 1994 and Article 7 ATC;

---

[23] Decree No. 389/95, first preambular paragraph. The original in Spanish reads *"prever la recaudación necesaria para contribuir al financiamiento de las actividades aduaneras vinculadas con la registración, computo y sistematización de la información de importación y exportación, con el fin de contar con estadísticas de Comercio Exterior en forma ágil y rápida"*.

[24] *Instituto Nacional de Estadísticas y Censos (INDEC).*

(b) Decree No. 389/95, which applied a tax on imports, violated Article VIII GATT 1994 and Article 7 ATC; and

(c) Decree No. 2275/94, Resolution No. 305/95, Decree No. 998/95, Resolution No. 103/96, and Resolution No. 23/97, which applied specific duties on footwear until February 1997, violated Articles II:1(a) and II:1(b) GATT 1994.

The United States also requested that the Panel include within its review "other measures which impose specific duties on various textile, apparel and footwear items in excess of the bound rate of 35 per cent *ad valorem* provided in Argentina's Schedule LXIV".[25]

3.2 Pursuant to Article 3.8 DSU, the United States further requested the Panel to conclude that the measures identified in (a) and (b) above nullified or impaired benefits accruing to the United States under the WTO Agreement and the measures identified in (c) nullified or impaired such benefits as well.

3.3 The United States requested that the Panel recommend that Argentina bring its measures into conformity with its obligations under GATT 1994 and the ATC.

3.4 **Argentina** asked the Panel to find that:

(a) As a special preliminary ruling, there were no grounds for it to consider the question raised by the United States in connection with the application of minimum specific import duties to imports of footwear as the duties in question had been eliminated before the Panel was established;

(b) The application of the specific duties in force, to the extent that they did not exceed the "*ad valorem* equivalent" of Argentina's bound rate of 35 per cent under the WTO Agreement, was not inconsistent with Argentina's obligations under Articles II:l(a) and II:1(b) GATT 1994 and Article 7 ATC;

(c) The statistical tax applied by Argentina was consistent with Article VIII GATT 1994.

3.5 On the basis of the above, Argentina requested the Panel to reject the claim by the United States that the measures adopted by Argentina nullified or impaired benefits accruing to the United States.

[25] WT/DS56/5.

A. Requests for Preliminary Rulings by the Panel

1. Request of Argentina for a Special Preliminary Ruling Regarding the Inclusion of the Measures on Footwear in the Submissions of the United States

3.6 **Argentina** requested the Panel to issue a special preliminary ruling to the effect that there were no grounds for the Panel to examine the claims of the United States regarding an alleged violation of Article II as a result of the application of minimum specific import duties on imports of footwear. According to Argentina, the United States had asked the Panel to find that a measure was inconsistent in spite of the fact that it was no longer in effect at the time when the Panel was established. Argentina asked that its request be examined by the Panel before proceeding to address the question of substance as requested by the United States and continuing with the examination of the case.

(a) Potentiality of a Reintroduction of the DIEM on Imports of Footwear

3.7 The **United States** argued that Argentina's revocation of the footwear specific duties during the dispute settlement process should not prevent the Panel from determining that the measures imposing them were contrary to Article II GATT 1994. Previous panels had reviewed the consistency with the GATT of measures no longer in effect.[26] Such review was especially appropriate in this case given that Argentina may impose the footwear specific duties again in the future.[27] The likelihood that Argentina would restore its footwear specific duties was indeed considerable. Argentina had repeatedly renewed them in the past, even after having received repeated objections from its trading partners. Argentina also may restore the footwear minimum specific import duties when the provisional measures that replaced them would have expired.

3.8 The United States added that, alternatively, Argentina might reinstate the footwear specific duties should a subsequent panel rule that its "safeguard" measures were improper. There were significant reasons to believe that such a result would occur. The Argentine "safeguard" rested on a weak foundation. The Argentine Ministry of Economy and Public Works and Services, in its technical report preceding the imposition of safeguard relief, had found that "critical circumstances would only have occurred if the Minimum Specific Duties had been

[26] The United States referred to the Panel Reports on *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, adopted on 23 May 1997, WT/DS33/R, para. 8.1; and *EEC - Measures on Animal Feed Proteins*, adopted on 14 March 1978, BISD 25S/49.

[27] The United States referred to the Panel Report on *United States - Prohibition on Imports of Tuna and Tuna Products from Canada*, adopted on 22 February 1982, BISD 29S/91, para. 4.3, where the panel found that analysing a measure that had been disinvoked was proper where there was a threat of recurring action.

eliminated".[28] Thus, Argentina had triggered the critical circumstances that were a prerequisite to imposing provisional safeguard relief by removing its own purportedly WTO-consistent duties. Not surprisingly, the Ministry of Economy and Public Works and Services further found that "injury might be attributable less to current imports than to consumption trends and industrial reorganization, which was major".[29] In reaching this conclusion, the Ministry had noted that importation of footwear had declined by 9 per cent in 1994, by 24 per cent in 1995 and by 21 per cent in the first six months of 1996.[30] Moreover, an Argentine administrative law judge had found Argentina's provisional safeguard duties on footwear to be improper and had suspended their operation.[31]

3.9 The United States equally recalled that the EC's third party submission also detailed the numerous inadequacies in the Argentine safeguard investigation. While the United States did not seek any finding by the Panel on the particular issues in the safeguards investigation, these facts were relevant for the purpose of demonstrating the possibility that Argentina could reinstate the footwear specific duties.

3.10 **Argentina** argued that the Panel had to be guided by the following considerations: the minimum specific import duties applied by Argentina pursuant to Resolution No. 1696/93 on certain items of footwear had been explicitly revoked by Resolution No. 225/97 of 14 February 1997. The WTO had been officially notified of the revocation.[32] Thus, the US claim pertained to the illegality of a measure which had been revoked prior to the establishment of this Panel and the adoption of its terms of reference.

3.11 Argentina contended that the United States' arguments related to the likelihood that Argentina would restore its specific duty regime on imports of footwear represented an effort to sustain facts through a reasoning based on a series of speculations. A safeguard investigation was under way. No definitive measures had been adopted. There had been no challenge under the DSU nor had any panel issued recommendations on the matter. Finally, if Argentina's intention had been to reintroduce the specific import duties on footwear, it would have suspended them rather than revoking them.

3.12 Argentina further argued that the decision to eliminate the DIEM applied to footwear imports had been taken in view of the fact that, in October 1996, the

---

[28] The United States referred to: Argentina Ministry of Economy and Public Works and Services - National Commission for External Trade: Preliminary Analysis of Evidence of the Existence of Serious Injury and/or Threat of Serious Injury to Domestic Industry Owing to the Increase in Imports of Footwear, in Response to the Application for Safeguard Measures, CNCE Docket No. 75/96. Annexed to Act No. 266, at para. 12.

[29] *Ibid.*, para. 9.

[30] *Ibid.*, para. 8.

[31] The United States referred to case No. 8.447/97 *FILA (Argentina) S.A. et al. v. The National State - Ministry of Economy and Public Works and Utilities - Decree No. 226/97 - About the Proceedings* (suspensive order of the judiciary dated 4 June 1997).

[32] See documents WT/L/204, 25 February 1997 and WT/L/204 Add.1, 18 March 1997.

domestic industry had formally requested the application of a safeguard measure. The domestic industry also had provided proof and documentary evidence of the existence of injury caused by increased imports and the existence of critical circumstances, in accordance with the requirements of Decree No. 1059/96 establishing the Regulations concerning the WTO Agreement on Safeguards.[33] The National Foreign Trade Commission had made a preliminary determination of injury based on the absence of minimum specific import duties. The Argentine Government had decided to open an investigation and, at the same time, apply a provisional measure because critical circumstance existed and could have caused damage to the industry which could not have been repaired. The minimum specific import duties had been eliminated because it was illogical to apply safeguard measures in accordance with the provisions of the WTO Agreement and at the same time maintain the previous minimum specific import duties.

3.13 Argentina stated that the investigation concerning the application of a safeguard measure with respect to footwear was following its course. The National Commission for Foreign Trade had produced its report on injury which would be notified to the WTO in accordance with the Agreement on Safeguards. At the same time, the provisional safeguard measure had had its effects partially suspended by a precautionary measure ordered by a judge. Consequently, it was highly unlikely that the revoked measure would be reinstated as suggested by the United States.

3.14 Finally, Argentina replied that the order of the administrative judge to which the United States referred, relating to the provisional safeguard measure for footwear, was precautionary, applied to a specific case, was currently being appealed and had no *erga omnes* effect. There was nothing whatsoever to suggest that the DIEM might be reintroduced, even if a definitive safeguard measure was not applied or the precautionary measure ordered by a judge was confirmed by the court of appeal. Thus, the conditions mentioned by the United States itself to justify the analysis of the DIEM on footwear by the Panel did not exist. It would not be possible to reinstate the minimum specific import measures for the very reason given by the United States: if the court of appeal were to reject the provisional measure, it would make it absolutely clear for the Argentine Government and for all individuals that any attempt to reintroduce the specific duties would be automatically challenged in courts.

3.15 According to the **United States**, a review of the Argentine measures imposing footwear specific duties applied until February 1997 also was appropriate because of their close factual connection to the specific duties on textiles and apparel at issue. The footwear duties were part of a broader regime of minimum specific import duties. The measures imposing the footwear as well as the textile and apparel specific duties applied parallel provisions. In some instances, the footwear specific duties and the textile and apparel specific duties had been im-

[33] *Boletín Oficial de la República Argentina*, No. 28.485 of 24 September 1996.

posed through the same measure.[34] Moreover, the rationale for all of the specific duties was the same[35], and the same GATT provisions applied to all. Accordingly, the United States requested the Panel to find that Argentina's specific duties on footwear violated Article II before they were revoked.

3.16 **Argentina** argued that the United States insisted on defining the regime applied to imports of textiles and footwear as a "common legal regime". Such a common legal regime did not exist, since the measures were prepared on the basis of differentiated analyses and formed part of different legal instruments, each one developed according to the characteristics of the market concerned. Even the measures applied, *i.e.* the DIEM, had to be adjusted to the needs of each tariff heading involved.

3.17 The **United States** claimed that Argentina had not attempted to rebut the connection established by the United States and the EC between the footwear specific duties and the almost identical duties established under the safeguard procedures.

3.18 **Argentina** replied that it had clearly shown that these two measures were completely different and separate from each other. The application of a provisional safeguard measure was not the result of an urgent need to give a measure a title in replacement of the DIEM. Even if this had been the case, Argentina would have been legally entitled to do so. In any case, from a legal point of view, it was neither possible nor reasonable to establish a connection between a measure applied under Article II of GATT 1994 and a measure applied under Article XIX, which was by definition an exception to Article II.

3.19 For Argentina, the continuous mention by the United States of the safeguard measure was a way of introducing through the back door a subject which had not been resolved and was not relevant to the context of this Panel. Although it had not gone to the EC's extreme of asking the Panel to rule on the subject, the United States was straying dangerously near to the edge by giving its opinion as to the legality of the safeguard measure while at the same time recognizing that the measure in question was not the subject of this proceeding, thus taking the same contradictory approach as the EC.

3.20 Argentina contended that if the United States had reasons to question the provisional safeguard measure applied by Argentina, it may do so in the appropriate Committee, and had indeed already done so. If the United States felt that any definitive measure that may be adopted would be questionable, it may discuss it in the appropriate forum.

---

[34] The United States referred to Argentina's Presidential Decrees No. 2275/94 and No. 998/95.

[35] The United States referred to a letter of the National Director of Industry Affairs explaining the Argentine minimum specific import duties.

(b) Similarities of this Case with Previous Cases

3.21 **Argentina** argued that its request that the Panel determine that there were no grounds for it to examine the issue in question did not represent a new practice in the GATT/WTO system. There were numerous precedents in GATT 1947[36] and in the WTO dispute settlement system[37] in which a party had asked the panel to rule on whether or not an argument with respect to all or certain specific elements of a claim should be examined before considering the substance of the matter. In the case of *United States - Denial of Most-Favoured-Nation Treatment as to Non-Rubber Footwear from Brazil*, the request submitted by Brazil had led to a ruling by the panel which had preceded its conclusions, resolving the preliminary objection that had been raised.[38] In its report on *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, the Appellate Body had determined that:

> "Previous GATT 1947 and WTO panels have frequently addressed only those issues that such panels considered necessary for the resolution of the matter between the parties, and have declined to decide other issues".

Further on, the report stated that:

> "Given the explicit aim of dispute settlement that permeates the DSU, we do not consider that Article 3.2 of the DSU is meant to encourage either panels or the Appellate Body to "make law" by clarifying existing provisions of the WTO Agreement outside the context of resolving a particular dispute. A panel need only address those claims which must be addressed in order to resolve the matter in issue in the dispute".[39]

3.22 As regards the precedents mentioned by the United States in support of its position,[40] Argentina contended that they referred to situations that were completely different from the one under consideration. In the first case, *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, the challenged measure was still in effect during the dispute. In fact, it had remained in force until the report was circulated. The present case was completely different in that the minimum specific import duties had already been revoked when the

---

[36] Argentina referred to the Panel Reports on *United States - Measures Affecting Alcoholic and Malt Beverages*, adopted on 19 June 1992, BISD 39S/206 and *United States - Denial of Most-Favoured-Nation Treatment as to Non-Rubber Footwear from Brazil*, adopted on 19 June 1992, BISD 39S/128.

[37] Argentina referred to the Panel Reports on *Japan - Taxes on Alcoholic Beverages*, adopted on 1 November 1996, WT/DS8/R, WT/DS/10/R, WT/DS/11/R, and *Brazil - Measures Affecting Desiccated Coconut*, adopted on 20 March 1997 WT/DS22/R.

[38] BISD 39/S128, para. 3.1 and para. 6.2.

[39] Appellate Body Report on *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, *op. cit*., DSR 1997:I, 323 at 339-340.

[40] See *inter alia*, footnotes 26 and 27, para. 3.7 above.

Panel had been established and its terms of reference adopted. As regards the case *United States - Prohibition on Imports of Tuna and Tuna Products from Canada*,[41] while the United States revoked the prohibition, not only did there remain in force a law permitting the reintroduction of the measure, but the United States also had informed Canada that it might be obliged to do so. Finally, in *EEC - Measures on Animal Feed Proteins*[42], both parties to the dispute knew from the time the panel had been established that the measure was temporary, and indeed raised no objection to the establishment of the panel, knowing it would issue its conclusions when the measure was no longer in force.

3.23 Argentina noted that the report of the panel on *United States - Standards for Reformulated and Conventional Gasoline* had established that:

> "The Panel observed that it has not been usual practice of a panel established under the General Agreement to rule on measures that, at the time the Panel's terms of reference were fixed, were not and would not become effective. In the 1978 Animal Feed Protein case, the Panel ruled on a discontinued measure, but one that had terminated after agreement on the Panel's terms of reference. In the 1980 Chile Apples case, the Panel ruled on a measure terminated before agreement on the Panel's terms of reference, however, the terms of reference in that case specifically included the terminated measure and, it being a seasonal measure, there remained the prospect of its reintroduction. In the present case the Panel's terms of reference were established after the 75 per cent rule had ceased to have any effect, and the rule had not been specifically mentioned in the terms of reference. The Panel further noted that there was no indication by the parties that the 75 per cent rule was a measure that, although currently not in force, was likely to be renewed [...] . The Panel did not therefore proceed to examine this aspect of the Gasoline Rule under Article I:1 of the General Agreement".[43]

3.24 Argentina stressed that in the case under consideration, there was no evidence whatsoever that the minimum specific import duties on footwear would be reintroduced. On the contrary, it was clear from Resolution No. 225/97 that the measures had been revoked and not temporarily suspended. Even if, hypothetically, it was considered to weigh up the 'probability that the measure would be reintroduced', the application for initiation of the safeguard investigation in the framework of the relevant Agreement had put such a possibility to rest.

3.25 The **United States** reaffirmed that in several instances previous panels had examined measures that were no longer in effect, including the panel reports

---

[41] Adopted on 22 February 1982, BISD 29S/91.
[42] Adopted on 14 March 1978, BISD 25S/49.
[43] Panel Report on *United States - Standards for Reformulated and Conventional Gasoline*, adopted on 20 May 1996, WT/DS2/R, para. 6.19.

on *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, *EEC - Measures on Animal Feed Proteins*, and *United States - Prohibition on Imports of Tuna and Tuna Products from Canada* cited by Argentina. Argentina attempted to distinguish between these decisions by arguing, for example, that the footwear specific duties were outside the purview of this Panel because, unlike previous matters, the measures had been revoked prior to formation of the Panel. This point of differentiation ignored the fact that the footwear specific duties were in effect during the four rounds of consultations held between the parties in this dispute, and they were in effect at the time the United States made its first panel request. The measures were revoked only after Argentina delayed formation of this Panel for one month.

3.26 **Argentina** contended that, as the measures at issue had been revoked before the composition of the Panel, the fact that the minimum specific import duties on footwear had been discussed during the consultations was irrelevant when it came to deciding whether the Panel should examine a measure which did not exist.

3.27 The **United States** argued that the report of the panel on *United States - Standards for Reformulated and Conventional Gasoline*, on which Argentina principally relied, revealed the weakness of its argument. If that panel decided to refrain from examining a measure no longer in effect, it did so because the measure in question was not included in that panel's terms of reference and there was no chance of its recurrence. However, the passage from the panel report quoted by Argentina,[44] noted that the earlier cases in which panels had examined measures no longer in effect were factually dissimilar. Indeed, that passage stated "in the 1978 Animal Feed Protein case, the Panel ruled on a discontinued measure, but one that had terminated after agreement on the Panel's terms of reference. In the 1980 Chile Apples case, the Panel ruled on the measure terminated before agreement on the Panel's terms of reference, however, the terms of reference in that case specifically included the terminated measure and, it being a seasonal measure, there remained the prospect of its reintroduction".

3.28 The United States consequently underlined that the facts of this matter were quite similar to those present in the cases on *EEC - Measures on Animal Feed Proteins* and on *EEC - Restrictions on Imports of Apples from Chile*[45] and unlike those of *United States - Standards for Reformulated and Conventional Gasoline*. The footwear specific import duties were explicitly listed in the Panel's terms of reference, and there was a considerable possibility that the measures would be resurrected.

3.29 The United States further argued that Argentina had sought to distinguish the case on *United States - Measures Affecting Imports of Woven Wool Shirts*

---

[44] Panel Report on *United States - Standards for Reformulated and Conventional Gasoline*, adopted on 20 May 1996, WT/DS2/R, para. 6.19.

[45] Adopted on 10 November 1980, BISD 27S/98.

and Blouses from India by claiming that the United States had not withdrawn the measure until the report was circulated. This was incorrect. The United States withdrew the measure *before* the panel issued the final report to the parties and this fact was noted by the panel:

> "We note that the United States [withdrew the measure] in a Federal Register Notice dated 4 December 1996. In the absence of an agreement between the parties to terminate the proceedings, we think that it is appropriate to issue our final report regarding the matter set out in the terms of reference of this Panel in order to comply with our mandate, as referred to in paragraph 1.3 of this report, notwithstanding the withdrawal of the U.S. restraint".[46]

3.30 The United States stressed that, as in this dispute, the panel's terms of reference in the report on *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India* permitted the panel to "comply with [its] mandate" notwithstanding that the measures had been withdrawn before the panel's decision. Similarly, the terms of reference of the panels in *United States - Prohibition on Imports of Tuna and Tuna Products*, and *EEC - Measures on Animal Feed Proteins* had provided panels with the mandate to rule on measures that had been withdrawn before each panel issued its determination.

3.31 The United States argued that the measures on footwear were part of the terms of reference, as outlined in document WT/DS56/6, dated 11 April 1997. This document referred to the panel request in document WT/DS56/5 which specifically stated that the United States was seeking review of the consistency of Argentina's specific duties on footwear with its WTO obligations. The request of the United Stated also outlined a number of measures such as Resolutions No. 305/95 and No. 103/96 which applied only to footwear. The United States had indicated in the panel request that the consultations had failed to settle the dispute as it related to Argentina's specific duties, including specific duties relating to footwear. Document WT/DS56/6 provided that the "parties [had] agreed to the standard terms of reference," which by definition incorporated the measures specified in the US panel request. Thus, while Argentina may maintain that the Panel should not review its specific duties on footwear, Argentina could not dispute that the terms of reference, as articulated in document WT/DS56/5, included the footwear specific duties.

3.32 **Argentina** acknowledged that the Panel's terms of reference contained in document WT/DS56/6 explicitly included "specific duties on footwear". The problem was whether the minimum specific import duties on footwear having been included in the terms of reference (as they formed part of the United States request) there was still merit in the Panel's considering them, inasmuch as these specific duties had already definitively ceased to exist at the time the Panel's

[46] Panel Report on *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses*, para. 6.2.

terms of reference were adopted. There was no point in ruling on a question which, being non-existent, could in no way impair or affect the rights of WTO Members. Argentina did not dispute the content of the Panel's terms of reference, but the nature of the examination which the Panel would be obliged to carry out if it acceded to the United States' request. Indeed, the minimum specific import duties applied to footwear imports, mentioned in the Panel's terms of reference, were those which had been revoked by Resolution No. 225/97.

3.33 Argentina added that in the case on *United States - Standards for Reformulated and Conventional Gasoline*, the measure questioned had been revoked before the adoption of the terms of reference and there was nothing to indicate that it was to be reintroduced. The same was true of the present case. In *EEC - Measures on Animal Feed Proteins*, it was a question of a measure abolished after the adoption of the terms of reference. In the case on *EEC - Restrictions on Imports of Apples from Chile*, the measure was a seasonal one which might obviously be reintroduced. The present Panel was completely different from the two previous ones mentioned above, since the United States was objecting to a measure which simply did not exist at the time the Panel had been established and its terms of reference defined.

3.34 Argentina noted that the United States had dismissed Argentina's comments on the background to the *EEC - Measures on Animal Feed Proteins*, *United States - Prohibition on Imports of Tuna and Tuna Products* and *EEC - Restrictions on Imports of Apples from Chile* cases claiming that they were technical points with little meaning. The Panel could not regard as a technical point with little meaning a note such as that which the United States had sent Canada in the second case mentioned above threatening to reintroduce the measure if the Canadian Navy were to seize a vessel.[47] Nor could one attribute "little meaning" to the fact that the United States informed the panel in the same case of its readiness to continue collaborating with the panel and, secondly, requested the latter to make a ruling justifying the United States measure on the basis of Article XX(g) of GATT.[48] In this case, Argentina was not trying to justify a particular measure, since there simply *was no measure*.

(c) Effect of Precedent of the Request of the United States

3.35 **Argentina** argued that the US request was not only contrary to the provisions of the WTO, but it also suggested that panels should rule on hypothetical cases, a dangerous evolution for the WTO system. It would encourage panels and the Appellate Body to legislate whereas Article IX:2 of the Marrakesh Agreement Establishing the World Trade Organization ("WTO Agreement"), attributed this task exclusively to the Members of the WTO through the Ministerial Confer-

[47] BISD 29S/91, para. 2.12.
[48] *Ibid.*, para. 3.25.

ence and the General Council. This would also be contrary to GATT practice under Article XXV.[49]

3.36 Argentina argued that, pursuant to Article 3.7 DSU, parties should endeavour to reach mutual agreement, failing which the issue could be submitted to a panel which could recommend the withdrawal of the illegal measure. In the case under consideration, there could be no mutual agreement between the parties on the minimum specific import duties applied to footwear since they were no longer in effect, nor could there be any recommendation to withdraw a measure that did not exist. In other words, proceedings could not be initiated without a specific subject of dispute to which they could apply. The WTO Agreement in general, and the dispute settlement system in particular, rested on the principle of considering measures actually in force. Thus, the idea of panels ruling *in abstracto* or merely on the basis of allegations as to what might be expected was entirely inappropriate. That a panel could rule in respect of a hypothetical case when the minimum requirement for a recommendation was that it should pertain to a measure that was in force would leave Article 19.1 DSU meaningless.[50]

3.37 Argentina also noted that the United States had recently expressed its opposition to *in abstracto* rulings by panels or the Appellate Body. On the occasion of the adoption by the DSB of the Report on *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, the United States had declared that the Appellate Body had stated that "we do not consider that Article 3.2 of the DSU is meant to encourage either the panel or the Appellate Body to "make law" by clarifying existing provisions of the WTO Agreements outside the context of resolving a particular dispute. A panel need only address those claims which must be addressed in order to resolve the matter in issue in the dispute".[51]

3.38 Argentina was concerned by the effect on the multilateral trading system of a decision by a panel to receive complaints such as the one lodged by the United States, as Members, if this became an accepted practice, could contemplate the possibility of resorting to the dispute settlement system in order to make sure that laws abolished for a long time would not be reintroduced. A failure to rule adequately on the Argentine request for a preliminary ruling also would open up the possibility of disputes being initiated under the dispute settlement system as a means of obtaining "an anticipatory precautionary measure", that is to say,

---

[49] Argentina referred to Ernst-Ulrich Petersmann, *The GATT/WTO Dispute Settlement System*, Kluwer Law International, (1997), at pp. 75-76: "[u]nlike generally binding authoritative interpretations of GATT rules adopted by the Contracting Parties pursuant to Article XXV, the legally binding effect of dispute settlement rulings [...] is [...] limited".

[50] Argentina noted that Article 19.1 DSU stipulated that "where a panel or the Appellate Body concludes that a measure *is* inconsistent with a covered agreement, it shall recommend that the Member concerned bring the measure into conformity with that agreement" (emphasis supplied by Argentina).

[51] Argentina quoted from the statement by the United States to the Dispute Settlement Body on 23 May 1997 on the occasion of the adoption of the reports in case WT/DS33. See WT/DSB/M/33, p. 11.

using the DSU to prevent the implementation of a measure which a Member thought might injure it in the future.

3.39 The **United States** replied that contrary to Argentina's argument, it was not asking the Panel to "legislate" or to address an "abstract" question, but rather to review particular measures that Argentina had maintained until just days before the formation of the Panel, that were specifically included in the Panel's terms of reference and that may well be resurrected in the event Argentina's safeguard measures on footwear were terminated.

3.40 The United States argued that, like Argentina, it believed that panels had to approach the issue of withdrawn measures with caution. The test articulated by the panel in the case on *United States -Standards for Reformulated and Conventional Gasoline* (*i.e.* whether the measure was part of the terms of reference of the panel, and whether there was the possibility of its reintroduction) provided the necessary safeguard.

3.41 For the United States, the Panel had to bear in mind the negative effects on the functioning of the WTO dispute settlement if Members were permitted to evade panel review of WTO-illegal measures by simply withdrawing one type of measure and introducing another. If the test advocated by Argentina, *i.e.* no examination of any withdrawn measure by any panel, was used then Members may be inclined to introduce slightly revised measures to avoid panel review. If the Panel were to agree with Argentina, Members trying to escape WTO review would be able to delay the establishment of a panel indefinitely by withdrawing one measure and imposing another in its place. Pursuant to Argentina's theory, the new measure would mandate additional consultations under Article 4 DSU and the resetting of at least a 90-day period of time before a panel could be established. Argentina's position, therefore, was not only inconsistent with prior practice, it also would subvert the ability of the DSB to solve trade problems. The Panel should advance the objectives of the DSB and take care to refrain from unduly restricting the scope of its review.

3.42 **Argentina** argued that all WTO Members came under pressure from their domestic industries to resort to the dispute settlement system as soon as those industries considered themselves to have a problem. Although it was essential that every Member should be fully entitled to resort to the dispute settlement procedure, it was no less important to emphasize that the *system* had an obligation to close the door against possible abuse. Doing otherwise would give domestic industries an enormous incentive to demand from their authorities the establishment of panels with a view simply to confirming that another Member country or other Member countries would continue to fulfil their obligations as in the past. In other words, a panel could not be required to rule that Argentina should not re-establish specific duties which were not part of its legislation. To take the opposite view would be to question a fundamental principle of international law pursuant to which *pacta sunt servanda*. This would also raise uncertainty and speculation which, taken to the limit, might result in the collapse of the dispute settlement system.

3.43 Argentina noted that such elements were present in this case and Argentina's legitimate decision to initiate a safeguard investigation for footwear and its application of a provisional measure had led ultimately to the United States initiating a panel concerning the application of specific duties in another sector, that of textiles and clothing. As a way of responding to the complaint of the footwear manufacturers and given the legal impossibility of challenging directly a safeguard in process of investigation, the United States was trying to reach it indirectly. As a result, the Panel was faced with a theoretical case in which it has been clearly shown that there were no actual transactions involved. The question raised by the United States before the Panel masked the real issue: the Argentine decision to revoke the minimum specific import duties on footwear and subsequently to initiate an investigation at the request of the industry in that sector.

3.44 Argentina further contended that the EC's third-party submission and its oral submission were centred almost entirely on the specific footwear duties and even included a request for the Panel to rule on the safeguard measure, which not even the United States had suggested.

3.45 According to Argentina, all this demonstrated the need for the Panel to accede to Argentina's request that it made a special preliminary ruling to the effect that there was no grounds for it to express an opinion on the specific footwear duties since those duties had been definitively revoked before the Panel was established.

3.46 Argentina stated that the assertion that recourse to a safeguard measure today could mean recourse to Article XX or another article tomorrow, was also unacceptable. Not only was this not Argentina's intention, but it could not even be considered as a possibility. This would be tantamount to say that WTO Members could not make use of their rights under the different provisions of GATT 1994 and the WTO Agreement.

3.47 Argentina argued that the Panel was faced with a task that extended far beyond the particular case at issue, since its conclusions could clearly affect the proper functioning of the WTO dispute settlement system. In order to avoid using the DSU abusively, it was essential that the Panel should redirect this case, taking a decision on the special preliminary ruling requested by Argentina at the appropriate time.

2. Request by Argentina for a Ruling of the Panel Regarding the Submission of Certain Evidence by the United States

3.48 On 21 July 1997, the **United States** submitted to the Panel two exhibits that it intended to present at its second substantive meeting on 23 July 1997. The first exhibit was presented as a summary of a number of industry-supplied examples of export shipments to Argentina which had been assessed duties in excess of 35 per cent *ad valorem*. The second exhibit contained copies of 95 pages of Argentine customs documents which reflected the application of the specific du-

ties summarized in the exhibit previously mentioned. The United States mentioned that these documents had been submitted at that time in order to provide both the Panel and Argentina with the opportunity to review them prior to the second meeting of the Panel.

3.49 **Argentina** requested the Panel to disregard the evidence submitted by the United States as untimely. The United States had resorted to an extemporaneous submission inconsistent with the sequence of time-limits laid down in the DSU and ultimately intended to maintain, at each stage of the Panel procedure, the required balance between the parties.

3.50 The **United States** specified that it had produced new documents to contradict the claims of Argentina. For example, the evidence at issue contradicted Argentina's claims that the United States allegedly had no proof of duties being assessed over 35 per cent *ad valorem*. For the United States, the Panel should encourage the use of formal evidence such as those submitted by the United States as opposed to simply accepting oral denials and mere allegations of facts. The submission of new documents was a natural process in a dispute. Were a panel to prevent the submission of new documents during its second substantive meeting with the parties, this would inhibit the truth-testing process and prohibit a party from contradicting statements made at the last minute by the other party.

B. Violation of Article II in Relation to the Implementation of Argentina's Schedule LXIV

1. Introduction

3.51 The **United States** argued that, during the Uruguay Round, Argentina had agreed to a maximum bound rate of 35 per cent *ad valorem* on imports of textiles, apparel and footwear. However, Argentina imposed minimum specific import duties on hundreds of categories of these products. The specific duties often amounted to more than 35 per cent of the actual value of affected goods. On the eve of formation of a panel in this dispute, Argentina had eliminated its specific duties on footwear, replacing them with specific duties presented as "provisional safeguard" measures. However, Argentina's specific duties on textiles and apparel remained in effect.

3.52 The United States contended that in imposing minimum specific import duties on textiles, apparel and footwear, Argentina had violated Article II of GATT 1994. Even if the specific duties, as applied, did not exceed 35 per cent *ad valorem*, they still violated Article II. Each of Argentina's specific duties had the *potential* to exceed 35 per cent *ad valorem* with respect to some imports. Argentina also violated Article II by exceeding its bound tariff rate and failing to apply only *ad valorem* duties in accordance with its Schedule.

3.53 **Argentina** argued that the application of minimum specific import duties did not and could not violate Article II. The relevant laws in Argentina precluded any effective or potential violation of the 35 per cent *ad valorem* bound rate by the minimum specific import duties. This was so because the payment of a duty

could not be taken in isolation from the other rights and obligations accorded under national law to all the parties involved in an import transaction. No-one was obliged to pay more than the 35 per cent bound *ad valorem* rate, since there was a legal remedy available to challenge any amount that the authority may attempt to levy in excess of the legal commitments of Argentina.

3.54 This sub-section firstly addresses the arguments of the parties on the general notion of "predictability" of tariffs. It then includes successively the arguments of the parties regarding the alleged violation of Article II through: the application of minimum specific import duties when Argentina's Schedule allegedly refers only to *ad valorem* duties; the potential effects of the application of minimum specific duties and the situations where the 35 per cent *ad valorem* bound rate is allegedly exceeded. It also addresses the general issue of the burden of proof. The discussion of the arguments of Argentina related to the constitutional ranking of the WTO Agreements in the Argentine legal order and the existence of a *recurso de impugnación* (challenge procedure) is developed in the second part of this sub-section, even though arguments related to these aspects may appear briefly in the first part.

2. General Remarks on the Notion of "Predictability" of Tariffs

3.55 The **United States** submitted that Article II offered "predictability" to WTO Members and their traders by establishing upper limits on the imposition of tariffs. It did so in two ways. Firstly, Article II:1(b) made clear that bound tariff rates were maximum rates: products described in a Member's Schedule "shall [...] be exempt from ordinary custom duties in excess of those set forth and provided therein". This provision guaranteed that tariffs levied by WTO Members would be no more than the maximum rate stipulated in the relevant Schedule. Secondly, Article II reinforced this guarantee by stating that "[e]ach contracting party shall accord to the commerce of the other contracting parties treatment no less favourable than that provided for in the appropriate Part of the appropriate Schedule". Pursuant to this language, Members were forbidden to manipulate the administration of their duties so as to collect excessive duties through indirect means. Article II's proscription against levying duties in excess of a bound rate was unqualified. It was a guarantee that was not altered by the whims of the market, regardless of fluctuations in trade flows or prices. Through their Schedules, WTO Members in effect provided one another with an assurance that whatever duties were assessed at their borders would not and could not be more than the applicable bound rate. That was the central purpose underlying Article II and that was the "predictability" the article provided.

3.56 In relation to this, the United States referred to previous panel reports. The report of the panel on *European Communities - Import Regime on Bananas* had concluded that:

> "in determining whether treatment accorded by a tariff measure was no less favourable than that provided for in the Schedule, it

> had to take into account not only the actual consequences of that measure for present imports but also its effects on possible future imports. This followed from the principle recognized by many previous panels that the provisions of the General Agreement serve not only to protect actual trade flows but also to create predictability for future trade".[52]

3.57 It also referred to the report of the *Panel on Newsprint*, which stated that:

> "[it] shared the view expressed before it relating to the fundamental importance to the security and predictability of GATT tariff bindings, a principle which constitutes a central obligation in the system of the General Agreement".[53]

3.58 For the United States, Argentina's specific duties did not offer such "predictability". By their nature, Argentina's specific duties necessarily had the potential to exceed 35 per cent *ad valorem* for some products, especially low-price items. The United States supported this by making a description of how each of Argentina's more than 600 categories of specific duties had a "Break-Even Price" - i.e., a value below which all items were subject to duties greater than 35 per cent *ad valorem*. Whether an item imported into Argentina was below the "Break-Even Price" turned on market factors - i.e., whether goods of certain values would be imported - which were beyond Argentina's control. Given this situation, Argentina's trading partners had no way of knowing if Argentina would meet the obligations it assumed under its binding. The "unpredictable" nature of this regime was compounded by the fact that the fixed-rate specific duties remained constant while imports and their prices changed. A specific duty for a given article might be within the bound rate at one moment, but exceed it later. Argentina, therefore, was unable to provide fellow WTO Members with the essential assurance that Article II demanded: that its duties would not exceed the relevant bound rate for all covered imports.

3.59 According to the United States, Argentina had conceded that its specific duties - as applied at the border - could exceed 35 per cent in relation to some items. In the view of the United States, Argentina also did not appear to dispute the notion that it had to maintain duties that could not exceed the applicable bound rate. However, the United States recalled that Argentina had explained that it believed its regime was consistent with Article II because it maintained "challenge procedures" to reduce any overcharges. For the United States, this surely could not be the security and "predictability" in tariff rates that other WTO Members thought they had received from Argentina in the Uruguay Round. Argentina's trading partners had the right to expect that Argentina would impose only those duties which in form and amount were not capable of exceeding 35 per cent *ad valorem*.

---

[52] DS38/R, 11 February 1994, unadopted, para. 135.
[53] Adopted on 20 November 1984, BISD 31S/114, para. 52.

3.60 **Argentina** replied that in the case under consideration, the definition of predictability in the context of Article II stemmed from the effective implementation of the tariff concessions negotiated whose value was expressed in the respective national Schedules. It pointed out that what this Panel was examining was not the "unpredictable" nature of the specific duties, which could vary in accordance with the value of the goods, but whether or not the bound *ad valorem* level had been violated.

3.61 Argentina believed that its regime ensured predictability firstly because its Schedule bound the entire tariff. This commitment entered into by the Argentine Government during the Uruguay Round had been ratified by the Argentine Congress and had constitutional status in accordance with Article 75.22 of the Argentine Constitution. This feature of Argentina's constitutional system endowed Schedule LXIV with an absolute level of predictability. Any infringement would open the way, through a summary proceeding, to obtain a judicial decision obliging the Argentine Government to comply with international obligations deriving from WTO agreements, over and above any domestic norms, such as laws, decrees, ministerial resolutions, or others. On the other hand, the tariff applicable was well known and transparent. Furthermore, with very few exceptions, it could not be changed unilaterally by Argentina, any changes having to be agreed with the other members of MERCOSUR. This restricted the freedom of action of each of the parties to that treaty, thereby adding a further safety factor.

3. Imposition of Specific Duties Instead of Ad Valorem Duties

3.62 The **United States** considered that Article II of GATT 1994 prohibited WTO Members from exceeding their bound tariff rates and according treatment less favourable than the terms stipulated in Schedules. This conclusion was supported by a consistent line of prior GATT decisions which had found that the imposition of specific duties was impermissible when *ad valorem* duties had been promised. These decisions indicated that such a regime violated Article II:1(a) GATT 1994, which provided that WTO Members had to accord to other Members "treatment no less favourable than that provided for [...] in the appropriate Schedule", and Article II:1(b), which provided that imported goods from WTO Members had to be "exempt from ordinary customs duties in excess of" the applicable bound rate. In this light, prior GATT bodies had found that the imposition of specific duties was impermissible when the pertinent schedule provided for *ad valorem* tariffs.

3.63 For the United States, this was so, at least in part, because use of one form of duty instead of the other carried with it the potential to break a binding. As the panel on *EEC - Import Regime on Bananas* explained:

> "The Panel considered that the actual levying of a duty in excess of the bound rate clearly constituted a treatment of bananas less favourable than that provided for in the EEC's Schedule of Concessions. The Panel then proceeded to examine whether also the **mere**

> **possibility** that the specific tariff rate applied by the EEC might be higher then the corresponding bound *ad valorem* rate, rendered it inconsistent with Article II. *The Panel recalled the importance of security and predictability in the application of tariffs bindings. It noted that previous panels and working parties had emphasized that tariff bindings justify reasonable expectations about market access and conditions of competition.* The CONTRACTING PARTIES had consistently found that a change from a bound specific to an *ad valorem* rate was a modification of the concession [...] *The Panel [...] concluded that, in determining whether treatment accorded by a tariff measure was no less favourable than that provided for in the Schedule, it had to take into account not only the actual consequences of that measure for present imports but also its effects on possible future imports. This followed from the principle recognized by many previous panels that the provisions of the General Agreement serve not only to protect actual trade flows but also to create predictability for future trade*".[54]

3.64 The United States added that, for these reasons, it had long been recognized in the GATT that converting bound duties from *ad valorem* to specific, or *vice versa*, violated Article II and that such a change was permissible only through renegotiation under Article XXVIII.[55] As early as 1955, a GATT working party had addressed a regime of minimum specific duties akin to those imposed by Argentina.[56] In that case, Austria's Schedule allowed it to "change the specific into *ad valorem* rates". The Austrian Government, however, "felt that it would not be impairing the value of the concessions if it retained beside the *ad valorem* duty the old specific rate as a minimum rate". The working party disagreed, finding "that such changes would constitute modification of Austria's obligations and that it could not recommend their acceptance as rectifications. Such modifications could only be inserted in a protocol of rectifications and modifications after negotiations authorized by the CONTRACTING PARTIES in

---

[54] DS38/R, Op. Cit., para. 135 (emphasis added by the United States).

[55] The United States referred to the Report of the Ninth Session Working Party on Schedules on *Transposition of Schedule XXXVII (Turkey)*, L/294, adopted on 20 December 1954, BISD 3S/127, which mentioned, at paras. 3-4, that "no provision in the General Agreement [...] authorizes a contracting party to alter the structure of bound rates of duty from a specific to an *ad valorem* basis. [...] The obligations of contracting parties are established by the rates of duty appearing in the schedules and any change in the rate such as a change from a specific to an *ad valorem* duty could in some circumstances adversely affect the value of the concessions to other contracting parties. Consequently, any conversion of specific into *ad valorem* rates of duty can be made only under some procedure for the modification of concessions".

[56] The United States referred to the Working Party Report on *Fourth Protocol of Rectifications and Modifications*, adopted on 3 March 1955, BISD 3S/130. (hereafter also the Working Party on Austria).

accordance with the proper procedures". Austria accepted the decision of the working party.[57]

3.65 In the opinion of the United States, subsequent decisions had found this reasoning compelling. In fact, all GATT bodies that had addressed the question - regardless of whether it was the imposition of specific or *ad valorem* duties that was objected to - had likewise determined that the application of an alternative mode of tariff was impermissible when the other form of duty was bound. Reviewing this history, the *Panel on Newsprint* explained that "under long-standing GATT practice, even purely formal changes in the Schedule of a contracting party, which may not affect the GATT rights of other countries, such as the conversion of a specific duty to an *ad valorem* duty without an increase in the protective effect of the tariff rate in question, had been considered to require negotiations".[58] The *Panel on Newsprint* found that the EC was not permitted to reduce the metric tonnage eligible for duty free treatment under a bound tariff rate quota ("TRQ") to take into account the merger into the EC of three nations that formerly had been the principal beneficiaries of the TRQ. In reaching this conclusion, the panel stated that it "shared the view expressed before it relating to the fundamental importance to *the security and predictability of GATT tariff bindings*, a principle which constitutes a central obligation in the system of the General Agreement".[59]

3.66 **Argentina** noted that the United States had expressed "concern" over the imposition of specific duties, but its main line of argument attacked the right question, namely ensuring that the bound level could not be violated. In this respect, the United States itself recognized that the problem did not lie with the conversion of specific into *ad valorem* duties or *vice versa*. Argentina noted that the United States had acknowledged that an *ad valorem* tariff could also violate a binding. The question was whether there were any guarantees that, whatever form the tariff took, the bound level would not be exceeded.

3.67 In Argentina's view, it was quite inaccurate to state that *ad valorem* duties were converted into specific duties. No such conversion was possible, since the specific duties were already in effect. Argentina had bound a maximum *ad valorem* "ceiling" of 35 per cent for all tariff headings, including the sector under consideration. Argentina had applied minimum specific duties to textiles and

---

[57] The United States referred also to the Working Party Report on *Rectifications and Modifications of Schedules*, adopted on 24 October 1953, BISD 2S/63, para. 8, where the working party reviewed a proposal by Greece to"introduce a minimum *ad valorem* rate for certain specific rates and came to the conclusion that such changes could not be considered rectifications [...] It decided therefore to refer the question to the CONTRACTING PARTIES so that such changes could form the object of consultations and negotiations [...]". In addition, the United States referred to John H. Jackson, *World Trade and the Law of GATT*, Bobbs-Merrill Co. (1969), which mentioned at p. 215 that "the introduction of a minimum specific rate where the Schedule rate is only *ad valorem* is not permitted under GATT without going through these special renegotiation procedures".

[58] Op. Cit., para. 50.

[59] *Ibid.*, para. 52 (emphasis added by the United States).

clothing since the adoption of Resolution No. 811/93 of the Ministry of Economy and Public Works and Services, dated 29 July 1993, in other words since before the conclusion of the Uruguay Round. Argentina's Schedule LXIV was approved as part of Law 24.425, which gave effect to all the WTO Agreement in Argentina as from 1 January 1995. Schedule LXIV bound tariffs at a maximum ceiling of 35 per cent *ad valorem*, with the exception of certain tariff headings bound below this level as a result of the Kennedy, Tokyo and Uruguay Rounds. The fact that Argentina continued to apply minimum specific import duties to textiles and clothing was not inconsistent with its commitments under the Uruguay Round in so far as the bound *ad valorem* level was not exceeded. As to how a WTO Member could be aware of Argentina's intention to keep its practice of using specific duties within the maximum *ad valorem* ceiling, Argentina said that it had submitted its tariff to the Committee on Market Access. In addition, it had formally notified the tariff within the context of MERCOSUR, a notification which, in itself, ensured the total transparency of the tariff levels applicable. Moreover, it was well known that during the Uruguay Round negotiations Argentina was applying minimum specific import duties on textiles. In this connection, at the close of the Uruguay Round the United States and the EC bilaterally threatened not to accept the Argentine Schedule if the minimum specific import duties were not removed. In these circumstances, Argentina had replied that the minimum specific import duty regime would not be changed.

3.68 Argentina rejected the argument based on the alleged conversion of *ad valorem* import duties into specific duties because the precedents cited by the United States were not applicable to this case. Firstly, none of the mentioned precedents pointed to a conversion of *ad valorem* duties into specific duties. In the case of the *Working Party on Austria*, Austria wanted to retain the specific duty as a minimum without being able to give an assurance that the specific duty would not exceed the bound *ad valorem* rate. The present case was radically different inasmuch as the Argentine minimum specific import duties operated as a minimum only to the extent that it did not exceed the bound 35 per cent *ad valorem* rate. In the instance addressed by the *Working Party on Austria*, it was a question of binding tariff rates for certain specified tariff headings. By contrast, in the present case it was a question of binding a maximum tariff ceiling of 35 per cent *ad valorem* for the entire universe of goods, with the exception of certain headings bound at lower levels, and the maintenance of pre-existing specific duties for particular sectors calculated so as not to exceed the bound level.

3.69 Argentina also contended that the GATT 1947 practice cited by the United States was not relevant as precedent to the present case for the following reasons. The case on *Transposition of Schedule XXXVII (Turkey)*[60] showed diverging conclusions reached by a working party concerning the transformation of a specific into an *ad valorem* duty. That case was qualitatively different because

[60] This case was referred to by the United States in footnote 55 above.

the working party stated that "a change from a specific to an *ad valorem* duty could in some circumstances [...] affect the value of the concessions [...] Consequently, any conversion [...] can be made only under some procedure for the modification of concessions".[61] The working party's statement mentioned "some circumstances" applicable to the specific case (that of Turkey). No conclusion should therefore be drawn from it and applied *erga omnes* to all cases that may entail the conversion of specific duties to *ad valorem* duties. The working party report did not contain unanimous viewpoints. Quite to the contrary, various members expressed disagreement with the above-cited conclusion. The representative of Brazil said "the conversion of specific duties to *ad valorem* duties does not affect the value of negotiated concessions and in most cases nothing more is involved than a simple arithmetic calculation. Except in cases where such calculation cannot be made, in its opinion such conversions are merely a matter of form and should not require special authority".[62] On the same occasion Austria stated that "the recommendation which is based on exceptional circumstances could not be considered as a precedent for other proposals relating to the conversion of specific duties into *ad valorem* duties".[63]

3.70 For Argentina, some other precedents mentioned by the United States were no more than incidental to the topic of changing one type of duty into another, considering that the matter in dispute did not concern the possible conversion of *ad valorem* duties into their equivalent specific duty as in the present case. Strictly speaking, they merely addressed the possibility of less-favourable treatment. Hence, in the *Panel on Newsprint*, the complaint by Canada questioned the "unilateral EEC decision to implement a duty-free tariff quota of 500,000 tonnes for 1984, which impaired its GATT binding to open a tariff quota of 1.5 million tonnes".[64] This "tariff quota less than the amount bound in its Schedule invalidated the principle of the security and predictability of access".[65] In this case, the panel had found that "although in the formal sense the EC had not modified its GATT concession, it had in fact changed its GATT commitment unilaterally".[66] This seemingly contradictory line of reasoning refocused the discussion on what was the crux of the matter: the value of the concession and not its form. The panel recognized that while the EC did not fail to comply with a particular formal obligation, its action changed the value of the negotiated concession. This therefore justified the EC "engaging in renegotiations under Article XXVIII".[67] In this case the panel did not object to the formal procedure, but to the change in the value of the concession. It was this *de facto* situation that triggered the negotiating procedure and which the panel believed should be handled

61 BISD 3S/127, para. 4.
62 BISD 3S/127, para. 6.
63 *Ibid.*
64 BISD 31S/114, para. 14.
65 *Ibid.*, para. 17.
66 *Ibid.*, para. 50.
67 *Ibid.*, para. 54.

through the negotiation process provided for in Article XXVIII. The statement that "even purely formal changes [...] without an increase in the protective effect [...] have been considered to require negotiations" did not in itself represent a finding. This observation had no practical impact on the panel's conclusion, which was based on a substantive consideration as to the value of what had been negotiated. Consequently, the findings of the panel referred to a modification of the value of the concession and not to the legal implications of formal changes in the Schedules. In Argentina's opinion, the statement quoted by the United States "Under long standing [...] require negotiations" was not a finding of the Panel but an *obiter dictum*, an opinion expressed incidently in delivering a judgement which did not constitute one of its essential elements.

3.71 For Argentina, the only case that bore a certain resemblance with the present situation was that on *EEC - Import Regime for Bananas*, but the corresponding report had not been adopted. Moreover, even in the hypothetical case of a transfer (and this did not apply to the case at issue), this would not be enough to constitute a violation of the commitments assumed with respect to bound import duties, since Argentina had a legal mechanism to ensure that the bound level of 35 per cent was not exceeded. This was the challenge procedure laid down in the Argentine Customs Code, the existence of which put at rest the United States assertions with respect to the security and predictability of tariff bindings as well as to potential effect on, or expectations of, market access by trade partners.

3.72 Argentina contended that the case in question was quite similar but certainly not identical, for the following reasons. The United States quoted paragraph 134 of the report of the panel on *EEC -Import Regime for Bananas*, and underlined the general obligation arising from Article II to accord ... "treatment no less favourable than that provided for in the [...] Schedule". The quotation then described the panel's analysis of the EC mechanism whereby the effective *ad valorem* duty depended on the value of the bananas, while the specific duties depended on their weight. On that basis and in regard to the two categories of specific duties under consideration, the panel considered that in one case, that of the specific duty of 850 ECUs per ton, they clearly violated the 20 per cent Community binding and in the other (the case of the specific duty of 100 ECUs per ton), the EC had neither argued nor submitted any evidence that this duty could never exceed 20 per cent *ad valorem*. In consequence, the panel found that the specific duties had in fact violated the binding.

3.73 For Argentina, the conclusions revealed significant qualitative differences between the case of the EEC import regime for bananas and the present case. To begin with, the Argentine minimum specific import duties had been calculated so as not to exceed the tariff ceiling of 35 per cent. This was explained in detail by Argentina in its analysis of the theoretical and practical examples of alleged violations of the tariff bindings submitted by the United States to the Panel.[68]

[68] See discussion in sub-sections B.4 and 5.

3.74 Argentina pointed out that contrary to the United States assertion, the panel on *EEC - Import Regime for Bananas* did not base its conclusions on the modification of the way in which the tariff was calculated, but on the fact that the EC could not guarantee that this specific duty would never exceed the bound level. This situation was entirely different from the one under consideration. Under Law No. 22.415, by means of the "challenge procedure", Argentine legislation fully guaranteed that the level of the tariff binding could never be exceeded.

3.75 Finally, Argentina formulated two observations regarding the legal value of that case. Firstly, that report was an unadopted panel report. The value of such reports as legal precedents within the GATT/WTO framework was minimal. Indeed, as stated by the panel on *Japan - Taxes on Alcoholic Beverages*, cited by the Appellate Body in the same case, they "have no legal status in the GATT or WTO system since they have not been endorsed through decisions by the CONTRACTING PARTIES to GATT or WTO Members".[69] Secondly, the possibility that it may provide "useful guidance" was contingent upon whether the precedent was "relevant" to the matter under examination.[70]

3.76 Furthermore, Argentina recalled that the limited scope of panel reports was accepted and unquestioned practice under GATT and had been reaffirmed by the WTO. The doctrine was clear in this regard: "The adoption by the Contracting Parties [...] of a dispute settlement report is regarded in GATT practice as a "ruling" and authoritative determination of existing GATT rights and obligations of the disputants in the instant case".[71] The provisions of the General Agreement, in particular of Article XXIII, may not be used to change the obligations deriving from the Agreement. "Article XXIII [...] should not be used in such a manner as to effectively impose positive obligations on GATT members that are not contained in the Agreement".[72] This was particularly applicable when the conclusions of a panel had been questioned by some of its members and other contracting parties had expressed disagreement at their adoption.

3.77 For the **United States**, the decisions of prior GATT bodies had determined that the imposition of specific duties was impermissible where *ad valorem* tariffs had been promised.[73] Argentina had not and could not find a meaningful basis to distinguish the reasoning underlying these earlier decisions from the present dispute. Argentina essentially had asked the Panel to overlook a firmly established principle of GATT jurisprudence, a tenet that had guided GATT Con-

---

69 WT/DS8/AB/R, DS10/AB/R, DS11/AD/R, pp. 14-15.

70 *Ibid.*

71 Ernst-Ulrich Petersmann, *The GATT/WTO Dispute Settlement System*, Kluwer Law International Limited (1997) p.75.

72 Par Hallstrom, *The GATT Panels and the Formation of International Trade Law*, Juristförlaget (1994), p. 156 (citing John H. Jackson).

73 The United States referred in particular to the Panel Reports on *EEC - Import Regime for Bananas* and *Panel on Newsprint*, Op. Cit.

tracting Parties and WTO Members since the earliest days of the General Agreement.

3.78 The United States argued that Argentina attacked these decisions on alternate grounds. In particular, Argentina pointed out that the report of the panel on *EEC - Import Regime for Bananas* had not been adopted. This was true, but the United States noted that the Appellate Body had indicated that "a panel could nevertheless find useful guidance in the reasoning of an unadopted panel report that it considered to be relevant".[74]

3.79 **Argentina** contended that Article II:1(b) GATT 1994 did not impose the application of a particular type of tariff but laid down the obligation that "ordinary customs duties" could not exceed "those set forth and provided" in the Schedule. If the text of Article II:1(b) had sought to define the scope of the concept of "customs duties" (limiting the options in terms of the type of tariff to be applied), the contracting parties would have specified this in due course or when negotiating the text of the Understanding on the Interpretation of Article II:1(b) of the General Agreement on Tariffs and Trade 1994.

3.80 Therefore, according to Argentina, one had to determine whether or not there was an obligation deriving from GATT 1994 which prohibited a Member from applying a specific duty rather than an *ad valorem* duty providing it did not exceed the bound rate. The key concept in Article II was *treatment no less favourable*. It made no reference whatsoever to the obligation to introduce a particular type of duty (in this case *ad valorem*), nor did it stipulate that such duty may not subsequently be transformed into a specific duty provided that the final duty effectively paid by the importer to release the goods into the market was not higher than the bound tariff.

3.81 The **United States** replied that it had no objection to specific duties *per se*. In fact, the United States recognized that WTO Members may bind their tariffs using either *ad valorem* tariffs or specific tariffs, or both. The concern of the United States was that Argentina chose to bind itself to an *ad valorem* tariff but nonetheless imposed specific duties. By imposing minimum specific duties despite its purely *ad valorem* binding, Argentina's regime allowed for certain goods to be subject to import duties higher than 35 per cent *ad valorem*. This deprived WTO Members and their traders of the "predictability" that should accompany a maximum bound rate. Article II offered WTO Members a guarantee that their products would not be subject to duties greater than the amount established in the relevant Schedules. They also guaranteed that WTO Members would not manipulate the administration of duties so as to collect excessive tariffs. This was true regardless of the vicissitudes of the marketplace. Trade flows or prices rise or fall should not disturb the sanctity of the commitment made in a tariff concession.

---

[74] The United States referred to the Appellate Body Report on *Japan - Taxes on Alcoholic Beverages*, Op.Cit., p. 15.

3.82 According to the United States, *ad valorem* and specific duties were quite distinct and had different aims and effects. *Ad valorem* duties garnered greater sums from high-value goods than low-value goods, and the amount assessed varied constantly as prices fluctuated. Such duties offered a hedge against inflation for countries imposing them, since any increase in the price of goods yielded a commensurate increase in the tariff charged. In contrast, specific duties bore no direct relation to the value of imported merchandise but instead were dependent upon quantity. One rate was levied per unit. As a practical matter, though, the flat rate of a specific duty affected low-price merchandise disproportionately in comparison with high-price items. A US$5 specific duty might be a bargain to the manufacturer of a US$100 product yet an almost insurmountable obstacle to the producer of a US$1 article.

3.83 The United States further argued that the fact that the two forms of duties differed was not to say that one was superior to the other or more or less legitimate. Rather, it was to say that the two were unique and thus were not interchangeable. Reliance on *ad valorem* rates rather than specific, or the other way around, necessarily involved the imposition or the threatened imposition of tariffs in contravention of a bound rate. For example, no matter how low or reasonable a specific duty might seem on its face, such a duty had the potential to violate a bound *ad valorem* rate for a sufficiently low-price item.[75]

3.84 For the United States, the problem was one of determining and ensuring equivalency. For instance, a US$5 specific duty amounted to 500 per cent for a US$1 item, but only 5 per cent of a US$100 item. Where tariffs had been bound in *ad valorem* terms, as was the case with Argentina, the imposition of specific duties necessitated the determination of the *ad valorem* equivalent for each item in each category. Even if no goods had entered Argentina subject to duties greater than 35 per cent, the use of minimum specific duties created the possibility that the bound rate would be exceeded. This could not occur if Argentina imposed only *ad valorem* tariffs.

3.85 The United States acknowledged that Argentina was free to bind its duties in a variety of ways, including a combination of specific and *ad valorem*. However, having selected a purely *ad valorem* binding, Argentina could not maintain a regime in which some items would be subject to duties in excess of its bound rate.

3.86 For **Argentina**, the application of minimum specific import duties that did not exceed the 35 per cent bound rate was not a violation of the commitment undertaken, nor did it impair the concession granted in the Uruguay Round. Argentina did not criticize the report of the panel on *EEC - Import Regime for Bananas* Panel because the report was not adopted, but stated that the EC had been found in breach of its obligations because no evidence had been presented that the spe-

[75] The United States added that, likewise, the converse was true. An *ad valorem* tariff could exceed a bound specific duty if sufficiently high-price merchandise were imported.

cific duty to be paid could not exceed the *ad valorem* tariff undertaking. Argentina, on the other hand, submitted concrete proof in this respect.

4. Violation as a Result of the Potentiality of Exceeding the Bound Rate of Duty

3.87 The **United States** argued that, even if Argentina's minimum specific import duties, as applied, did not exceed 35 per cent *ad valorem*, they still violated Article II because each of Argentina's specific duties had the *potential* to exceed 35 per cent *ad valorem* with respect to some imports. In fact, in all instances, the specific duties had the potential to exceed Argentina's tariff binding. This was especially true with respect to low cost products for which specific duties comprised a greater percentage of value than higher priced merchandise. Thus, by their very nature, the specific duties denied Argentina's trading partners the predictability and security for which they had negotiated a 35 per cent *ad valorem* binding.

3.88 The United States argued that the report of the panel on *EEC - Import Regime for Bananas* had addressed an issue quite similar to the one involved in this dispute. The panel had described the relevant considerations as follows:

> "The Panel noted that Article II required that each contracting party 'accord to the commerce of the other contracting parties treatment no less favourable than that provided for in the appropriate Part of the appropriate Schedule annexed to this Agreement'. The Panel then considered whether the introduction of a specific tariff for bananas in place of the *ad valorem* tariff provided for in its Schedule constituted 'treatment no less favourable' in terms of Article II. The Panel observed that while the bound *ad valorem* tariff was related to the value of bananas, the new specific tariff was based on the weight of bananas. Any change in the value of bananas per ton therefore led to a change in the *ad valorem* equivalent of the specific tariff [...] [T]he Panel also noted that the EEC had neither argued nor submitted any evidence that this tariff could never exceed 20 percent *ad valorem*; according to the complainants, the [...] specific tariff had already exceeded the equivalent of the bound 20 per cent *ad valorem* tariff [...] The Panel consequently found that the new specific tariffs led to the levying of a duty on imports of bananas whose *ad valorem* equivalent was, either actually or potentially, higher than 20 percent *ad valorem*".[76]

3.89 The United States added that, based on these facts, the report of the panel on *EEC - Import Regime for Bananas* had determined that complainants needed not prove that specific duties actually exceeded a binding. The mere possibility

[76] DS38/R, Op. Cit., para. 134.

of a breach sufficed to demonstrate a violation of Article II's requirement that imported products subject to a Schedule received treatment "no less favourable" than what was provided for in that Schedule:

> "The Panel considered that the **actual** levying of a duty in excess of the bound rate clearly constituted a treatment of bananas less favourable than that provided for in the EEC's Schedule of Concessions. The Panel then proceeded to examine whether also the **mere possibility** that the specific tariff rate applied by the EEC might be higher than the corresponding bound *ad valorem* rate, rendered it inconsistent with Article II. The Panel recalled the importance of security and predictability in the application of tariffs bindings. It noted that previous panels and working parties had emphasized that tariff bindings justify reasonable expectations about market access and conditions of competition. The CONTRACTING PARTIES had consistently found that a change from a bound specific to an *ad valorem* rate was a modification of a concession [...]. The Panel [...] concluded that, in determining whether treatment accorded by a tariff measure was no less favourable than that provided for in the Schedule, it had to take into account not only the actual consequences of that measure for present imports but also its effects on possible future imports. This followed from the principle recognized by many previous panels that the provisions of the General Agreement serve not only to protect actual trade flows but also to create predictability for future trade".[77]

The panel on *EEC - Import Regime for Bananas* thus had found that the mere possibility of exceeding a bound rate inherent in converting from *ad valorem* to specific duties was inconsistent with Article II. In reaching this conclusion, the panel followed prior GATT practice regarding conversions between *ad valorem* and specific duties. As that panel explained, such a change undermined the stability and predictability of Schedules, one of the cornerstones of the GATT. Based on these considerations, the *Bananas* panel concluded that the mere possibility of a breach sufficed to demonstrate less favourable treatment for purposes of Article II:1(a). The same reasoning was applicable in this dispute.

3.90 **Argentina** contended that the precedents cited by the United States were not applicable to the present case. In *EEC - Import Regime for Bananas*, the panel considered whether the "mere possibility" that a duty may exceed the bound rate made the said specific duty inconsistent with Article II of GATT 1994. After studying the cases concerning Turkey and newsprint from Canada, the panel concluded that "in determining whether treatment accorded by a tariff measure was no less favourable than that provided for in the Schedule, it had to

[77] DS38/R, Op. Cit., para. 135 (emphasis in original).

take into account not only the actual consequences of that measure for present imports but also its effects on possible future imports".[78]

3.91 Argentina argued that the conclusion in para. 135 of the report on *EEC - Import Regime for Bananas* seemed to diverge from the principle well anchored in GATT legal precedent and thinking, whereby GATT rules and GATT jurisprudence are constructed to protect expectations on the competitive relationship between imported and domestic products rather than expectations on export volumes. Where that potential to affect expectations of access was not accompanied by concrete measures that made it possible to verify its trade impact, it had been rejected under panel practice (even in cases where there were legal provisions that contemplated the possibility of adopting such concrete measures).

3.92 Hence, the report of the panel on *United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco*, agreeing with the United States position on a point related to tobacco inspection fees, stated: "that panels had consistently ruled that legislation which mandated action inconsistent with the General Agreement could be challenged as such, whereas legislation which merely gave the discretion to the executive authority of a contracting party to act inconsistently with the General Agreement could not be challenged as such; only the actual application of such legislation inconsistent with the General Agreement could be subject to challenge".[79]

3.93 Argentina submitted that to determine how these imports could be affected in the future, and whether that determination was relevant in terms of the GATT provisions, it had to be decided in the first place whether or not there was a restrictive measure affecting said imports. Only if such a measure existed and was inconsistent with the General Agreement would expectations of access be affected. It was those expectations of access and not a *quantum* of imports that the rules were designed to safeguard.

3.94 Argentina stated that in order to determine the differences between the case in the panel report on *EEC - Import Regime for Bananas* and the present case, it was first necessary to consider more closely the arguments of the complainants in the *EEC - Import Regime for Bananas* case. The complainants were of the view that Article II "set forth one of the central legal obligations of the General Agreement, namely the undertaking of contracting parties to respect the tariff concessions, thus prohibiting the application of tariffs for a specific product that were higher than those specified in each country's schedule of concessions".[80] The EC having adopted certain restrictive tariff and non-tariff measures, paragraph 1(a) of Article II had been violated insofar as this regime implied less favourable treatment than that established in the concession granted. The complainants further argued that "[...] the new monetary conversion rates yielded *ad*

[78] DS38/R, Op. Cit., para. 135 (emphasis in original).
[79] Adopted on 4 October 1994, DS44/R, para. 118, *in fine*.
[80] DS38/R, Op. Cit., para. 20.

valorem values of the newly introduced specific rates well above the bound rate of 20 per cent for bananas both within and above the quota. The 100 ECUs per ton translated to well over 25 per cent *ad valorem* whereas 850 ECUs per ton were eight to nine times higher than the bound duty".[81]

3.95 According to Argentina, these two paragraphs constituted the central argument of the complainants in the *EEC - Import Regime for Bananas* case. The United States was using this case not to support its arguments with regard to the obligation not to grant less favourable treatment but to salvage the panel's collateral finding (not finally adopted by the contracting parties) to the effect that "the **mere possibility** that the specific tariff rate applied by the EEC might be higher than the corresponding *ad valorem* rate rendered it inconsistent with Article II".[82]

3.96 Argentina considered that it was in this latter point that the two cases differed since the EEC did not argue that its specific duties did not violate the binding, whereas Argentina maintained, since its first submission, that the DIEM were not in excess of the bound *ad valorem* equivalent of 35 per cent. The findings of the panel on *EEC - Import Regime for Bananas* related to "the specific tariff rate applied by the EEC", which put their scope into perspective. This applied to the case under consideration and to the specific tariffs discussed therein, apart from the fact that the scope ascribed to any precedent should be limited, since otherwise it could be taken out of context. The EEC specific tariff which the panel had analyzed had the following characteristics:

(a) "the *ad valorem* equivalent of the 850 ECUs per ton specific tariff on bananas exceeded by far 20 per cent *ad valorem*" (para. 134);

(b) "as to the 100 ECUs per ton specific tariff, the EEC had neither argued nor submitted any evidence that this tariff could never exceed 20 per cent *ad valorem*" (same paragraph).

3.97 Argentina asserted that it was this specific tariff applied by the EEC, with these characteristics, in respect of which the panel examined whether "the mere possibility that the specific tariff rate applied by the EEC might be higher than the corresponding bound *ad valorem* rate rendered it inconsistent with Article II". The panel had not arrived at its finding in a vacuum or with respect to any specific tariff rate but with respect to one which had in fact already violated the bound ceiling (this finding was already part of the panel's conclusions) and with respect to which it also made this second collateral finding.

3.98 Argentina added that, in relation to this specific tariff, the panel had concluded "that, in determining whether treatment accorded by a tariff measure was no less favourable than that provided for in the schedule, it had to take into ac-

[81] DS38/R, Op. Cit., para. 24.
[82] *Ibid.*, para. 135 (emphasis in original).

count not only the actual consequences of that measure for present imports but also its effects on possible future imports". It was from this second conclusion that the United States inferred that Argentina's specific duties had the potential to exceed the tariff binding.

3.99 In relation to this, Argentina contended firstly that the panel's conclusion seemed to indicate that it was a question of protecting export volumes rather than expectations of access and it was this which Argentina challenged. Secondly, the potential as such would be an infringement only if trade were affected (as in the case of bananas in which tariff binding was violated). Otherwise, if one were to accept the idea of "potentiality" advanced by the United States, any regulation or provision which allowed for the possibility of an infringement would be potentially in violation of the GATT/WTO commitments. This has been clearly rejected by panels adopted by the contracting parties such as the panel on *United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco*.

3.100 Finally, to bring out the difference between the two cases still more clearly, Argentina argued that even if the concept of "mere possibility" (put forward by a panel whose report was not adopted), which the United States defined as "potential", were accepted as a valid precedent, in the case of Argentina this situation did not arise since the "challenge procedure" guaranteed the tariff binding in Law No. 22.425. Nothing similar was either argued by the EEC or considered by the Panel in the *EEC - Import Regime for Bananas* case.

3.101 The **United States** noted that the parties disagreed regarding the mandatory nature of a measure. According to the report of the panel on *EEC - Import Regime for Bananas*, as long as there were or could be imports that entered a WTO Member subject to duties in excess of a bound rate, those duties violated Article II. This reasoning of the panel on *EEC - Import Regime for Bananas* echoed the analysis of other panels which had determined that WTO Members may not maintain *mandatory* legislation that was inconsistent with GATT obligations, regardless of whether the inconsistency arose at the present or in the future. As the panel on *United States - Taxes on Petroleum and Certain Imported Substances* had stated in another context, the GATT served "to protect expectations of the contracting parties as to the competitive relationship between their products and those of the other contracting parties".[83] This was

> "not only to protect current trade but also to create the predictability needed to plan future trade. That objective could not be attained if contracting parties could not challenge existing legislation mandating actions at variance with the General Agreement until the administrative acts implementing it had actually been applied to their trade".[84]

[83] Adopted on 17 June 1987, BISD 34S/136, para. 5.2.2., hereafter the "*Superfund*" case.
[84] *Ibid.*

3.102 The United States recalled that, likewise, the panel on *United States - Measures Affecting Alcoholic and Malt Beverages* had noted that prior panels had consistently found GATT violations where contracting parties imposed mandatory legal measures that were inconsistent with provisions of the General Agreement solely as they related to future trade.[85] This important principle applied here. The measures instituting Argentina's specific duties were mandatory, and they allowed for the imposition of excessive duties in relation to certain products that may be imported into Argentina in the future. The mandatory nature of the measures was made plain by Argentina when it stated that "[t]he national tariff must be applied by the National Customs Administration which, of course, is not competent to change it". Further, the United States demonstrated in its submissions that Argentina's specific duties necessarily had the potential to exceed 35 per cent *ad valorem.* Even assuming that Argentina's minimum specific import duties had been enacted with effect from 1 January 1998, the Panel could, and should, have found that measures requiring the imposition of duties in excess of bound levels violated Article II, even if such measures were not yet in effect. Indeed, the passage cited from the *Superfund* panel report related to a mandatory tax, which was enacted in 1986 but was not to go into effect until three years later. The panel in the *Superfund* case found that because the tax in question was a mandatory tax, it could be challenged, that is to say, it was a matter justiciable by a GATT panel even though it was not yet being imposed.

3.103 The United States noted that Argentina further criticized the report of the panel on *EEC - Import Regime for Bananas* as being inconsistent with the panel report on *United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco* which had found that the non-application of discretionary measures could not be found to be in violation of GATT 1994. Argentina appeared to confuse the notions of possible future commercial disadvantages of *mandatory* legislation with that of *discretionary* legislation addressed in the report on *United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco*. This report relied on by Argentina dealt with a US discretionary provision on tobacco inspection fees which allowed, but did not *require*, the US authorities to impose a fee.

3.104 The United States argued that, in contrast, the Argentine measures in this case *required* Argentine officials to impose minimum specific duties without regard to the value of imported products. Argentina had admitted that its customs officials had no *discretion* not to apply the specific duties. As the United States had demonstrated, this lack of discretion had led to the imposition of specific duties well in excess of Argentina's bound 35 per cent *ad valorem* rate. Similarly, the report of the panel on *EEC - Import Regime for Bananas* dealt with *required*

[85] Adopted on 19 June 1992, BISD 39S/206, para. 5.39.

application of specific duties by the EC, and conducted its discussion of the potential to violate a bound rate in the future in that context.[86]

3.105 In the opinion of the United States, if Argentina's argument that WTO Members may adopt regimes capable of violating a binding so long as they did not do so in application were to be accepted, the security afforded by Article II would be diminished. WTO Members would only be able to enforce their rights under Article II by demonstrating excessive duties on a fact-specific, case-by-case basis, rather than through examination of the implementing measures themselves. Panels in effect would be put in the position of being a kind of final appeals court in each customs dispute. This surely had not been intended by the drafters of Article II, or of the DSU.

3.106 **Argentina** replied that its argument was not based on the fact that the panel report on *United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco* was different from that of the panel on *EEC - Import Regime for Bananas*. Argentina was not seeking freedom to authorize measures contrary to the WTO obligations, allow them to lapse and then subsequently indicate that they did not apply. Argentina asserted that the mere existence of a measure that might possibly be contrary to WTO obligations was not enough to condemn a country. In other words, any alleged violation of an obligation had to be proved by citing concrete cases and not simply by theoretical statements. It was only in this way that a *prima facie* case of nullification or impairment could be determined.

3.107 Argentina argued that the concept of the binding nature of a rule had to be analyzed in respect of a particular case. In the case of Argentina, both the Resolution imposing the DIEM regime and Law 24.425 incorporating the WTO Agreement in Argentine legislation were binding. The difference in status between the two binding rules was to be found in their place in the hierarchy, because the Law took precedence over the Ministerial Resolution.

3.108 The **United States** argued that, because market prices for textiles, apparel and footwear changed rapidly, especially for certain categories, Argentina's minimum duties based on "average import prices" could not be guaranteed to be equal to or less than the bound rate of 35 per cent *ad valorem*. A specific duty on a certain fabric or an article of clothing might be within the bound rate at one moment and above it the next. The potential to surpass the bound rate was ever present. Given such conditions, Argentina, like the EEC in the case on *EEC - Import Regime for Bananas*, had no way to assure other WTO Members and their traders that the specific duties would remain within the bound rate.

---

[86] DS38/R, Op. Cit., para. 135. The United States also referred to the Panel Report on *United States - Measures Affecting Alcoholic and Malt Beverages*, Op. Cit., para. 5.39 *in fine* which mentioned that "because Illinois legislation in issue allows a holder of a manufacturer's license to sell beer to retailers, without allowing imported beer to be sold directly to retailers, the legislation mandates governmental action inconsistent with Article III:4".

3.109 The United States noted that Argentina had argued that its specific duties were consistent with Article II because they were no more than 35 per cent of the adjusted "average import price" of each relevant HS category. However, inspection of the decrees imposing these duties showed that they simply specified a list of minimum specific duties, not a methodology for valuing imports. Argentina's use of an adjusted "average import price" instead of actual transaction values in setting its specific duties was contrary to Articles II:3 GATT 1994, as well as Article VII GATT 1994 as clarified by Articles 1 to 8 of the Customs Valuation Agreement.[87] These provisions made clear that a WTO Member may not "alter its method of determining dutiable value [...] so as to impair the value of any of [...] concessions",[88] and that WTO Members should rely on actual transaction values rather than "arbitrary or fictitious values".[89] That the specific duties may be no more than 35 per cent of an "average import price" was simply irrelevant for purposes of establishing duties to be imposed on particular imports.

3.110 The United States noted that a table produced by Argentina relating to imports under HS Chapters 51 to 63 showed that some of the minimum specific import duties were, on average, more than 35 per cent *ad valorem.* Argentina had explained that it derived the specific duties by multiplying a "representative international price" for a particular line-item - often an average of US prices - by the bound rate of 35 per cent. The table had four columns. The first represented the line-item; the second listed the "representative international price"; the third showed 35 per cent of the representative price; and the fourth identified the then proposed specific duty (which in almost every instance became the actual duty). The United States had found 32 line-items where the table concerned stated that the specific duty was greater than 35 per cent of the "representative international price". Argentina offered no explanation as to why so many of its specific duties were set at an amount greater than 35 per cent of the "representative international prices" or how it could justify imposing duties at these levels. Argentina similarly was unable to explain why it believed that no goods had entered Argentina with values less than the "international representative price" in categories where the specific duties were greater than or equal to the representative price. Essentially, Argentina was asking the Panel to believe that these *average* or *representative* prices were also *minimum* prices for entire categories of merchandise. In other words, Argentina assumed that international merchants and exporters could not possibly set their prices lower than the set "representative" price. However, as demonstrated, exporters and merchants of textile, apparel and footwear products could and did ship and sell the products for less than Argentina's "set price". The

---

87 In connection with this, the United States mentioned that Argentina was a signatory to the Customs Valuation Agreement and that, although Argentina had reserved limited rights with respect to the application of certain procedures under the agreement, Argentina had not timely invoked the five-year delay in coverage available to developing nations and could no longer do so. The United States referred to document G/VAL/6, of 10 January 1996.

88 Article II:3 GATT 1994.

89 The United States referred to Article 7 of the Customs Valuation Agreement.

result was that Argentina's specific duties exceeded 35 per cent *ad valorem* for an extensive number of products.

3.111 **Argentina** replied that its Customs applied only the provisions of the Customs Valuation Agreement. Consequently, it could not apply a criterion based on the "world import price" which did not exist in the Argentine legislation. The national tariff had to be applied by the National Customs Administration which was not competent to change it. However, in the unlikely situation of a hypothetical case in which customs were to require the payment of a minimum specific import duty which exceeded 35 per cent *ad valorem*, the importer would have the right to challenge the assessment made by the National Customs Administration. The customs authority would have to initiate a challenge procedure and the importer would automatically be allowed to request the release of the goods into the market after paying only the sum he considered appropriate for those goods and depositing a guarantee.

3.112 Argentina added that, since the establishment of the Panel, the minimum specific import duties had been reduced, through Resolution No. 597/97, to an *ad valorem* equivalent of approximately 25 per cent for textiles and 30 per cent for clothing. The new resolution fixing minimum specific import duties at 5 per cent and 10 per cent below the bound ceiling made it even less likely that there could be import transactions exceeding the 35 per cent ceiling.

3.113 The **United States**, in order to show the problems inherent in the minimum specific import duties applied by Argentina, provided the Panel with an example: for a given category of athletic shoes -for instance, soccer shoes - the *ad valorem* rate might be 20 per cent and the specific duty US$3.50 per pair. If one pair of soccer shoes were to enter Argentina with an actual transaction value of US$5.00, the specific duty would be assessed. This was so because the *ad valorem* rate would result in a duty of US$1.00, far less than the specific duty of US$3.50. In fact, a pair of athletic shoes in this category would have to be worth more than US$17.50 for the *ad valorem* rate to apply. This example revealed why Argentina's duties were excessively high. The US$3.50 specific duty would amount to 70 per cent of the US$5.00 transaction value of the shoes. This was double Argentina's maximum bound rate of 35 per cent. Each pair of soccer shoes in the category entering Argentina with a transaction value below US$10.00 would be subject to a duty in excess of 35 per cent *ad valorem*. Thus, by their very nature, Argentina's specific duties had the potential to exceed 35 per cent *ad valorem* in all relevant categories. For each specific duty imposed by Argentina, there were, or at the very least there could be, products with sufficiently low prices such that they would enter Argentina subject to specific duties above the bound rate. This would occur with regard to all shoes worth less than US$10.00.

3.114 The United States concluded that, given that Argentina's specific duties had the potential to exceed 35 per cent *ad valorem*, the Panel should find that the specific duties were inconsistent with Article II. Further, Argentina's imposition of minimum specific duties violated Article II because they impaired the value of

the concessions Argentina had made during the Uruguay Round. Even if these duties were not excessive for any products that had already entered Argentina, the duties necessarily had the potential to violate its bound rate of 35 per cent *ad valorem* for some covered items in the future. This was a breach of the guarantee Argentina had given to fellow WTO Members in negotiating its Schedule and, thus, it was a violation of Article II.

3.115 With respect to what happened when the transaction value for the good concerned was lower than US$10, **Argentina** argued that, according to the Argentine law, the specific duty was not payable because US$3.50 was greater than 35 per cent of the transaction value. On the other hand, the *ad valorem* duty of 35 per cent applied here as a result of the remedies available in Argentine law, essentially the challenge procedure *(recurso de impugnación)*.

5. Imposition of Duties Effectively Exceeding the Bound Rate

3.116 For the **United States**, one of the fundamental objectives of the GATT 1994 was "the substantial reduction of tariffs".[90] To ensure that tariff concessions, once made, had the full force and effect intended, Article II made plain that the duty rates set forth in bindings were maximum limits that may not be exceeded.[91] The United States argued that Argentina's specific duties were inconsistent with these rules because they exceeded Argentina's bound maximum rate of 35 per cent *ad valorem*. The amount by which Argentina's specific duties surpassed the bound rate in many instances was considerable, often equal to the entire value of imported products or even double or triple the value.

(a) US Examples Based on the Argentine Methodology for the Application of DIEM

3.117 In order to demonstrate that the application of specific minimum import duties exceeded Argentina's bound rate, the **United States** submitted to the Panel an hypothetical example illustrating how, in its opinion, the methodology used for the application of the minimum specific import duties operated. Assuming that the applicable *ad valorem* rate for a category of goods was 20 per cent and the specific duty was US$3.50 per unit, Argentina would assess the specific duty of US$3.50 on all goods in the category with an *actual transaction value* of less than US$17.50 per unit. This would be so because, in those cases, the specific

---

[90] GATT 1994, Preamble, para. 3. The United States stated that panels should address issues in light of the underlying purposes of the GATT 1994 and referred to the Panel Report on *United States - Restrictions on Imports of Sugar*, adopted on 22 June 1989, BISD 36S/331, paras. 5.2-5.3.

[91] The United States referred to the *Panel on Newsprint*, Op. Cit., pp. 131-132, which mentioned at para. 52 that "[t]he Panel shared the view expressed before it relating to the fundamental importance of the security and predictability of GATT tariff bindings, a principle which constitutes a central obligation in the system of the General Agreement".

duty would be greater than the *ad valorem* duty (*e.g.*, 20 per cent of US$10 is US$2.00, less than the specific duty of US$3.50). In contrast, goods with an *actual transaction value* of more than US$17.50 would be subject to the *ad valorem* duty, which resulted in a duty above US$3.50 (*e.g.*, 20 per cent of US$20 was US$4.00, which was more than the specific duty of US$3.50). While higher priced goods in the category would be subject to proper *ad valorem* duties, items worth less than US$17.50 would enter Argentina under a specific duty in excess of Argentina's bound rate of 35 per cent.

3.118 The United States, on the basis of data supplied by Argentina, had identified more than 100 HS categories in which Argentina's specific duties, *on average*, were higher than 35 per cent *ad valorem*. This meant that the specific duties constituted more than 35 per cent of the *average of actual transaction prices* of merchandise imported in each category. For example, the average of *actual* import prices for HS category 6303.19 was US$1.00 per kilogram, while the specific duty was US$4.80 per kilogram. The specific duty thus equalled 480 per cent of the average value of merchandise in the category, and all merchandise in the category entering Argentina with a value of less than US$13.71 per kilogram were subject to duties greater than 35 per cent *ad valorem*. This was so because 35 per cent of US$13.71 was US$4.80. The Argentine peso was pegged to the US dollar. Thus, dollar figures equalled the same amount in pesos.

3.119 The specific duties often were greater than Argentina's bound rate, because Argentina established them for the very purpose of imposing a duty *higher* than the *ad valorem* duty otherwise to be applied. The intention to raise duties above the bound *ad valorem* rate was clear from Resolution No. 1696/93, which stated that the specific duties served to combat "the harm to the [domestic] athletic footwear industry resulting from these commercial practices [that] cannot be offset through an increase in the *ad valorem* tariff rates currently in effect", and "the specific import duties [...] will operate as a minimum of the corresponding *ad valorem* import duty".

3.120 **Argentina** first stated that the specific duties were not calculated arbitrarily. In determining their amount, the Argentine authorities utilized the following methodology:

(a) A representative international price was calculated for each category of products and tariff heading. Since there were no standard international prices for textile and clothing products, the prices prevailing in the major markets were used, mainly the United States market. The use of data concerning these markets was determined in general terms by volume and the representative nature of the markets, and also by the degree of reliability of the statistics;

(b) a specific duty equivalent to a maximum *ad valorem* tariff of 35 per cent was applied to the international prices thus determined, adjusted to put them on a c.i.f. - Buenos Aires port basis.[92]

3.121 In order to explain in practical terms what was implied by the application of specific duties, Argentina analyzed the example cited by the United States above. This example made the mistake of comparing a level of specific duty with an *ad valorem* duty of 20 per cent. This may correspond to the tariff effectively applied to the tariff heading cited, but it did not represent Argentina's WTO obligation, which was not to exceed the bound level of 35 per cent *ad valorem* equivalent. In the example cited, if the specific duty was US$3.50 for a product with a value of US$17.50, the *ad valorem* equivalent would be 20 per cent. In this particular case, the 35 per cent level would only be breached if the price of the goods were less than US$10 and not, as mentioned by the United States, if it were less than US$17.50.

3.122 Argentina further argued that, on that basis, it might be imagined that the principal issue raised by the United States was the confusion between the tariff applied and the tariff bound by Argentina in the WTO. The *ad valorem* import tariff applicable to the textiles sector ranged from 12 per cent to 20 per cent depending on the product's level of processing, whereas the bound *ad valorem* import tariff remained at a uniform level of 35 per cent for the whole of this sector of goods and for many other sectors in the Argentine customs tariff. When it had been decided to apply minimum specific import duties according to the price of the goods, there had been no intention to utilize the methodology referred to above but to establish a level that did not exceed the 35 per cent bound by Argentina in the WTO.

3.123 For Argentina, the example cited by the United States revealed a conceptual error. A closer study showed that there had not simply been a calculation error, as might be imagined when first reading it (3.50 pesos was not 35 per cent of 17.50 pesos), but that the calculation showed that the methodology used to arrive at the conclusion that Argentina was violating its WTO commitments was flawed. The calculation showed that the United States based its case on the presumption that Argentina had to meet the *ad valorem* equivalent of the tariff actually applied and not, as was the case, the tariff bound in Schedule LXIV.

3.124 In order to illustrate the procedure, Argentina suggested to assume that the *ad valorem* import duty for a category of goods was 20 per cent and the specific duty was US$3.50 per unit. Argentina would apply the specific duty of US$3.50 to imports in this category with a transaction value of less than US$17.50 because in such cases the specific duty would be greater than the *ad valorem* duty of 20 per cent (*i.e.* 20 per cent of US$10 was US$2, less than the specific duty of US$3.50). On the other hand, goods whose transaction value exceeded US$17.50

[92] Argentina submitted to the Panel a table on the methodology for calculation of minimum specific import duties for HS Chapters 51 through 63.

would be subject to the *ad valorem* duty, because it would be higher than the specific duty (*i.e.* 20 per cent of US$20 was US$4, which was more than the specific duty of US$3.50). The example given by the United States did not make clear what happened when the transaction value for a good in this category was lower than US$10. In such cases, according to the Argentine law, the specific duty was not payable because US$3.50 was greater than 35 per cent of the transaction value. On the other hand, the *ad valorem* duty of 35 per cent applied here as a result of the remedies available in Argentine law, essentially the challenge procedure *(recurso de impugnación)* described in sub-section B.7.b) below (i.e. 35 per cent of US$5 was US$1.75, less than the specific duty of US$3.50).

3.125 To summarize, Argentina stated that, for a category of goods to which an *ad valorem* duty of 20 per cent effectively applied and which were subject to the payment of a specific duty of US$3.50, the following three possibilities occurred:

Transaction Value	*Import duty*
Over US$17.50	20 per cent *ad valorem*
Between US$17.50 and US$10	US$3.50
Less than US$10	35 per cent *ad valorem*

3.126 For Argentina, the confusion regarding its WTO obligation to respect the 35 per cent figure, and not the tariff in force, was all the more obvious when considering some of the submissions made by United States exporters in the course of the internal proceedings under Section 301 of the United States Trade Act.[93]

3.127 The **United States** responded by stating that it was not arguing that there was relevance in comparing whether Argentina's specific duty was higher than the otherwise applicable *ad valorem* rate. The United States focused on whether the specific duty went above the bound rate of 35 per cent, in actuality, or at least potentially.

(b) Obligation for the Argentine Customs to Assess the Full Amount of Duties

3.128 The **United States** argued that Argentina had acknowledged that its customs service could only impose the duties as provided for in the relevant resolu-

[93] Argentina referred to the submission from the Association of the Non-Woven Fabrics Industry to the Office of the United States Trade Representative of 5 November 1996 (Docket No. 301-108: Section 302 Investigation of Argentine Specific Duties and Non-Tariff Barriers Affecting Apparel, Textiles and Footwear), where this Association questioned the fact that the corresponding specific duty had an *ad valorem* equivalent that exceeded the applicable tariff of 18 per cent. In the subsequent paragraph, the *ad valorem* equivalent was calculated at 28.56 per cent. Argentina argued that, even though this submission recognized that the said equivalent was lower than 35 per cent, in order to prove the alleged violation it argued that the statistical tax and domestic taxes had to be added, although these elements bore no relation to import duties.

tions or decrees. It also declared that US traders had reported that the Argentine customs service assessed the full specific duty listed in the governing resolution or decree, even where that duty was in excess of 35 per cent *ad valorem*.

3.129 **Argentina** argued that the *ad valorem* equivalents of the minimum specific import duties assessed by Argentina were lower than the tariff levels in Argentina's Schedule LXIV. Argentina had difficulties in accepting or in considering the United States' argument since, on the one hand, there was no infringement of the commitments made in Argentina's Schedule and, on the other hand, Argentina's legal system constituted a single and inseparable whole which included the procedure for challenging assessments. In these circumstances, the Argentine authorities applied the minimum specific import duties laid down. This was done at the time of assessment of the import duties and other duties and charges which importers had to pay in order to release imported goods for consumption.

3.130 For Argentina, no duties in excess of 35 per cent *ad valorem* had been applied. Argentina had no knowledge of instances of the imposition of specific duties on textile or clothing imports which had resulted in an infringement of the bound tariff of 35 per cent *ad valorem*. Moreover, there had been no cases of imports of textile products and clothing in which importers had raised the question of the application of specific duties in excess of the 35 per cent *ad valorem* bound in the WTO.

3.131 Argentina specified also that in each import operation the Argentine customs administration assessed taxes on the basis of the customs value of the goods. There was no documentation of any kind that indicated the imposition of DIEM in any tariff category in excess of the bound tariff of 35 per cent *ad valorem*. The United States did not offer evidence of the alleged imposition of minimum specific import duties in excess of the tariff bound in the WTO for textiles and clothing imports. In these circumstances, it could only be assumed that such cases did not exist.

(c) Data Regarding the Income for Argentina from Levying Duties Above the Bound rate

3.132 The **United States** supplied a chart to the Panel showing the approximate amount that Argentina had allegedly collected as a result of the imposition of the specific import duty in excess of what would have been collected had valuations been conducted based on a 35 per cent *ad valorem* basis in specific HS categories between January and September 1996. This chart showed a break-down of duty collection for sweaters (US$161,000), fabrics (US$544,000), carpets (US$348,000), apparel (US$450,000), other textiles (US$291,000) and total (US$1,634,000). In addition, the United States claimed that the chart was prepared based upon customs data supplied by Argentina.

3.133 With reference to those data, **Argentina** replied that the United States wrongly assumed that Argentina was applying specific duties in excess of 35 per cent equivalent *ad valorem*. There had been no refunds to importers for duties

imposed in excess of the bound tariffs inasmuch as no proceedings on these grounds had been brought before the Argentine customs.

3.134 Argentina stated that Resolution No. 597/97, which reduced the minimum specific import duties applicable on a number of textile and apparel products had been adopted as part of the trade policy measures of the Argentine economic authorities. This trade policy was in keeping with the trend to reduce import tariffs and, with this in mind, it had been decided that in the textile product and clothing sector tariffs should not exceed maximum levels of approximately 25 per cent for the former and 30 per cent for the latter. This meant that a large number of tariff headings corresponded to specific duties whose *ad valorem* equivalent was lower than these levels. The reason why it was desirable to take this action at this time was related to the fact that it was precisely in the month of April every year that the foreign trade statistics corresponding to the totals for the previous year became available. The events of 1996 in the textile and clothing sector, as confirmed by the statistics available in April of the current year, formed the basis for the analysis leading to the adoption of this measure. The calculation method employed was based on the import prices of goods entering Argentina. This decision was taken because, from 1996, with total imports of textiles and clothing valued at US$871 million, the quantities considered were sufficiently representative to be taken into account. In 1993, when the minimum specific import duties were established for the purpose of providing a certain level of tariff protection for the domestic industry, the volumes were not sufficiently representative of Argentine imports in order to take them into account to set an average import price. In 1990, imports amounted to US$100 million. Accordingly, in 1993 it was decided to work on the basis of the prices for these goods in representative markets of other countries.

3.135 Argentina contended that the above-mentioned chart submitted by the United States was intended to persuade the Panel that, in actual fact, US$1,634,000 had been paid over and above the amount which should have been collected on the basis of a 35 per cent tariff, but this was only theoretical, since the mentioned amount was based on a theoretical calculation and not on evidence of a payment actually made.

(d) Arguments Regarding the Use by the United States of Tables Prepared by Argentina

3.136 The **United States** recalled that, during consultations with the United States, Argentina had produced customs data reflecting c.i.f. values and quantities (in tonnes) of textile and apparel for line-items within HS chapters 51-64 for the period January-September 1996. This document consisted of two tables: a

table of total imports for 1995 and 1996[94] and a table on the principal countries of origin of Argentine imports for 1995 and the period January-September 1996.[95] Based upon this *Argentine* data, the United States calculated average *ad valorem* equivalents for each line-item.

3.137 The United States had requested the data in question for the purpose of performing the calculations of *ad valorem* equivalents. This information should be viewed as highly credible and showing Argentina's specific duties to be above its bound rate. The United States elected to rely upon this data, rather than using other information, because it wanted to minimize factual conflicts for the Panel.

3.138 **Argentina** stated that the first list in the above-mentioned document had been prepared for the purpose of analysing price problems concerning certain tariff headings. In the consultation meetings there had been extensive discussion of the considerable differences which had emerged between Argentine import prices and United States export prices for exports to Argentina. These differences suggested the existence of significant underinvoicing in many transactions. This resulted in the information being supplied to the United States as a basis for assessing the magnitude of the problem. The second list in the above-mentioned Argentine document had been provided so that the United States could note its minor importance as a textiles supplier to Argentina, as compared with other exporters such as China. Thus, the information on the origin of imports had been provided to show the United States that the commercial interests alleged to be affected were actually confined to a very few tariff headings. At no time had it been envisaged that the data in question might be used for deducing prices according to the origin of the goods.

3.139 Argentina further specified that, in the second list, the figures related to imports per country of origin were expressed in thousands. Given the low volume of transactions in many tariff headings this yielded an unacceptable margin of error, as shown by the following example. If 160 kg of a particular good were imported for US$1,495, the price per kilogram would be US$9.34. However, if the same information was rounded off to the nearest thousand, the import value would be US$1,000 for 0.2 thousand kg. The average price calculated on the basis of the latter data would be US$1/0.2 = US$5. There was a considerable difference between US$9.34 and US$5, but both figures were derived from the same information. This was the cause of the error made by the United States in its table identifying 118 cases of imposition of duties above the 35 per cent *ad valorem* bound rate. (see para. 3.141).

3.140 The **United States** replied that Argentina's contention that the rounding of certain numbers affected the conclusions to be drawn from the document it had

---

[94] *Importaciones de Productos de los Capitulos 51 a 64 de la Nomenclatura Arancelaria Armonizada (1995 y 1996, en Valor, Cantidades y Precios por Kilogramo).*

[95] *Importaciones de Productos de los Capitulos 51 a 64 de la Nomenclatura Arancelaria Armonizada (1995 y 9 Meses de 1996, en Valor y Cantidades, por Pais de Origen).*

submitted lacked merit. Firstly, Argentina ignored the fact that the January to September 1996 import data in the first list were not rounded to thousands, but rather to tens of dollars. This was reflected by the use of the two-place decimal points in the fifth and seventh columns of the first list. Moreover, even the second list contained a decimal point so the rounding in dollars was only to hundreds. Moreover, to the extent rounding had any impact on the calculations that the United States performed on the basis of these tables, the effect was minimal. Fifty-nine of the 118 categories identified by the United States in the table referred to in para. 3.141 involved imports worth over ten thousand dollars, of which 17 reflected imports amounting to hundreds of thousands and even millions of dollars. The rounding in these categories would be insignificant.

(e) Evidence of Violation on an Average Basis

3.141 The **United States** emphasized that, in this dispute, the Panel needed not rely solely on possibilities of binding breaches. Argentina's specific duties not only had the potential to exceed the bound rate, but in fact did. To demonstrate this, the United States had identified in a table gathering Argentina's textiles and apparel imports from the United States subject to *ad valorem* rates higher than 35 per cent 118 HS categories of textiles and apparel in which Argentina's specific duties, *on average*, were greater than 35 per cent *ad valorem*.The data contained in that table represented (a) the value of Argentine imports from the United States for January-September 1996; (b) their volume, (c) the average price for the same period (a/b); (d) the Argentine DIEM in US$/kg; (e) the break-even price in US$/kg (*see* below) and; (f) the *ad valorem* equivalent duty for imports for the same period. The listed specific duties constituted more than 35 per cent of the *average of transaction prices* of merchandise imported in each category. This table made plain that, at the least, all merchandise having a lower actual value than the average were subject to duties above 35 per cent *ad valorem*. For example, with respect to HS category 6110.30, the average transaction price was US$11.39 per kilogram while the applicable specific duty was US$6.40 per kilogram. This resulted, on average, in duties equivalent to 56 per cent *ad valorem*. All goods with a value *less* than the average of US$11.39 per kilogram were subject to duties *greater than* 56 per cent. In addition, the calculations of "break-even price" signified that all goods in category 6110.30 worth less than US$18.29 per kilogram would be subject to duties in excess of 35 per cent *ad valorem*. This column was called the "break-even price" because only goods with a value greater than the amount listed entered Argentina subject to specific duties within the bound rate.

3.142 The United States also adjusted its calculations contained in these table and chart to take into account Resolution No. 597/97, which provided 5 stages of modifications of specific duties in certain categories.[96] The adjusted figures were

[96] *Boletín Oficial de la República Argentina*, No. 28.650 of 20 May 1997.

reflected in a table where the new specific duties were applied to imports for the period January-September 1996. Applying the Argentine data submitted by Argentina during the consultations[97] to the new duties, the United States had found that Argentina still was in excess of 35 per cent, on average, with respect to 72 line-items. The United States had attempted to show how these figures broke-down in terms of product sectors. A chart covering specific sectors reflected how high Argentina's specific duties were with respect to a variety of textile and apparel groupings, ranging on average from 40.9 per cent to 56.2 per cent.

3.143 The United States contended that the table described in para. 3.141 above not only showed that Argentina's minimum specific import duties were excessive for products in the listed categories, but it also revealed how minimum specific import duties - no matter how low or seemingly modest -would violate an *ad valorem* bound rate for at least some products in a category. For example, under HS 5514.22, the specific duty for this category was US$1.20 per kilogram. However, the average of actual transaction values for the category was only US$2.61 per kilogram, resulting in an average *ad valorem* equivalent of 46 percent. Thus, while a US$1.20 specific duty may seem reasonable on its face, in application it would exceed the bound rate for some products.

3.144 The United States specified that it had no data on import prices for 1995. The table it had presented in para. 3.141 above, which reflected 118 categories in which Argentina's specific duties exceed 35 per cent *ad valorem*, was based on price data supplied by Argentina for the period January through September 1996. Information on 1995 figures was exclusive within the control of the Argentine authorities. The United States had however applied the 1996 price data previously supplied by Argentina[98] to the specific duties that were in effect under Decree No. 2275/94 through September 1995. The results demonstrated that even the lower duties in place for much of 1995 still were excessive when compared against the Argentine price data for January through September 1996, the most reliable data available. Accordingly, Argentina's specific duties, on average, would have exceeded 35 per cent *ad valorem* with respect to 76 tariff line-items. The averages frequently were quite high, even exceeding 100 per cent *ad valorem*. As excessive as were the duties as calculated above, the specific duties imposed by Resolutions No. 304/95 and No. 305/95 were even higher. Thus, the United States had identified far more categories (118) which on average exceeded 35 per cent *ad valorem*.

---

[97] The document submitted by Argentina was entitled *Importaciones de Productos de los Capitulos 51 a 64 de la Nomenclatura Arancelaria Armonizada (1995 y 1996, en Valor, Cantidades y Precios por Kilogramo)* and *Importaciones de Productos de los Capitulos 51 a 64 de la Nomenclatura Arancelaria Armonizada (1995 y 9 Meses de 1996, en Valor y Cantidades, por Pais de Origen)*. See footnotes 94 and 95 above.

[98] *Ibid.* The United States noted that volume data was not provided for 1995 which made the calculation of average duties paid for that period impossible.

3.145 Referring to an evidence provided by the United States with respect to imports under tariff heading HS 6303.19, **Argentina** noted that the United States alleged that the *ad valorem* equivalent of the specific duty applicable was 480 per cent. If certain data were examined closely, however, it could be seen that this information was incorrect. The representative price data used to calculate the minimum specific import duties in 1994 corresponded to values for 1992-1993 and showed a price of US$48.60 per kg for tariff heading HS 6303.19. The corresponding representative price for the same tariff heading for 1996 amounted to US$16 per kg. Making a comparison, by way of example, it could be seen that the *ad valorem* equivalent of the minimum specific import duties applicable to this tariff heading (6303.19) remained below 35 per cent, despite the sharp fluctuation in prices. During 1996, imports into Argentina of goods under tariff heading 6303.19 had amounted to 256 kg. for a value of US$342. This corresponded to five samples and the average price of US$1.33 was solely due to the cost of freight and insurance. Samples with no commercial value were not subject to payment of import duties in Argentina. Moreover, it was well known that there was no textile product with a commercial value of US$1.33 per kg. This price did not even come close to the value of international prices for the raw materials.

3.146 Argentina contended that if, for the sole purpose of an academic mathematical exercise, one used another price basis for comparison with the minimum specific import duty rates that appeared in the methodology for the establishment of the DIEM criticized by the United States, the result could be totally different. For example, taking export prices for textiles and apparel from the United States to Argentina, many tariff headings whose *ad valorem* equivalent exceeded 35 per cent in the US examples would be now below this figure.

3.147 Argentina was of the view that it was impossible to ignore the differences between the theoretical prices of the goods on entering Argentina and the prices declared for the same headings by the exporters in the United States. For example, if one took the first four-digit heading (5208) in the United States table described in para. 3.141 above and compared it with the figures declared at exportation for that heading during the same period, according to the United States, the *ad valorem* equivalent of the specific duties for the first six lines of the table would range from 45 per cent to 97 per cent with an average price of US$7.67 c.i.f. - Port of Buenos Aires - and an average "break-even price" of US$/kg12.71. If one took the declarations made by the exporters in the United States for the same headings and the same period, one saw that the average export price for Argentina was US$12.97 f.a.s., i.e., approximately US$15 c.i.f. Buenos Aires. This was without taking into account the above-mentioned considerations concerning the effect of rounding off to the nearest thousand, together with the weight of the packaging, the non-payment of duty on samples, etc. The conclusions were obvious with respect to both the validity of the above mentioned evidence submitted by the United States and the reason why no importer had been prepared to challenge a transaction. Indeed, it had to be borne in mind that underinvoicing may constitute an offence.

3.148 Argentina argued that, as the other tables submitted by the United States showing infringements of the 35 per cent ceiling on a HS line basis had been produced in the same way, there was really no way of knowing the actual grounds on which the United States was claiming for a right which it did not know to have been infringed. In particular, the charts prepared by the United States on the basis of the table submitted by Argentina used data which presupposed or took it as an accepted fact that the prices and values corresponded to actual import transactions. These were suppositions, not fact, since the data derived from the two tables mentioned by Argentina in paras. 3.138-3.139 above and had all the shortcomings and defects previously noted.

3.149 The most important thing was that the price basis had to be derived from data other than those declared by the alleged importers of textiles and apparel in Argentina. Certainty could only be found in import transactions that actually took place. The only way of knowing whether these import transactions existed and were effectively subject to payment of minimum specific import duties exceeding 35 per cent was to use the full customs documentation corresponding to the transactions, including the receipt for payment of the import duties and taxes.

(f) The Use of Net *v.G*ross Weight

3.150 **Argentina** contended that the *ad valorem* equivalents of particular specific duties could be calculated theoretically by taking the average prices of imports. Nevertheless, it could not be claimed that these theoretical calculations constituted a demonstration or proved the real existence of import transactions actually corresponding to the theoretical analysis. One of the reasons for this was that the import figures in kilograms included samples with no commercial value (which did not pay import duties) and the weight of the outer packaging. This packaging was often heavy enough to affect the weight actually used for assessing minimum specific import duties.

3.151 Moreover, Argentina stressed that these specific import duties were calculated on the basis of the gross weight of the goods, *i.e.* without taking into account the packaging of each shipment or the wooden supports for the rolls of cloth, the crates, etc. Thus, the import statistics expressed the weight in kilograms corresponding to the transport documents which the importer presented when registering the importation and not the weight on which the calculation of the specific duty was based. In accordance with the above, the prices indicated in the US table identifying 118 cases of imposition of duties above the 35 per cent *ad valorem* bound rate should not be used even for making theoretical calculations of the *ad valorem* equivalents of the specific duties. Inasmuch as the United States had used data which were not compiled to form the basis for an analysis of the *ad valorem* equivalents of specific duties, the above-mentioned table represented a result which could not be considered useful for drawing conclusions of any kind.

3.152 The **United States** considered that, by arguing that its own data reflected "gross" weight instead of "net" weight, Argentina sought to reduce the kilograms

reflected in the tables submitted by the United States. These kilograms were then divided into the value (which Argentina did not seek to change) to achieve a higher average price. The higher the average price, the more likely it would be that the equivalent *ad valorem* figures would be below 35 percent. For the United States, there were compelling reasons to believe that the Argentine data discussed in sub-section B.5.(d) above already reflected "net", not "gross" weight. The document said *"importaciones de products de capitulos 51 a 64" and their "valor, cantidades and precios por kilogramo"*. Thus the title made it clear that these were the weights of products in these HS items. Further, a handwritten portion said "*posiciones sujetas a derechos especificos 1996: enero - septiembre y valor anualizado*". As Argentina asserted that its *derechos specificos* were calculated on the basis of net weight, why would Argentina make any reference to positions "*sujetas a derechos especificos*" if the data could *not* be used to calculate such specific duties? Argentina attempted to show the "difference of prices in Argentina and prices in export market". US export data was reported and collected on a net, not gross, weight basis. Indeed, the tables submitted by Argentina in relation to US and EC exports reflected US export data based on a net weight basis. If the purpose of Argentina when preparing this document were to compare average import prices, it should have compared its import prices to those of the United States, calculated using net weight basis.

3.153 For the United States, the data Argentina tried to impeach were the data it supplied when the United States had asked for information to perform its calculation of equivalents *ad valorem*. The data formed an important part of the consultations between the parties. Argentina never asserted in the consultations, in the first meeting with the parties, or in its answers to the Panel's or the United States' questions that this data included "gross" weight. Such *post hoc* analysis, without any evidence other than Argentina's bald assertion, could not be a valid basis for Argentina to reject its own statistics which demonstrated its repeated and clear violation of Article II.

3.154 The United States further stressed that, even assuming *arguendo* that Argentina was correct, and that the statistics referred to in sub-section B.5.(d) above did reflect the gross weight figures, the substitution of "net" figures did not change the results significantly. According to a leading US expert on the subject, use of gross weight would result in a distortion in the range of 2 to 5 per cent for textiles and 10-12 per cent for apparel items. In more extreme cases of high-priced apparel items, the packaging could add as much as 33 per cent to the weight. To show the negligible impact, the United States had adjusted the table it had presented in para. 3.141 above to reduce the weight of merchandise in the subject categories by 5 per cent for textiles and 12 per cent for apparel. This adjustment was illustrated in a revised table which reflected that there were still 99 line-items where the specific duties, on average, exceeded 35 per cent *ad valorem*.

3.155 Moreover, the United States recalled that it had submitted a table on imports from the European Communities for certain tariff headings on textiles which reflected calculations of the "equivalents *ad valorem*" and reflected the

minimum specific import duty. Argentina had asserted that it calculated specific duties on the net weight of the goods, *i.e.*, not counting the weight of the shipping packaging. Thus, it simply would make no sense for Argentina to calculate the *ad valorem* equivalent duty using the gross weight. Indeed, the purpose of this document appeared to be to show the EC that there were "only" four HS categories in which duties were applied on average in excess of 35 per cent *ad valorem.* Such a demonstration could be made only if the weight reflected on the document was that used to calculate the application of specific duties.

3.156 The United States further argued that Argentina had also stated regarding the use of "gross weight" that "we do not have net weight data", "Argentina cannot do it [collect the data] in any other way [than by gross weight]", and "we have always used gross weight in presenting our import and export data". The United States submitted the 1983 issue of the INDEC statistical yearbook, which described how Argentina presented and collected its export and import data in 1983. This document was the introduction to a much larger sets of Argentine import and export data for 1983. Near the bottom of the second page of the above mentioned document was a note which stated "*comprende las cantidades netas declaradas para cada articulo por los exportadores e importadores, expresadas en la unidad de medida que corresponda"*. This document made it clear that at least in 1983, the Argentine authorities did collect only net data to report their imports and exports. Argentina had to come forward with *documents* to show that it did not collect data this way.

3.157 The United States recalled that Argentina also had stated that "Peso *bruto* could be found in all the individual customs forms [...] submitted by the United States". This was incorrect. In fact, the only *peso* (weight) which was found in all specific shipment documents was peso *neto* (net weight). Argentina gave some examples where it claimed that gross weight was reflected and where it showed that gross weight differed substantially from net weight. However, Argentina ignored the fact that it had only counted one page reflecting one portion of multi-HS shipments. For example, Argentina cited page 2 of the document. However, it ignored pages 3 and 4 where there was no gross weight reflected, but instead there was a reference at the top of the page to "item 1". This item 1 referred back to the first page of the group of documents where the total gross weight for the total shipment was reflected. The grouping of three documents was shown in the US document summarizing the main data mentioned in the customs documents at issue. The same situation existed for other examples mentioned by Argentina. These examples showed that gross weight was *not* computed or reflected in all Argentine customs documents. Only net weight was reflected in all documents.

3.158 The United States added that textile, apparel, and footwear products were shipped in large crates or containers. In most instances, products of different HS categories were shipped together. In order to determine the gross weight, the crate or container was weighed once only. It was the weight of the goods coming out of the crate that had to be weighed to determine the specific duties. This was net weight. The data Argentina had collected and tabulated in its HS annual statistics, was that which it collected, i.e., on a net basis. There was simply no evi-

dence that gross data was collected on an 8 digit line basis, only net data was. Indeed, it would be impossible to collect gross weight on an 8 digit line basis using the import documents at issue.

3.159 In sum, for the United States, the Argentine data represented net weight, not gross weight. As such, this data was a reliable data source to create the documents demonstrating violations of the 35 per cent *ad valorem* rate referred to in paras. 83 *et seq.* above.

3.160 Regarding United States statements on the statistical data concerning imports of products of HS Chapters 51 to 64 in value, quantities and prices per kilograms and by country of origin, in particular on the volume/quantity of imports and their "net" or "gross" value, **Argentina** argued that the conclusions drawn by the United States regarding the alleged *ad valorem* equivalents did not correspond to the actual import transactions to which they supposedly relate. In order to ascertain the true situation, a distinction has to be drawn between gross and net weights and, if this was done, the result of calculating the *ad valorem* equivalent would most likely be different from that submitted by the United States. This statement was confirmed by the information given in the alleged customs documents submitted by the United States. Some of these documents showed the differences between gross and net weights. These differences could not be explained solely, as the United States had done, by stating that the imports in question formed part of shipments that contained other imports. The information supplied by Argentina and submitted by the United States regarding imports of products of HS Chapters 51 to 64 in value, quantities and prices per kilograms and by country of origin had been prepared on the basis of data directly compiled by the Department of Foreign Trade on the basis of tariff headings, and the values corresponding to quantities were gross kilograms. This information could not be compared with the foreign trade statistics published each year by INDEC in its statistical yearbooks. Moreover, it was particularly significant that criticism was directed at Argentina by submitting a copy of the 1983 Yearbook. Not only had 15 years gone by since then, but Argentina's tariff nomenclature had changed, the data collection system was not the same and, since 1991, Argentine Customs (52 offices throughout Argentina) had begun computerizing its operations, a process which affected and modified the collection of data.

(g) Evidence Based on Imports from the EC and the Rest of the World

3.161 The **United States** considered that, regardless of any problems Argentina may have with its own data, which formed an important part of the consultations preceding the formation of this Panel, Argentina had separately confirmed that its specific duties, on average, exceeded 35 per cent *ad valorem* in a number of categories. In a table on Argentina's textile and apparel imports from the EC and the rest of the world of selected categories of textiles and apparel subject to ad valorem rates higher than 35 per cent (January-July 1996), the United States had listed specific duties for selected categories of textile and apparel items from the

European Communities that Argentina had acknowledged were greater than its bound rate. The document consisted of four pages and covered four different types of information: EC imports to Argentina in 1995; EC imports in the first seven months of 1996; all other imports during 1995; and all other imports during the first seven months of 1996. The document identified for each line-item the total kilograms of textiles imported, their total value, the *average* c.i.f. value, the specific duties charged, and the *ad valorem* equivalent. This table also showed categories that Argentina had determined to be in excess of 35 per cent *ad valorem*, on average, with respect to textiles and apparel from sources other than Europe. These numbers were not only based on data supplied by Argentina, but Argentina had actually performed the calculation of *ad valorem* equivalency.

3.162 **Argentina** contended that this table was based on statistical information whose origin remained obscure.[99] Methodologically, the volume and value figures could not be used for calculating an average price for comparing with the Argentine minimum specific import duty and obtaining an *ad valorem* equivalent. The minimum specific import duty applicable to heading 57.04.90 was in fact US$1.70 during 1996. It was applied to the weight of the imported goods, excluding outer packaging and supports.

3.163 The **United States** replied that the information contained in its document was particularly reliable, since it had been created by Argentine officials who used Argentine customs data to calculate the *ad valorem* equivalency of 35 line-items of textiles. Argentina had given this document to the EC, and the EC had provided it to the United States. Argentina's calculations showed that 4 of the 35 line-items of EC imports during 1995 and 1996 exceeded 35 per cent *ad valorem.* For the rest of the world, 22 of the 35 textile and clothing categories exceeded the bound rate on average in 1996 and 26 of 35 for 1995. Many of the average percentages for the rest of the world for 1995 and 1996 were well-over 50 per cent *ad valorem*. Since the prices of products within each of the 35 HS tariff headings varied, some imports were above and some were below the average prices. Given the large number of HS categories with an average greater than 50 per cent, there *necessarily* were many individual transactions well-above 35 per cent *ad valorem.*

3.164 In the opinion of the United States, Argentina had made no real attempt to attack the validity of the equivalent *ad valorem* calculations its officials had performed for the European Communities. At the consultation between the EC and Argentina, the EC presented and discussed this document extensively. The EC stated at the consultations that Argentine customs officials had presented the document to them in Buenos Aires in the late fall of 1996. Argentine officials at the 12 June 1997 consultation did not dispute this fact. The EC gave the United States a copy of the document at the consultation to which the United States was a joined party. The document was in Spanish, it referred to the DIEM, and it

[99] See para. 3.166, below.

contained import data that *only* the Argentine Government could generate. Accordingly, there could be no doubt that this was a document produced by the Argentine Government. It was simply not sufficient for Argentina to claim that the origins of the document were obscure. Significantly, Argentina did not claim that the statistics and data of the same nature regarding imports of certain textile products from the European Communities, which the United States had submitted separately to the Panel, were inaccurate.

3.165 **Argentina** stated that with respect to the *ad valorem* equivalents mentioned in the above-mentioned table and, in particular, regarding the *ad valorem* equivalent of 49.2 (imports from the EC) or 45.7 per cent (imports from the rest of the world) mentioned for heading 5704.90 (carpets), it should be pointed out that, on the basis of the average prices of imports from the United States in 1996 for heading 5704.90, the minimum specific import duty collected ($1.66) represented an *ad valorem* equivalent of 35 per cent.

3.166 Argentina added that, generally, the documents submitted by the United States were the result of a compilation of statistical information supplied by Argentina, but for purposes other than those put forward at the time it was requested. The statistics supplied by Argentina in the course of its consultations with the United States had been supplied for other purposes, and their use in the calculations made by the United States had led to a number of problems and inaccuracies in the results obtained. In this respect, the table submitted by the United Sates regarding Argentina's textiles and apparel imports from the EC and the rest of the world of selected categories subject to *ad valorem* rates higher than 35 per cent for January-July 1996 had not been supplied by Argentina either to the United States or to the European Communities. The documentation in question was not provided by Argentina during formal consultations with the EC in the framework of the DSU. On the occasion on which the United States saw the mentioned document (that is, in association with the Article XXII consultations with the EC), Argentina made it clear that the paper did not come from Argentina and was not subject to discussion.

3.167 The minimum specific import duties on imports of textiles and apparel did not exceed 35 per cent *ad valorem* because the rates had been established on the basis of calculations made prior to application of those specific duties. The calculations made by the United States in order to show that the 35 per cent *ad valorem* equivalent had been exceeded were not correct because they were based on statistics that were inappropriate. A comparison of average prices based on statistics of import volume and value and the minimum specific import duties gave a theoretical *ad valorem* equivalent. This was not the import duty actually paid by importers in each case.

3.168 Noting Argentina's statement that the "best and closest statistics to reality available in this dispute came from the United States export data", the **United States** mentioned that it had refrained from using its export data because it wanted to focus on Argentina-produced data to avoid any assertions of inaccuracy of data. It had some doubts about the accuracy and completeness of its ex-

port data. Nevertheless, given the fact that Argentina had made the statements above, the United States felt compelled to provide the Panel with the US export data evidence available. The United States produced a document which listed 104 entire HS categories where the average *ad valorem* equivalent price exceeded 35 per cent. The prices and quantities therein reflected prices and quantities reported from US export data. This was another example that demonstrates that no matter how the Panel examined the data, no matter what the source of the data was, it showed that Argentina's specific duties violated its 35 per cent *ad valorem* bindings.

(h) Examples of Individual Transactions

3.169 The **United States** stated that particular shipments also reflected payments in excess of 35 per cent ad valorem. It consequently submitted, during the first substantive meeting of the Panel, copies of two commercial invoices as well as part of the customs documentation pertaining to two import transactions, together with a summary table of the information contained in those documents. The documents referred to shipments of 9 May 1996 and 4 April 1996. The example of a shipment on 9 May 1996 of US carpets (style 1) in HS category 5703.20 included a c.i.f. value of US$56,271.90. Argentine customs documents indicated that specific duties of US$20,531, or a 36 per cent ad valorem equivalent, had been imposed and paid. The other documentation showed imports on 4 April 1996 of three types of US carpets (styles 2, 3 and 4) in HS category 5703.30. These invoices and Argentine customs documents reflected that the imposition of specific duties had resulted in the payment of duties of respectively 40; 60 and 67 per cent ad valorem.

3.170 **Argentina** had doubts concerning the validity and reliability of the invoices for the alleged import transactions regarding shipments dated 9 May 1996 (one category of product under HS 5703.20) and 4 April 1996 (three categories of products under HS 5703.30) submitted by the United States. It could be seen from these two commercial invoices, especially the second one, that not only was there no mention of the importer's name, tax identification number (CUIT), etc., but also that corrections and additions had been made by hand that were incomprehensible. The second of the alleged invoices submitted contained prices per unit of US$1.97, 2.61 and 3.77 per square metre for styles 2, 3 and 4 respectively. The information on United States textile exports in 1996 provided by Argentina indicated an average export price to Argentina of US$5.91 per square metre for the same tariff heading, a difference which highlighted the fact that if the invoiced price had been closer to the average levels, once adjusted to c.i.f. it would in none of the cases have exceeded 35 per cent. Thus, the next item of the invoice, which represented double the volume of the three previous items together, with a price per unit of US$6.92 was not claimed to exceed the 35 per cent limit. It was difficult to understand why the importers had not had recourse to the challenge procedure under those circumstances. Moreover, the invoices showed that samples valued at US$2,340 entered duty free when the maximum

amount that may legally be imported into Argentine customs territory under this heading was US$100. This raised further doubts regarding the value of this document as evidence. In addition, if the value of the samples was added to the import total, the *ad valorem* equivalent did not exceed 35 per cent. Regarding the other transaction (styles 2, 3 and 4), taking the United States export prices, it could be seen that in no case did they exceed 35 per cent. Taking the prices allegedly declared by the importer on this invoice, however, the total was different. Consequently, it was not clear why the importer did not utilize the challenge procedure to contest the difference.

3.171 The **United States** also provided the Panel with copies of six Argentine customs documents relating to duties charged during 1996, identifying examples where specific duties in excess of 35 per cent *ad valorem* had been imposed and paid by importers. Examples 1-5 had been derived from 2 shipments of different types of footwear produced by a US manufacturer in Indonesia. Example 6 involves woven cotton fabric produced in the United States.

- Example 1 consisted of an Argentine customs form indicating a total c.i.f. value of US$15,722.53 and a total specific duty of US$10,560.00. This demonstrated that the specific duties constituted an *ad valorem* equivalent of 67 per cent.
- Example 2 consisted of an Argentine customs form indicating a total c.i.f. value of US$23,046.20 and a total specific duty of US$14,476.00. This demonstrated that the specific duties constituted an *ad valorem* equivalent of 63 per cent.
- Example 3 consisted of an Argentine customs form indicating a total c.i.f. value of US$7,444.33 and a total specific duty of US$4,809.60. This demonstrated that the specific duties constituted an *ad valorem* equivalent of 65 per cent.
- Example 4 consisted of an Argentine customs form indicating a total c.i.f. value of US$94,846.13 and a total specific duty of US$56,909.70. This demonstrated that the specific duties constituted an *ad valorem* equivalent of 60 per cent.
- Example 5 consisted of an Argentine customs form indicating a total c.i.f. value of US$30,690.17 and a total specific duty of US$19,576.20. This demonstrated that the specific duties constituted an *ad valorem* equivalent of 64 per cent.
- Example 6 consisted of an Argentine customs form indicating a total c.i.f. value of US$19,384.01 and a total specific duty of US$7,087.61. This demonstrated that the specific duties constituted an *ad valorem* equivalent of 37 per cent.

3.172 According to the United States, the calculation of these percentages was easily accomplished by examining the lower portion of each of the six Argentine customs forms presented, and dividing the specific duties (*derecho especifico*) by the total c.i.f. value (*Valor en Aduana en Divisa*).

3.173 With respect to the above-mentioned copies of invoices submitted by the United States involving footwear import transactions, **Argentina** considers them irrelevant since it was not appropriate for the Panel to rule on a measure which had been revoked prior to the adoption of its terms of reference. In any case, it could easily be determined that all these cases corresponded to import operations carried out by a large US manufacturer of athletic shoes.[100] According to the information available, these operations presumably form part of the various actions which that company had brought against the Argentine State. Secondly, the specific operations submitted related to imports of footwear originating in Indonesia and not to textile imports from the United States.

3.174 Finally, Argentina could not give an opinion regarding the copy of invoice submitted by the United States (Example 6 above) which was said to correspond to the importation of a textile product (woven cotton fabric) produced in the United States and according to which the duties collected were 2 per cent in excess of the bound rate. Argentina did not have the name of the importer or the number of the operation, the tariff heading was illegible and, at the same time, there was no stamp or confirmation that this was a document that had been processed by the customs authorities.

3.175 In addition to the above-mentioned examples, the **United States** presented a specific example from October 1995 (a copy of a *despacho de importación*) regarding a shipment of US carpet on which specific duties of US$1,775.00 on a c.i.f. value of US$2,811.58 had been assessed. Application of specific duties in this instance resulted in a duty equivalent to 63 per cent *ad valorem*. If further particular examples of how Argentina's specific duties exceeded 35 per cent *ad valorem* were needed, Argentina had provided them by submitting copies of the challenges by importers of Company X (involving footwear) and Company Y (involving textiles) against the imposition of minimum specific duties greater than 35 per cent *ad valorem*.

3.176 **Argentina** replied that the operation of October 1995 referred to by the United States involved only an amount of US$3,000 and the unit transaction value was US$1.90 although, in 1995, the year of the transaction, the average price for exports from the United States to Argentina in the same tariff heading gave a f.a.s. unit value of US$2.79. If this transaction had been carried out at the average value indicated, with the adjustment needed to be regarded as c.i.f.-Port of Buenos Aires, the minimum specific import duty applied (US$1.09) would have resulted in an *ad valorem* equivalent of less than 35 per cent (average c.i.f. value equalled US$3.18; *ad valorem* equivalent equalled 34 per cent). Argentina also noted that the duty had not been challenged, even though it was precisely for these specific cases, *i.e.* the operations with a transaction value much lower than the average for the tariff heading, that the challenge procedure was available. Similarly, as the documentation provided by the United States recorded, the op-

[100] This company is hereafter referred to as "Company X".

eration was carried out under the "Green Channel" procedure, so that the goods were not examined by the Argentine customs administration.

3.177 For Argentina, it was highly significant that the United States could only submit a single transaction among the thousands corresponding to the approximately 580 tariff headings to which minimum specific import duties were applied. Moreover, the transaction value represented approximately 60 per cent of the average price of Argentine imports from the United States in this tariff heading and the importer chose not to make use of the procedure established by Argentine law for correcting possible excessive duty assessments.

3.178 The **United States** stressed that the best evidence of the excessive nature of Argentina's specific duties were the Argentine customs forms identifying assessed duties. However, these were in the possession of the Argentine Government. For this reason, the United States had requested Argentina to produce all relevant customs forms involving imports in HS line-items 5407.81 (woven synthetic fibre fabric), 5703.20 (carpets), and 6110.30 (manmade fibre sweaters) for the period January-September 1996. The United States had chosen these three categories in part because Argentine customs data showed that the average duty paid for these three groups of imports from the United States was 99, 43 and 56 per cent, respectively, during the period January-July 1996.[101] Argentina had failed to produce these documents.

3.179 The United States also presented additional evidence before the second meeting of the Panel. This evidence consisted of a table and copies of import documents. The copies of import documents reflected the underlying Argentine customs documents that were summarized in the table. The page numbers on the copies of the import documents related to the first column in the table. Like other Argentine customs documents presented by the United States to the Panel, these documents showed examples in which Argentina had applied duties in excess of its 35 per cent *ad valorem* duties. The tables reflected a large number of specific examples where Argentina had applied and enforced specific duties that violated Argentina's 35 per cent *ad valorem* bindings. One of the above-mentioned documents summarized them all: it referenced a total of 11 shipments of hosiery and socks during 1996 and 1997 within the apparel HS categories covered by the Argentine measures at issue in this dispute. Because many of these shipments included products in different HS categories, these 11 shipments involved a total of 20 instances of products in which Argentina had applied duties in excess of 35 per cent *ad valorem.* The same tables also summarized examples regarding footwear shipped during 1996. As with most of the apparel examples, there were more than one product category in each shipment. In 58 separate instances of products within these examples, the specific duties applied resulted in payment in

[101] The United States specified that these three categories, on average, would remain in excess of 35 per cent *ad valorem* even under Argentina's latest revision of its specific duties on textiles and apparel.

excess of 35 per cent *ad valorem* duties. Thus, in total, the table reflected 78 different instances of shipments in which specific duties had been levied and paid in excess of 35 per cent equivalent *ad valorem.*

3.180 Among the data submitted by the United States, **Argentina** considered the example of the import document in which the export originated in United States customs territory. Apart from the general consideration that it concerned an import transaction for which customs clearance had been carried out manually, this particular case suffered from a number of formal defects which could ultimately invalidate the substantive arguments they were intended to support. Firstly, it represented only part of a larger shipment for which the customs documentation had not been supplied. What the total shipment consisted of was not said, nor was the full assessment of import duties and the amount to be paid by the importer on the basis of that full assessment mentioned. In addition, there was no receipt from the *Banco de la Nación* which represented the last step in the customs clearance procedure for imported goods. Secondly, the legal basis indicated for determining the *ad valorem* duty applied to the mentioned goods was erroneous, since Decree No. 2275/94 was not in force in March 1996, when the transaction took place, as it had been replaced by Decree No. 998/95 on 1 January 1996. Thirdly, the legal basis for determining the specific duty applicable to the tariff heading declared by the importer was apparently Resolution No. 1554/94, which in fact dated back to 1993 and in any event was not in force on the day in March on which the said import allegedly went through clearance procedures upon entry into Argentina. Fourthly, the legal basis on which the three per cent statistical tax was levied was definitely erroneous, since Resolution No. 1031/94 was not in force on the day in March on which the import allegedly went through Argentine customs clearance procedures. Indeed, at that time, the applicable statistical tax had been brought into force by Decree No. 389/95. Fifthly, the values declared by the alleged importer of the goods in question were US$6.19 per dozen pairs in two cases and US$8.05 per dozen pairs in the third case. These values were considerably lower than the average export prices of like goods (of the same tariff heading) originating in the United States in 1996. How was it possible for the alleged Argentine importer of the goods to accept to pay a specific duty of US$12,578 for this import transaction as against the applicable *ad valorem* tariff of US$3,999 without having recourse to the challenge procedure? Finally, Argentina found it impossible to delve further into all of these matters as the alleged importer's registration number and tax identification number (CUIT) as well as the import registration number, and the name and registration number of the customs agent, had been rubbed out. All of these considerations casted serious doubt on the credibility of this document.

3.181 Argentina believed that it was unacceptable, in the framework of the WTO, to continue addressing trade issues on the basis of anonymity of the actors involved and disputes settled between States on the basis of anonymous challenges. It would have been extremely useful for Argentina to have access to the elements which would have not only made it possible to verify, before the Panel, the credibility of the documentation submitted, but which would also been very

useful to the Customs Authorities and the General-Directorate of Taxes in combatting fraud, evasion and smuggling which, to a certain extent, underlaid this discussion.

3.182 Argentina added that, of all of the evidence submitted by the United States there was not a single one that provided evidence of import duties actually paid to the Argentine Customs by importers. Only if such documentation had been included in the presentation would it have been possible to assert that tariffs in excess of 35 per cent *ad valorem* were collected for given textile or clothing imports. Argentina also provided the following documents:

- payment of import duties, Form OM 2132 (electronic registration);
- form OM 686 B (manual registration) (*Banco de la Nación*);
- full set with a sample of an import transaction processed through the so-called "manual system" (as opposed to the MARIA computer system).

3.183 Argentina argued that it could be seen from these documents that the evidence presented by the United States did not include all these different elements involved in the full processing of an import transaction by Argentine customs.

3.184 Argentina also raised the fact that the goods concerned in the evidence submitted by the United States were of Italian origin in all cases but one. Second, all of the transactions occurred in 1997 except one. Third, they involved different types and varieties of the same product, i.e. tights under tariff heading 6115. Fourth, all of the transactions were processed using the "manual system" while theoretically all transactions processed by the Buenos Aires Customs should use the MARIA computer system. The essential difference was that, with the manual system, the clearance form was filled in completely by the customs agent and then submitted to Customs, whereas with the computer system, the agent has direct access to the Customs computer, but may only feed in certain data, the rest of the information coming from the Customs data bank. The clearance forms provided did not signify that the duties were actually paid. The payment voucher, which represented the last step in the customs clearance process, had not been provided either. Finally, at least two of the shipments were partial shipments; in other words, only part of the customs documentation for a complete shipment was provided.

3.185 The **United States** argued that Argentina appeared to claim that the specific examples put forth by the United States that did not reflect imports from the United States were irrelevant. Thus, Argentina appeared to confuse two separate issues. The first issue was whether the United States had initiated a dispute settlement proceeding without any legitimate trade interest. Even assuming such a defense was valid, Argentina had not asserted it. In any event, there was no doubt that the United States had substantial exports of textiles, apparel and footwear to Argentina. The second issue was entirely separate, *i.e.*, whether Argentina was applying specific duties to textile, apparel, and footwear imports in excess of 35 per cent equivalent *ad valorem*. This was an issue not dependent on the origin of the imported goods. Argentina had admitted that its customs officials had no dis-

cretion not to apply the minimum specific import duties, whatever the exporting country. Accordingly, evidence that imports from any WTO Member had been subject to duties in excess of a 35 per cent equivalent *ad valorem* rate in the relevant HS categories was very relevant to demonstrate Argentina's violation of Article II GATT 1994.

3.186 For the United States, Argentina repeatedly claimed that the above-mentioned import documents were not reliable or authentic because they did not include any proof of payment. However, Argentina did not contest that for each of the 78 examples submitted by the United States (see para. 3.179) there was a reflection of the calculation of specific duties in excess of 35 per cent equivalent *ad valorem*.

3.187 With respect to Argentina's argument regarding one of the documents that it quoted the wrong legal texts, the United States submitted that the products in question were socks from the United States found under HS 6115.92.00. Argentina was correct that Resolution No. 2275/94 cited in the lower left hand corner of the document was no longer in effect in March 1996. However, the resolution in effect at the time the products in document 34 were imported - Resolution No. 304/95 -had exactly the same specific duty (US$7.6) as Resolution No. 2275/94 - and it was the correct US$7.6 specific duty which was reflected in the import document concerned. Argentina's arguments did not show that the duty had not been paid or that the document was somehow not authentic. Rather, it showed that the importer could not keep track with the constant changes in the Argentine resolutions.

3.188 In response to the arguments of the United States that whether or not the legal measures referred to in this alleged customs document were correct was not important; that the minimum specific import duties rate applicable on the reported date of import (sometime in March 1996) was the same as that indicated; that Argentina did not contest the "assessments of specific duties" and thus acknowledged that they had been paid, **Argentina** reaffirmed the doubts that this alleged customs document raised as to whether it could be accepted as valid and recognized as part of an import transaction that actually took place.

3.189 Argentina also argued that the United States statements concerning the difficulty of obtaining this alleged documentation from Argentine importers, indicating that they did not provide it because they feared reprisals, were extremely surprising. One possible reason for the difficulty encountered by the United States in collecting evidence from Argentine companies could be inferred from the data on export prices from Italy to the United States for the same products that had allegedly been imported into Argentina according to the documentation submitted by the United States. Information on imports into the United States under heading HS 6115 showed that articles entering the United States at a price of US$51.52/kg were being imported into Argentina at a much lower price.

3.190 Argentina added that these alleged customs documents submitted by the United States related to an alleged import processing through the Buenos Aires Customs under the so-called "manual system". This made it virtually impossible

to carry out any verification unless all the elements needed to identify the import and the importer were available. Without the possibility of checking, it was not possible to differentiate between real and fictitious imports.

3.191 The **United States** replied that, with respect to the authenticity of these customs documents and invoices, customs stamps and signatures could be found on many of the documents. Many of these stamps were from Argentine customs agents and were found at the bottom or the top of some forms under *Oficializado - Firma y Sello Despachante de Aduana.* Argentina had admitted in its replies to questions of the United States that "customs agents were considered to be auxiliary customs officials for import operations". Certainly, these official stamps of customs agents constituted a presumption that the documents were official unless Argentina could present evidence - not just oral assertions - that they were not authentic or constituted forgeries. No such evidence had been presented.

3.192 The United States added that Argentina admitted that its customs officials had no discretion not to apply the specific duties. "Applying" specific duties meant these customs officials had to charge and insist on payment of the duties before customs clearance. Given this lack of discretion, Argentina could not possibly claim that the specific duties reflected on the documents were not paid. There was no other way that the goods could have cleared customs, at least legally. Argentina had presented no evidence that there was no payment of these specific duties. It had presented no evidence that there were huge supplies of goods piling up in customs warehouses where no payment had been made.

3.193 **Argentina** replied that in the present case duties in excess of 35 per cent *ad valorem* had not been applied. Furthermore, there had been no cases of imports of textile products and clothing where the importers had challenged the application of specific duties on the grounds that they exceeded the 35 per cent *ad valorem* bound in the WTO. Under its legislation the commitment not to exceed the bound tariff level of 35 per cent ranked above the domestic laws and regulations. Moreover, the so-called challenge procedure provided for in Law No. 22.415 (Customs Code) fully guaranteed that the bound level could not be exceeded. The existence of this remedy neutralized the potential for exceeding the binding which, according to the United States, was inherent in the minimum specific import duty.

6. Burden of Proof

(a) Principles Applicable to the Burden of Proof

3.194 **Argentina** argued that one of the various precedents regarding burden of proof was the report on *EEC - Measure on Animal Feed Proteins*, in which the panel stated that:

> "having heard no evidence that either the purchasing obligation, the security deposit [...] discriminated against imports of 'like products' [...] the Panel concluded that the EEC measures were not inconsistent".[102]

3.195 Argentina added that in the case *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, the Appellate Body had specifically elaborated this concept and given its interpretation:

> "In addressing this issue, we find it difficult, indeed, to see how any system of judicial settlement could work if it incorporated the proposition that the mere assertion of a claim might amount to proof. It is, thus, hardly surprising that various international tribunals, including the International Court of Justice, have generally and consistently accepted and applied the rule that the party who asserts a fact, whether the claimant or the respondent, is responsible for providing proof thereof. Also, it is a generally accepted canon of evidence in civil law, common law and, in fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence".[103]

3.196 Argentina recalled that this interpretation had been explicitly supported by the United States in its statement to the DSB when the report was adopted. On that occasion, the United States' delegation had stated that it supported adoption of the report mentioning, in particular, several of the points contained therein, in respect of which it asked that its statement be placed on record. The United States stated the following regarding these points:

> "The Appellate Body reaffirmed a general principle of GATT and WTO jurisprudence that 'a party claiming a violation of a provision of the WTO Agreement must assert and prove its claim'. Once the claiming party has satisfied this obligation, the burden then shifts to the responding party to bring forward evidence and argument to disprove the claim".[104]

3.197 Argentina considered that the question raised by the United States before this Panel was a theoretical one. The United States had failed to demonstrate that Argentina levied tariffs exceeding the maximum bound rate of 35 per cent *ad valorem*. Nor had it been able to present argument sufficient to establish a presumption, the prerequisite for shifting the burden of proof to the other party in

---

[102] Panel Report on *EEC - Measures on Animal Feed Proteins*, Op. Cit., para. 4.21, as cited in the Appellate Body Report on *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, Op. Cit., p. 15.
[103] *Ibid*., p. 14.
[104] Statement by the United States at the DSB meeting of 23 May 1997, Op. Cit.

accordance with the report on *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*.

3.198 The **United States** replied that, in submitting its evidence, it had met its burden of proof as articulated by the Appellate Body in *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India*. The Appellate Body had indicated that it was up to the party asserting a violation "to present evidence and argument sufficient to establish a presumption" that the violation has occurred.[105] Once that presumption was established, "the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption".[106] The Appellate Body further noted that "precisely how much and precisely what kind of evidence will be required to establish such a presumption will necessarily vary from measure to measure, provision to provision, and case to case".[107]

3.199 The United States contended that, by any standard, the evidence submitted by the United States was sufficient to establish a presumption of a violation of Article II. In fact, the Panel needed look no further than the face of the Argentine resolutions and decrees imposing the specific duties that were the subject of this dispute. For every line-item in which Argentina applied specific duties, there was a "break-even point" below which lower-priced merchandise entered Argentina in excess of 35 per cent *ad valorem.* Thus, the specific duties necessarily had the potential to exceed 35 per cent *ad valorem*. Previous GATT jurisprudence had made clear that this potential, in and of itself, was a sufficient basis for the Panel to find that Argentina had violated Article II.

3.200 The United States also argued that a panel could condemn Argentina's mandatory minimum specific import duties even if they were not yet being applied. In that case the panel would examine the minimum specific import duties' structure and the manner in which it could be predicted to operate. In the present case the minimum specific import duties provisions were in fact being applied but they could equally be judged by this Panel on the same criteria. The fact that the tariff was being applied did not make it necessary for a complaining party to provide elaborate proofs concerning its application in practice. Examination of the tariff's structure, the basis on which it was charged, and the manner in which it would predictably operate, were sufficient to meet the complaining party's burden of proof. By these criteria, and with the application of simple arithmetic, the Panel could easily conclude that the Argentine tariff mandated the imposition of duties in excess of bound rates.

---

[105] Appellate Body Report on *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, Op. Cit., pp. 12-17.
[106] *Ibid.*, p. 14.
[107] *Ibid.*

(b) Application in the Present Case

3.201 The **United States** stressed that there were two factual issues before the Panel: first, whether the United States had established a presumption that the application of Argentina's specific duties violated Argentina's bound *ad valorem* rate of 35 percent; and second, whether Argentina had produced sufficient evidence to rebut the presumption. The United States believed that it had presented sufficient evidence to establish a presumption of a violation of Article II and that Argentina had not produced sufficient evidence to rebut it.

3.202 **Argentina** argued that the United States had provided no or insufficient proofs of its affirmations.

3.203 The **United States** contended that it had demonstrated that Argentina imposed specific duties in numerous HS line-items for textiles, apparel and footwear in excess of its 35 per cent *ad valorem* bound rate. The US evidence consisted of: (1) invoices and customs forms for particular textile, apparel and footwear shipments during 1995 and 1996, (2) calculations performed by Argentina showing HS line-items where average duties paid by importers in 1995 and the first 9 months of 1996 exceeded 35 per cent *ad valorem*, and (3) computations based on Argentine import data reflecting 118 textile and apparel line-items which, on average, exceeded 35 per cent *ad valorem*. This information proved that Argentina's specific duties were above its bound rate in violation of Article II.

3.204 For the United States, given the weight of the evidence presented to the Panel, the burden had shifted to Argentina to "adduce sufficient evidence to rebut the presumption" that Article II had been violated. Argentina had not provided any such evidence, let alone evidence sufficiently credible to rebut the proof submitted by the United States. Instead, Argentina had relied on unsubstantiated, categorical denials that Argentine customs authorities had applied, or even could have applied, specific duties in excess of 35 per cent *ad valorem*.

3.205 **Argentina** replied that the evidence supplied by the United States were generally theoretical or not based on proven facts. With respect to the assertion that the minimum specific import duties imposed were 100 to 300 per cent of the value, such an allegation was not acceptable without concrete proof. The allegations made by the United States did not permit an assessment of whether there had been any non-compliance, or its possible extent. The evidence submitted by the United States concerning textile and clothing imports consisting of invoices and customs documents did not suffice to establish a "presumption" with respect to the allegations against Argentina. Indeed, the comparison of average import price statistics with the minimum specific import duty in force to obtain an *ad valorem* equivalent did not signify that the tariffs in question were actually collected from importers in the course of transactions that were actually carried out. These documents did not correspond to the reality of what actually may have been paid to the Customs. Other evidence were out of proportion with Argentina's imports of textiles. In the recourse by Company Y to the challenge procedure, the three transactions at issue represented a value of US$42,698, when tex-

tile imports in Argentina totalled more than US$1,500 million for the period 1995/1996. Each transaction was important and was subject to WTO regulations, but the amount involved led Argentina to wonder whether the minimum requirements of Article 3.7 of the DSU, which stipulated that a member "shall exercise its judgement as to whether action under these procedures would be fruitful", had been met.

3.206 Argentina further recalled that, in response to the Panel's request to provide concrete cases of violation, the United States had submitted as evidence certain transactions whose shortcomings were sufficiently clear. Argentina noted that all of the textile transactions, with the exception of one, had been carried out by EC exporters. The EC was not a complaining party in this case. It was interesting to note in this connection that the evidence submitted by the United States showing import transactions involving goods of Italian origin corresponded to a tariff heading (HS 6115, tights) that was not included among the examples of violation of Argentina's 35 per cent tariff binding mentioned by the EC itself in its third party submission. All the transactions corresponded to goods of Italian origin and all had taken place in 1997, with one exception. The United States could not have known of these transactions when it requested the establishment of this Panel. Argentina's conclusion regarding the additional series of invoices submitted by the United States before the second meeting of the Panel was that the information on textile exports from and originating in the United States was both unclear and imprecise. This was the best proof that the United States was fighting a case in which it needed to resort to sources of information outside its own market to try to substantiate its claim that Argentina had violated its obligations. Argentina also questioned the acceptability for a party to present evidence pertaining to alleged transactions of another country after the deadline for rebuttals.

3.207 For Argentina, the above observations clearly demonstrated the lack of argument for establishing a presumption in respect of the allegations contained in the complaint by the United States. Without this presumption, Argentina could not be asked to submit evidence of facts which had not been shown to exist. If the United States was unable to substantiate a presumption that its complaint was legitimate, it could not be claimed that the burden of the proof had shifted to the point where evidence had to be submitted to refute the presumption. If the United States was unable to provide clear and precise examples of import transactions in the textiles and clothing area, it could only be assumed that the United States claim was purely theoretical, since Argentina had not been given reason to believe that its customs authorities collected minimum specific import duties in excess of the 35 per cent WTO binding.

3.208 The **United States** argued that the documents, data and calculations discussed with the Panel identified numerous line-items where Argentina’s specific duties on average were greater than 35 per cent *ad valorem*. These documents did not reflect isolated instances in which Argentina had exceeded its bound rate. Argentina did not contest the accuracy of the specific duty rates reflected on its own documents. Argentina did not contest the figures on value, ton, or price per

kilogram contained in the documents originally prepared by Argentina and provided to the Panel by the United States. With respect to the specific examples of invoices and customs documents submitted by the United States, Argentina did not contest that the importers actually paid these charges or had to file bonds to cover the amounts in excess of 35 per cent *ad valorem* duties. Argentine documents and Argentine data conclusively demonstrated that Argentina's position was incorrect.

3.209 The United States contended that, in light of the import data provided by Argentina to the United States, production of the relevant documents would have resulted in many other examples of duties in excess of 35 per cent *ad valorem.* The Panel was faced with Argentina's refusal to produce directly relevant evidence in its possession as requested by the United States. Given that Argentina did not produce these documents, the Panel was free to draw an adverse inference that these documents would reflect additional examples of duties imposed and paid in excess of a 35 per cent *ad valorem* duty. Argentina's recalcitrant behaviour should not be used against the United States in an effort to assert that the latter had somehow failed to adequately satisfy its burden of proof with the limited documents in its possession.[108] In fact, the United States has fully met its burden of proof. It had demonstrated that the Argentine duties predictably and mandatorily resulted in imposition of duties in excess of bound levels in a range of situations. In addition, it had provided examples of actual levying of such duties.

3.210 **Argentina** contended that the United States appeared to be trying to obtain from Argentina evidence substantiating the alleged infringement of the bound tariff which it had so far been unable to provide. It was surprising that the attempt to justify the allegations had been based solely on theoretical speculation which did not correspond to the realities of trade and that no concrete evidence had been provided of import operations in which duties in excess of 35 per cent had been assessed. The burden of proof should fall on the party bringing the complaint before the Panel. Argentina also argued that, with respect to evidence relating to imports of footwear, such data were not relevant to the present case since the DIEM on footwear no longer existed and did not exist at the time the Panel was established.

3.211 According to the **United States**, Argentina did not respond to United States arguments concerning the document regarding imports into Argentina from the EC and the rest of the world which the United States had produced before the Panel. The Panel was left with Argentina's last-minute attempt to discredit its own documents that it had produced and relied on during consultations with the

[108] The United States referred to the judgement of the International Court of Justice of 9 April 1949, in *The Corfu Channel case*, ICJ Reports 1949, p. 4, at p. 32, in which, taking formal note of the refusal by a party to produce documents, the Court stated that it "cannot, however, draw from this refusal to produce the [naval] orders [requested by the Court] any conclusions differing from those to which the actual events gave rise".

US and the EC. Indeed, Argentina's "rebuttal" consisted of an assertion that the document did not exist. This document formed an important element of consultations between the EC, Argentina and the United States. Argentina should not be free to rely upon information that it generated for purposes of consultations only to disavow it later in a panel proceeding.

3.212 The United States noted that Argentina also claimed that the specific examples of footwear products were irrelevant. The United States replied that the measures imposing footwear specific duties were part of the Panel's terms of reference. The evidence submitted by the United States, in particular the invoices and customs documents related to specific import transactions submitted before the second substantive meeting of the Panel, established without any doubt that up until the time that Argentina revoked the footwear measures on 14 February 1997, Argentina applied specific duties in violation of its 35 per cent *ad valorem* bindings on those products. Moreover, exactly the same specific duty system existed for footwear products as for textiles and apparel throughout 1996 to this time. The examples relating to footwear were a very good illustration of how the Argentine system functioned in many instances to impose duties in excess of 35 per cent *ad valorem* rates.

7. Direct Effect of the WTO Agreement in the Argentine Legal Order and Role of the Challenge Procedures

3.213 The **United States** noted that Argentina had attempted to defend its specific duties by arguing that they were not above 35 per cent *ad valorem* and under no circumstances could they be above the bound rate because they were essentially capped at 35 per cent *ad valorem* for two reasons. Firstly, Argentina maintained that the WTO Agreement, including Argentina's binding, had direct application in Argentine law and was supreme to domestic laws. Secondly, Argentina had procedures under Law No. 22.415 whereby importers had the right to challenge any duties assessed beyond the bound rate which was purportedly a part of Argentine law.

(a) Direct Effect of the WTO Agreement in the Argentine Legal Order

3.214 **Argentina** stated that the stability and predictability of concessions in its Schedule were supported by Article 75.22 of the Argentine Constitution of 1994. These commitments were at the top of the legal hierarchy and, therefore, took precedence over domestic legislation. Any judge in Argentina had the power to declare, at the request of an interested party, the unconstitutionality of any measure adopted in breach of rules contained in an international treaty, such as the WTO Agreement. This feature of the Argentine legal system was absolutely essential to its functioning, which differed fundamentally from that of countries where international treaties were interpreted by domestic legislation. Another fundamental characteristic of the Argentine legal system was that subsequent

domestic law could not annul an international treaty, as such law was lower in rank. This constitutional provision provided a high degree of legal certainty. If the procedures envisaged in Articles 1053 to 1079 of Argentina's Customs Code (essentially the challenge procedure referred to in sub-section B.7.(b) below) were not satisfactorily resolved by the authority concerned, the summary proceeding was always available before domestic courts by which importers could obtain a judicial decision obliging the Argentine Government to comply with international obligations deriving from WTO Agreements, over and above any domestic regulations, such as laws, decrees, ministerial resolutions, or others.

3.215 Argentina noted that US traders had reported that the Argentine customs service regularly asked for payment of the full specific duty and did not inform them of a right to pay only those duties that "they consider correct", as it seemed to be possible. Asked by the United States whether it considered it the responsibility of importers to know that they were being asked to pay amounts in excess of 35 per cent *ad valorem* duties, Argentina replied that the legislation in force in the Argentine Republic was assumed to be known to all inhabitants and was public knowledge once published in the Official Journal (*Boletín Oficial*) of the Argentine Republic (Title I of the Civil Code of the Argentine Republic). This was the case with Law No. 24.425, published on 5 January 1995, which approved the WTO Agreement, including as annexes the respective texts of each agreement, and Argentina's Schedule LXIV, which contained the commitment to maintain a tariff ceiling of 35 per cent and details of the corresponding tariff headings. Similarly, it was not considered necessary for the customs authorities expressly to inform importers of the provisions of Law No. 24.425 or of the possibility of resorting to the options provided for in the Customs Code (Law No. 22.415). Importers themselves were responsible for knowing their rights in the event of their being required to pay a minimum specific import duty in excess of 35 per cent of the declared value of the goods. The same would apply if they were required to pay an *ad valorem* duty in excess of that laid down in the Argentine tariff. This was because the importers knew the value of the goods they declared and could make a comparison either immediately or in advance, before presenting their sworn declaration and requesting clearance of the goods.

3.216 With respect to whether it had any regulations or published procedures instructing its customs service to refrain from assessing specific duties that were greater than the equivalent of 35 per cent *ad valorem*, Argentina stated that Law No. 24.425, which approved the WTO Agreement and all its annexes, including Argentina's Schedule LXIV, was mandatory and binding on all national authorities, including the customs authorities, which had to accept and observe the commitments contained therein in their entirety. Argentina also contended, regarding potential regulations or published procedures instructing Argentina's customs service to apprise importers of the applicability of the maximum rate of 35 per cent *ad valorem* on imported products subject to specific duties, that importers and the customs service itself could rely on longstanding publications such as the *Practical Guide for Importers and Exporters*, the *Customs Tariff Directory* and the publications of the *Centro de Despachantes de Aduana*. These

publications kept importers continuously up to date and informed of the tariff levels in force. Similarly, importers could always count on the expert advice of the customs agents. Under the law, the latter were considered to be auxiliary customs officers for import operations and were personally responsible for informing importers of the provisions of the legislation in force, including the remedies which Argentine law provided.

3.217 Argentina considered it the responsibility of importers to know that the supremacy accorded to WTO commitments under Argentine law mandated that specific duties on textiles, apparel and footwear had to be no greater than the equivalent of 35 per cent *ad valorem*, even if no Argentine legal measure specifically so provided. The question of the supremacy of the provisions of an international treaty approved by a law of the Argentine Congress over domestic law was specifically dealt with in Article 75.22 of the Constitution, as amended in 1994. The Constitution, like laws and other administrative enactments, was considered to be public knowledge, from the day following its publication in the Official Journal.

3.218 For the **United States**, this argument appeared to rest on a legal fiction. While Argentina's tariff binding may be the "supreme" law in the Argentine constitutional framework, Argentina maintained a series of mandatory legal measures imposing duties inconsistent with its binding. In operation, Argentina systematically undermined the significance of its WTO commitments by requiring its customs officials to collect the full specific duties, even in circumstances where an overcharge was obvious or grossly excessive. If the Panel were to accept the direct application of treaty law and supremacy of the WTO Agreement as a defense, then Members with such legal systems in effect would be immune from dispute settlement proceedings. Argentina in effect was asking this Panel to bestow immunity from WTO review on any Member which treated WTO Agreements as self-executing under their law. These Members always would be able to argue that the provisions of the WTO Agreements were part of their law and thus, by definition, non-conforming domestic laws had been rendered consistent with any relevant WTO provisions. Such an outcome would undermine the vitality of the dispute settlement understanding. The United States further considered that Argentina's argument regarding direct effect of treaties had no inherent limitation to tariff obligations. Argentina was in effect arguing that it could take *any* action it wished in violation of *any* WTO obligation, and that Argentina could then escape any finding of responsibility under the DSU, because affected private parties could ask the Argentine courts to nullify the Argentine Government's actions as inconsistent with the WTO Agreement. For the United States, the argument of Argentina concerning the mandatory nature of its constitutional law was an argument which Argentina continued to assert based on a legal hierarchy which ignored the actual operation of mandatory laws. It may well be that there was a constitutional ranking of the Argentine laws. However, the fact remained that Argentina had admitted that its customs officials had no discretion not to apply the decrees mandating the use of the minimum specific import duties. In fact,

Argentine customs officials were required to violate the Argentine constitutional law.

3.219 **Argentina** considered that the comments of the United States concerning a "non-conforming law consistent with the agreement" did not stand up, since the supremacy of the treaties over the other laws and regulations under the Argentine constitutional system was demonstrated by the copy of the judicial order in case 8.447/97 *FILA (Argentina) S.A. et al.* submitted by the United States,[109] which constituted factual evidence of the full and total incorporation of the WTO Agreement into the Argentine legal system.

(b) The Challenge Procedure (*recurso de impugnación)*

3.220 **Argentina** mentioned that Argentina's legal system constituted a single and inseparable whole which included the procedure for challenging assessments: the challenge procedure (*recurso de impugnación*). In a hypothetical import transaction where the specific duty would exceed 35 per cent *ad valorem*, the importer would have a remedy available which guaranteed that by means of a simple submission the amount to be paid would be limited to the amount resulting from the WTO obligation. The procedure was automatic, free of charge, required neither middlemen nor legal advice of any kind and had predetermined time-limits. The challenge procedure was laid down in Argentina's Customs Code - Law No. 22.415 (Articles 1053 to 1067). Its purpose was to protect the importer in case of discussions about classification, valuation or the level of import duties applicable in a particular instance. The Argentine Customs Code provided that importers may express disagreement if they considered that the valuation of the goods or the import duties levied had been inappropriate. It allowed importers to request the release of the goods into the market after paying only the sum that they considered appropriate under the relevant laws. The National Customs Administration may require the importer to deposit a security to cover the difference between the amount actually paid and the amount claimed. When importers had recourse to this procedure, they had 10 days in which to submit the necessary arguments and information. In the meantime, the importation process continued. As far as specific duties were concerned, it had to be demonstrated that the amount set in a particular case following their application exceeded 35 per cent of the customs value of the goods.

3.221 According to the **United States**, the availability of "challenge procedures" did little to make Argentina’s specific duties "predictable". In fact, these procedures only added to the confusion. By assessing the full amount of the applicable specific duties at the border, regardless of their *ad valorem* equivalent, and by requiring importers to employ ancillary procedures involving either an initial overpayment or the posting of a bond, Argentina leaved traders and WTO Mem-

[109] See footnote 31 above.

bers with great uncertainty as to what the actual duties charged would be and when that amount ultimately would be determined.

3.222 **Argentina** stressed that the challenge procedure was not viewed by Argentine law as purely theoretical. On the contrary, and to illustrate how it worked in practice, Argentina referred to two cases concerning textiles and footwear. In the first case, the company representing Company X in Argentina, made a submission to the National Customs Administration,[110] challenging the payment of specific duties on several shipments on the grounds that they exceeded the 35 per cent *ad valorem* equivalent. On the basis of that one submission, several shipments of goods were released into the market with the deposit of a surety to cover the unpaid duties. A second example concerned textile products involving Company Y, relating to the challenge by a textile articles importing firm of the inclusion of packaging in the calculation of specific duties. The example included the document certifying payment of a security covering the difference between the tariff paid and the tariff set by customs and the customs clearance certificate. Both cases clearly showed that the procedure guaranteed in a simple and direct manner the release of numerous shipments of imported goods into the market without payment of duties exceeding the 35 per cent bound rate.

3.223 The **United States** argued that the first time Argentina raised Law No. 22.415 to explain why its specific duties were within its bound rate was in its submissions before the Panel. Argentina had previously taken the position that its specific duties were consistent with its WTO obligations because the duties were no more than 35 per cent of an adjusted average import price for each category. Likewise, the availability of domestic procedures to challenge an assessed duty did not justify the establishment of duties in excess of the bound rate. Argentina seemed to be taking the position that its Schedule may list any duty rate, no matter how high, and it may assess that rate at the border as long as a final appeal adjusted the duty to no more than 35 per cent *ad valorem*. Argentina's argument ignored the extreme uncertainty such practices would create. Importers would be required either to pay the full amount of the specific duties and await a refund from Argentina or pay a partial amount and provide a bond for the rest. Under both scenarios, importers on a regular basis were subject to charges in excess of the bound rate. In reality, they would only know what the duty was after the customs service or the courts had made a final decision. Surely this was not the predictability and security in tariff rates that the GATT and WTO were designed to achieve.

3.224 **Argentina** was not of the opinion that Article II GATT 1994 permitted a WTO Member to assess any duty at its border, no matter how high, so long as that Member provided appeal or challenge procedures to subsequently conform the duty to the bound rate. If there were bound tariffs in the Schedule of a WTO Member, the latter may only require the payment of the maximum tariffs bound.

[110] Argentine Customs Administration, File No. 404.349.

However, below that level it could apply the tariff level it considers most appropriate and assess it on an *ad valorem* or specific basis. Asked by the United States whether it was of the opinion that no impairment of Argentina's tariff concessions existed where importers were assessed duties in excess of the bound rate but were permitted to pay a portion of the duties assessed, post a bond and then wait for appeal or challenge procedures to conclude before receiving a return of their bond, Argentina replied that the United States question was based on a purely hypothetical premise, since Argentina was not infringing the tariffs bound in its Schedule for any product category. Argentina considered that impairment of the concessions granted by a country existed if the latter assessed a tariff in excess of the bound level, thereby adversely affecting imports which should have received the treatment provided in its WTO Schedule. In exceptional situations which might hypothetically arise and in which the tariff applied exceeded the bound tariff level, Argentine legislation provided for the challenge procedure that enabled importers to question the administrative act requiring the payment of a tariff higher than that which had been bound.

3.225 The **United States** contended that the existence of administrative "challenge procedures" did not justify violations of Article II. Argentina had acknowledged that its customs service charged specific duties as set by relevant resolutions and decrees even if such duties amounted to more than 35 per cent *ad valorem*. Argentina defended this practice by stating that, to the extent the specific duties exceeded the bound rate, importers were free to use "challenge procedures" to recover any overpayment. Argentina explained that such challenges were bound to succeed because, under the Argentine constitution, WTO obligations were self-executing and supreme to domestic law. However, Argentina's argument lacked merit for several reasons. Argentina's invocation of its challenge procedure raised form over substance. The reality of importing textiles, apparel and footwear into Argentina was that the Argentine customs service charged excessive specific duties and expected payment of the full amount. Although Argentina admitted that it could "only require the payment of the maximum bound rate", it had explained that the specific duties were to be applied by the Argentine customs officials who had *no competence to modify the duties.*

3.226 For the United States, the rate Argentina charged at its border had to be the relevant duty for purposes of Article II, not some amount adjusted later on appeal. Argentina has conceded as much when it had recognized that GATT Article II did not "permit a WTO Member to assess any duty at its border, no matter how high, so long as that Member provides appeal or challenge procedures to subsequently conform the duty to the bound rate". This had to be the case, otherwise Argentina or any other WTO Member could charge hundreds and even thousands of dollars for each kilogram of textiles and still meet its WTO obligations since, at some undetermined point in the future, the duty would be reduced to within the bound rate. The fact that Argentina had a mechanism for appealing an initial duty assessment, as did almost all WTO Members in accordance with Article X:2(b) GATT 1994, is simply immaterial.

3.227 The United States also argued that Argentina ignored the extreme uncertainty that resort to the challenge procedures created. Importers were required either to pay the full amount of the specific duties and await a refund from Argentina or pay a partial amount and provide a bond for the rest. Under both scenarios, importers on a regular basis were subject to charges in excess of the bound rate. Importers only learned what the actual duty would be after the customs service or the courts had made a final decision. If the mere availability of challenge procedures was a defense to the imposition of excessive duties at the border, as Argentina seemed to suggest, then one of the fundamental principles underlying Article II, that Members shall be exempt from duties in excess of a bound rate, would lose much of its meaning.

3.228 The United States further contended that, by charging excessive specific duties and requiring importers to take action to recover any balance owed, Argentina had collected far more in duties than what was permissible under Article II. During the January - September 1996 period alone, Argentina had apparently overcharged importers handling relevant types of textiles and apparel from the United States by approximately US$1,634,000. Based on other evidence of similar overcharging, Argentina had reaped large sums in overcharges in connection with imports from other sources, including Asia and the EC.[111]

3.229 To this, **Argentina** replied that the repeated claim that a sum amounting to US$1,634,000 had been paid was simply a theoretical calculation using statistical data that were inappropriate for the purpose, since they were not intended for elaborating average prices.[112]

3.230 In the view of the **United States**, administrative and even legal challenges to the initially assessed duties were not simple. Such appeals often were lengthy, complicated and expensive. This system also inherently contained a less favourable treatment aspect as foreign traders received the benefit of a bound rate only after employing ancillary procedures. Contrary to Argentina's suggestion, Company X had not found the procedures simple or painless. In fact, Company X had attempted to use two ways of challenging the assessment of specific duties. In one instance, Company X paid the full specific duties charged and later claimed a refund. To date, Company X had not recovered any of the approximately US$2.5 million it expected to be returned. Company X also had tried paying a portion of the duties assessed and posting a bond for a rest. With regard to these entries, Company X had been waiting more than 18 months for a decision by the Argentine customs service for a determination as to whether Company X would be held liable for the difference.

3.231 **Argentina** insisted that it had mentioned the example of a submission by the firm representing Company X in Argentina as constituting one of the first of such cases it had identified. In this case, the Argentine customs administration,

[111] See sub-section B.5(c) above.
[112] *Ibid.*

while recognizing that the challenge was in order, decided to declare it improper because an appeal by the same company on the same issue had been lodged with the Ministry of the Economy which preceded the challenge procedure. However, the point to be stressed was that the challenge procedure was based, among other elements relating to domestic legislation, on the assumption that the resolution imposing the duties was contrary to the law ratifying the WTO Agreement and on the fact that the Constitution stipulated that treaties and concordats are to supersede laws, and therefore the provision in question should not establish a duty which exceeds the said rate (35 per cent) or that constitutes a breach of the provisions of the International Treaty. These arguments were largely in line with those presented by Argentina to show that in the hypothetical case that a minimum specific import duty were applied to a given transaction or shipment in excess of the *ad valorem* equivalent of 35 per cent, the challenge procedure would be applied as a direct means of ensuring that the importer did not have to pay more than the 35 per cent ceiling.

3.232 The **United States** considered that the challenge procedures had offered no genuine relief to importers. Argentina had not refunded any amount of duties to importers of textiles, apparel and footwear under these procedures. Argentina had explained that this was so "because there have not been any restitution proceedings brought before Argentine customs officials" and "no cases exist in the area of imports of textile and apparel products where importers have raised the issue of the imposition of specific duties that exceed the 35 per cent *ad valorem*". However, the total absence of a challenge by *any* textile or apparel importer - a remarkable fact in light of the grievances filed by European, Hungarian and US traders with their respective governments - strongly suggested the inadequacy of Argentina's regime.

3.233 For the United States, the fact that the challenge procedure was seldom if ever used by textile and apparel importers could be attributable to the fact that Argentina did not publicize this remedy, nor did it inform importers when the specific duties, as applied in particular cases, were above 35 per cent *ad valorem.* Indeed, the existence of procedures purportedly guaranteeing that Argentina would not assess duties above its bound rate was not only unknown to traders, but also to the United States. The United States and Argentina had held four rounds of consultations in this matter and at no time had Argentina attempted to justify its regime based on the availability of challenge procedures.

3.234 **Argentina** acknowledged that this remedy had not been discussed until the Panel proceedings began. However, the existence of the challenge procedure was public knowledge and had been part of domestic legislation since 1981. The fact that it was not mentioned in consultations with the United States was irrelevant, both as regards its status as an integral part of Argentina's legal order and as a tool used by importers. The procedure had been applied frequently since its introduction in disputes or issues relating to tariff classification, valuation and other preparatory measures for the assessment of customs duties. Argentina recalled that the total number of current challenge proceedings on all grounds - classification or estimated value - was calculated to be about 12,000. This indi-

cated that importers were perfectly accustomed to using this procedure. Among the 12,000 cases recorded it had not been possible to find a single challenge relating to textile products based on the application of a minimum specific import duty in excess of 35 per cent *ad valorem*. It was understandable that Argentina's trade partners wondered why this challenge procedure had not been used in the past for alleged violations of the 35 per cent bound rate by the minimum specific import duties. The first explanation was that the specific duties applied did not in fact exceed the 35 per cent binding, even on exceptional occasions. However, this may not be the only explanation. First of all, even though the procedure was well known, importers might not have become aware of the fact that it was also available for alleged violations of the bound rate, as Argentina's obligation to apply a tariff ceiling for textile products only dated back to 1995, with the entry into force of the WTO Agreement. Moreover, only since 1994, with the amendment of the Constitution, had Article 75 thereof stipulated that international treaties maintained a higher position in the constitutional hierarchy than Argentine law. This may have caused a certain delay before the importing firms reached the conclusion that the same challenge procedure that they were probably using to challenge assessments in connection with other types of problems could also be used to challenge the imposition of specific duties exceeding 35 per cent.

3.235 Secondly, according to Argentina, another element could help to explain the lack of recourse to the challenge procedure: the problem of underinvoicing and, in general, the problem of customs control. Under-invoicing was a chronic problem in Argentina. The magnitude of the customs problem, which was not limited to under-invoicing but involved all kinds of illegal operations, had been described during consultations. A series of modifications in the customs system had been made in 1996 to address it, including changes in the way it operated and the establishment of a system of preshipment inspection. The volume of under-invoiced transactions was enormous (it was said that, in the last years, some 27,000 containers had been smuggled across the border causing losses to the Argentine treasury estimated at US$3,000 million and inestimable damage to the domestic industry). The judicial investigations carried out thus far had shown that large quantities of textile products and clothing were also involved. In this context dominated by the inefficiency of the customs system and the widespread practice of underinvoicing, it was highly unlikely that many importers would resort to the challenge procedure. By doing so, they would have run the risk of drawing the attention of the authorities to the question of the legality of their operations. As from 1996, the investigations conducted by the Argentine Government, the courts and the Congress with respect to import transactions began to make underinvoicing difficult and the decision by the Government to bring the customs body and the Directorate-General of Taxation together under a single authority made it possible, among other things, to carry out electronic cross-checking of information supplied in the import price declarations against domestic tax payments, thereby completely altering the economic equation for those intending to under-invoice: if the domestic tax-collection body was much more efficient and difficult to evade, the risk considerably outweighed profits that

might be derived from underinvoicing. This also explained why, in 1996, import prices for textile products and clothing increased in Argentina, a trend which was not reflected in the international market.

3.236 Argentina declared that the challenge procedure, which may have appeared to have been nothing more than "window dressing", now provided a clear and transparent guarantee of compliance with international commitments. Indeed, under the challenge procedure, if an import duty assessment was challenged because it exceeded the 35 per cent limit set by Law No. 24.425, the goods were nonetheless released. In other words, to secure the entry of the imports, the importer may pay the tariff in force and challenge any minimum specific import duties applied in excess of the duty bound within the WTO. The importer, the holder of the clearance documents, was the one legally authorized to file a challenge application. There was no process for the automatic initiation of a challenge procedure by the Argentine customs officials. The process could only be initiated at the request of an individual who showed that his rights had been infringed. As Argentina did not apply specific duties or tariffs in excess of 35 per cent *ad valorem*, it was not deemed necessary to set up notification machinery for purely hypothetical cases. The procedure had to be entered into by the importer within 10 days of the notification of the customs duty assessment.[113] The challenge had the effect of suspending payment of the difference in the duty rates.[114] By paying a security to the customs authorities reflecting the difference between the tariff in force and the minimum specific import duty claimed by customs, the importer may automatically (within three or four days at the most) release the goods into the market. The customs authorities then had 40 days to produce evidence against the importer's claim.[115] If such evidence was produced, the importer had six days to refute the evidence.[116] Once that time-limit had elapsed, the customs authorities had 60 days to confirm or revoke the challenged administrative measure.[117] Thus, in accordance with these time-limits, the process may last 116 days. If the measure was confirmed (the assessed import duties being below 35 per cent), the importer had to pay the difference between the two amounts. If the measure was revoked, the duties exceeding the 35 per cent *ad valorem* limit, the importer was freed of all obligations. The only form which importers had to complete to obtain the release of their security was form 1190-A which was used for both lodging and releasing the security.

3.237 Argentina specified that if the customs authorities decided against the importer, the importer had two alternatives: either to appeal the decision before the Tax Court or to appeal to the Federal Administrative Tribunal. Title III (Remedies) of the Customs Code (Articles 1132 to 1183) described the procedure for

[113] Argentine Customs Code, Article 1054.
[114] *Ibid.*, Article 1058.
[115] *Ibid.*, Article 1062.
[116] *Ibid.*, Article 1063.
[117] *Ibid.*, Article 1065.

appealing a final decision signed by the head of the local customs department. If the local manager took a final decision unfavourable to the importer, the law allowed the latter 15 working days following the notification of the decision to appeal to the Tax Court. The appeal was presented to the Tax Court together with the evidence, and the records were submitted to the Court by the Proceedings Division of the customs service. If the challenger lost his case, he could appeal the decision of the Tax Court to the National Chamber in the Federal Administrative Litigation Division.

3.238 Regarding the nature of proof (facts, documentation, testimony statements) requested under the challenge procedure, Argentina stated that an importer could initiate a challenge proceeding without having to provide any proof. For the remedy to be available it was sufficient for the importer to indicate to the customs administration his intention to challenge the duty assessment. In the particular case of challenges entered against duties in excess of 35 per cent, the procedure was even simpler since it was only necessary to provide the commercial invoice or an identical copy. The proceeding was substantiated by the documentation in the possession of the customs, the certificate of payment of the duties which, in the opinion of the importer, should be paid and the corresponding bond for the difference in duty.

3.239 The **United States** questioned the meaning of Argentina's statement that the process was "automatic" and "without cost", in particular it asked whether it was its contention that importers challenging such assessments in excess of the 35 per cent *ad valorem* rate had "no costs" imposed on them in terms of time, opportunity costs, costs of security, experts and attorney's fees, and delay and uncertainty in the shipment of goods.

3.240 **Argentina** replied that saying that the process was automatic signified that the importer could enter the goods for consumption by paying only the duties which he considered applicable. Saying that the process was without cost meant that it was not a procedure for which there were charges.

3.241 Regarding legal representation, Argentina mentioned that experts were not needed to calculate 35 per cent of the customs value of the goods. For the purposes of initiating a challenge proceeding, Article 1034 of the Customs Code required legal representation. The relevant documentation was provided by the customs administration itself. Asked whether there were established procedures if any, for refunding attorney's and expert's fees, the costs of obtaining a bond or other security, and the costs of employee time expended in a successful challenge procedure, Argentina replied that the attorney's fees were paid by the importers concerned. The same would apply to the fees of experts who participated in the proceedings at the request of the importer, since customs did not automatically require their participation which, moreover, was non-existent in these cases. The cost of bond insurance was very small, generally consisting in the payment of an annual premium which varies between only 1.8 per cent and 2 per cent depending on the type of activity and the amount of security which, it should not be forgotten, represents only the difference in duty. Finally, if despite the fact that the

costs of the challenge proceeding were low (bearing in mind that there were no charges) the importer wanted to be reimbursed, he always had the option of suing for reimbursement in the competent court.

3.242 With respect to interests on the money held by Argentina if the full amount of duty exceeding 35 per cent *ad valorem* had been paid, Argentina mentioned that the action for restitution which could be brought against the customs, if won by the importer, would provide for the refunding of the amounts improperly collected plus interest due from the point at which the return of wrongly collected duties had been requested (form 1724-B), that is to say, after payment of the assessment resulting from clearance. Within 10 days of the Valuation Technique Division notifying the importer of the application of specific duties, the latter may opt for the challenge procedure (payment of the duty applicable, without payment of the DIEM, lodging of a deposit or property bond for the difference) or to pay everything the customs required and bring an action for the restitution of the amounts he considers to have been overpaid.

3.243 The **United States** submitted that challenge procedures were not an essentially painless process by which importers may rectify any overcharges. The procedures were not necessarily quick or simple, as was evidenced by the lone instance in which a US manufacturer had attempted to rely on the challenge procedures. Company X had attempted to use two ways of challenging the assessment of specific duties. In one instance, Company X had paid the full specific duties charged and later claimed a refund. To date, Company X had not recovered any of the approximately US$2.5 million it was expecting to be returned. Company X also had initiated a challenge procedure in April 1996. It had paid a portion of the duties assessed and posted a bond for the remainder. It had used legal counsel who filed a substantial brief and supporting documentation. Despite Company X's experience, Argentina claimed that the maximum length of time for such a proceeding was 116 days. In the case of Company X, it had not been respected. Company X also noted that under Argentine law, if it wanted to appeal any eventual ruling of the Argentine customs service, it would have to pay the full amount of the specific duties. As Company X learned, importers were put at a competitive disadvantage by the delay and uncertainty of having to use these procedures instead of being charged a proper duty at the border. Importers also were forced to bear needless costs in terms of interest on the value of any bond posted.

3.244 According to the United States, this could have easily been avoided if Argentina had imposed only *ad valorem* rates of no more than 35 per cent. There was no reason why Argentina could not do so. Argentina had admitted it collected value and quantity information from which an *ad valorem* duty could be applied in the case of each shipment of imports. It further had admitted that it had spent US$328 million collecting statistical information in 1996, and it could not deny that it had levied its statistical tax on an *ad valorem* basis. At minimum, Argentina could have instructed its customs officials to refrain from charging specific duties in excess of 35 per cent *ad valorem*.

3.245 For **Argentina**, although the example of Company X was not pertinent since it concerned a question relating to footwear, the United States' criticism of the challenge procedure and its duration, which mentioned the cases of Company X, was not correct. If in a specific case, Company X chose to appeal against the imposition of minimum specific import duties to the Ministry of Economy, the Argentine authorities could not be responsible for the proper choice, in a specific case, of the remedies which the law placed at the importer's disposal. The challenge procedure was not a justification for applying minimum specific duties. The characteristics of the challenge procedure could not be evaluated solely on the basis of the experience of Company X. If this company had decided to utilize other bodies when dealing with the administration, this was beyond the Argentine Government's control. It was a matter for decision at a legal level. This experience did not prove that the challenge procedure was not an appropriate mechanism for the purposes explained in Argentina's submission. It was also important to clarify that Company X was not awaiting a refund as a result of using the challenge procedure. According to this procedure, nothing more than the *ad valorem* rate in effect was paid and a bond was deposited. There could be no refunds because what was paid was the sum considered to be payable. Company X had utilized another appeals procedure known as *repetición* (reimbursement procedure). The company paid and then requested the refund of the amount that allegedly exceeded the 35 per cent level. The challenge procedure mechanism provided guarantees to reassure operators that they would not be requested to pay an import duty exceeding 35 per cent *ad valorem*.

3.246 According to the **United States**, by citing its challenge procedures, Argentina was essentially asking the Panel to adopt a new rule requiring WTO Members and their traders to exhaust local remedies before bringing a matter to a panel. However, GATT law did not include the "local remedies rule" as it was recognized in public international law.[118] Disputes under the GATT addressed rights and obligations between WTO Members, not individuals, and the doctrine did not apply to disputes solely between nations.[119] Neither the GATT nor the WTO had ever adopted a practice of requiring exhaustion of local remedies before bringing a matter to a dispute settlement panel. To the United States' knowledge, no prior panel or working party had made exhaustion of local remedies a prerequisite to commencing dispute settlement proceedings. Thus, there was nothing within the tradition or practice of the WTO dispute settlement system which supported Argentina’s argument and, accordingly, it had to be rejected.

---

[118] The United States referred to Ernst-Ulrich Petersmann, "Settlement of International and National Trade Disputes Through the GATT: The Case of Antidumping Law" in *Adjudication of International Trade Disputes in International and National Economic Law*, Ernst-Ulrich Petersmann & Gunther Jaenicke, eds, Fribourg University Press, (1992), pp. 126 127.

[119] The United States referred to the judgement of the International Court of Justice of 20 July 1989 in case *Elettronica Sicula (ELSI)*, ICJ Reports, p. 15, and mentioned that, even though governments often brought an issue before the WTO on behalf of private citizens, disputes were fundamentally between States. Consequently, requiring exhaustion of local remedies of States would be futile.

3.247 **Argentina** replied that it was not requesting the Panel to establish a new rule requiring the Members of the WTO and their entities to "exhaust local remedies". Argentina was stating that it was not possible for a country to come before the WTO and utilize the dispute settlement mechanism without sufficient evidence of the facts it wished to prove.

3.248 Argentina recalled that there was a challenge procedure that formed an integral part of the Argentine legal system and to which it was customary to resort. It was difficult to explain how this alleged "legal fiction", which included recourse to the ordinary courts and had generated about 12,000 cases, had not been used by the importers of United States goods.

3.249 For the **United States**, the direct application of the WTO Agreement in Argentine domestic law and the existence of a customs appeals mechanism offered no meaningful relief to aggrieved importers and did not justify the breaking of bindings. Argentina had confirmed that no specific duties on textiles or apparel had been refunded. The United States had described the efforts Company X had been forced to make in attempting to recover overpaid duties, and had furnished the Panel with a statement from Company X that it had had recourse to the "challenge procedures", a fact that Argentina contested. Argentina had to explain why Company X was still waiting for a decision 18 months after it had invoked the *recurso de impugnación* proceedings. Nor did Argentina contest that Company X was forced to pay specific duties far in excess of 35 per cent equivalent *ad valorem*, regardless of the procedures it invoked.

3.250 **Argentina** replied that the constitutional status of the Uruguay Round Agreements did not pretend to be a justification for authorizing measures that violated the commitments undertaken. Consequently, it was not true that the measures adopted by Argentina imposing the minimum specific import duties systematically violated its WTO obligations. Argentina did not seek nor ask for any "immunity" in order to apply measures of any sort that were contrary to its WTO obligations. The legislation in force and the challenge procedure were intended to guarantee to all importers that there would be no uncertainties. The absence of challenges, far from showing that the procedure was not valid, showed that importers had not utilized it specifically to query the minimum specific import duties on textiles. Either importers did not find it necessary to utilize the procedure or they did not do so for reasons known only to them.

C. The Statistical Tax

3.251 The **United States** argued that Argentina's three per cent *ad valorem* import tax was a charge on imported products inconsistent with Argentina's obligations under Article VIII GATT 1994. The United States referred in particular to Article VIII:1(a) and Article VIII:4(c) which made clear that fees and charges relating to "statistical services" fell within the scope of Article VIII.

3.252 **Argentina** contended that the statistical tax was a commitment undertaken by agreement between Argentina and the International Monetary Fund (IMF).

This commitment obliged Argentina to maintain the statistical tax at a rate of three per cent until it expired in 1998. Any alteration of the rate before completion of the period laid down in the agreement with the IMF would imply non-compliance with the obligations assumed by the Argentine State *vis-à-vis* that organization.

1. Violation of Article VIII

(a) *Ad Valorem* Tax *v.* Fixed Tax

3.253 The **United States** noted that the requirement in Article VIII:1(a) that the charge be "limited in amount to the approximate cost of services rendered" was "actually a dual requirement, because the charge in question had first to involve a 'service' rendered and then the level of the charge had not to exceed the approximate cost of that 'service'".[120]

3.254 The United States argued that, as for the"level of the charge," an *ad valorem* levy with no fixed maximum fee, by its very nature, was not "limited in amount to the approximate cost of services rendered". With respect to a service largely identical, high-price items necessarily bore a much greater tax burden than low-price goods, because any differences that may exist in gathering statistical information with respect to each would not account for the difference in the amount assessed.

3.255 The United States contended that GATT precedent indicated that an unlimited *ad valorem* charge on imported goods violated Article VIII because such a charge was not related to the cost of the service rendered. In the report on *United States - Customs User Fee*, the panel had examined the consistency of 0.22 and 0.17 per cent *ad valorem* customs merchandise processing fees with no upper limits. The complaining parties had argued that an *ad valorem* fee approximating the actual costs of services could be consistent with Article VIII, but such a charge had to have a maximum to ensure that importers of high-value goods did not pay excessive amounts.[121]

3.256 The United States further noted that, confronting the same type of charge as was at issue in the present matter, the report of the working party on *Accession of the Democratic Republic of the Congo* had stated that:

> Members of the Working Party pointed out that *the statistical tax of 3 per cent ad valorem* applied by the Congolese authorities on

---

[120] The United States referred to the Panel Report on *United States - Customs User Fee*, adopted on 2 February 1988, BISD 35S/245, para. 69.

[121] *Ibid.*, para. 86, where the Panel concluded that "the term 'cost of services rendered' [...] in Article VIII:1(a) must be interpreted to refer to the cost of the customs processing for the individual entry in question, and accordingly that the *ad valorem* structure of the United States merchandise processing fee was inconsistent with, [...] Article VIII:1(a) to the extent that it caused fees to be levied in excess of such costs".

> imports was not commensurate with the service rendered and was contrary to the provisions of Article VIII:1(a). The representative of the Congo recognized that this tax exceeded the cost of the service, and explained that the surplus revenue from the tax would be employed toward improving the service. His authorities were prepared to consider the adjustment of the statistical tax, in the light of the provisions of Article VIII as soon as they were in a position to afford it. The Working Party took note of this statement and invited the Government of the Democratic Republic of the Congo to re-examine its present method of application of the statistical tax and to report to the CONTRACTING PARTIES on the possibilities of bringing the tax into line with the provisions of Article VIII:1(a).[122]

3.257 The United States argued that the Argentine tax on imports could not be meaningfully distinguished from the charges at issue in the panel report on *United States - Customs User Fee* or the report on *Accession of the Democratic Republic of the Congo*, nor could it be squared with the reasoning cited above. In fact, the charge examined by the working party on the *Accession of the Congo* was identical to the charge at issue in this dispute and the working party had found the charge to be inconsistent with Article VIII. Argentina's tax was levied on an *ad valorem* basis with no ceiling. The tax as assessed on many goods was not in proportion to the cost of any service rendered.

3.258 **Argentina** contended that, as far as the *Working Party on the Accession of the Democratic Republic of the Congo* was concerned, it had been required to examine a fiscal charge different in nature from the statistical tax applied by Argentina. The purpose of this charge had nothing to do with the rendering of services and the report on the accession of the Congo, which involved simply a fiscal charge without the supply of any service, did not therefore apply.

3.259 Argentina added that the drafting history of Article VIII showed that the alternatives involving the use of a systematic method such as a uniform duty did not rule out the possibility of using *ad valorem* duties for the purpose.[123] Any approach that was selected for administering the service may have advantages or disadvantages. The trend towards automation of customs transactions required methods of calculation which served to facilitate the procedure, with the aim of processing as many transactions as possible with a limited stock of customs resources. Calculating the cost of each transaction would have created a trade barrier and establishing a schedule of transaction fees would have caused trade distortions, with the risk of transactions being manipulated in order to minimize the impact of such fees.

---

[122] Adopted on 29 June 1971, BISD 18S/89, para. 5 (emphasis added by the United States).

[123] Argentina referred to the Panel Report on *United States - Customs User Fee*, Op. Cit., paras. 87-94 which stated, at para. 94, that "[W]hether considered individually or as a whole, the events which constitute that history simply do not demonstrate any such understanding".

3.260 Argentina argued that one of the advantages of the *ad valorem* tax was its minimal impact on low-value imports and the lack of a protective effect. In addition, the *ad valorem* method had seldom been placed in doubt as a mechanism for recovering the approximate costs of the services rendered. In the proceedings of the Working Party reviewing Venezuela's accession to GATT, the representative of that country had indicated that:

> "recent experience had shown that the application of any system other than an *ad valorem* fee would be extremely complex and bring in an element of administrative discretion which might lead to undesirable delays or obstacles to imports. Moreover, the administrative cost of operating a transaction-based fee would be very high".[124]

It was noteworthy that the Working Party had reached the conclusion that "subject to the satisfactory conclusion of the relevant tariff negotiations, Venezuela be invited to accede".[125]

3.261 Argentina further noted that, at the time of Tunisia's accession, although objections were raised to a customs levy of five per cent on the grounds of incompatibility with GATT, this did not prevent approval of Tunisia's accession.[126]

3.262 The **United States** replied that Argentina's argument that an *ad valorem* fee was more equitable and efficient than any alternative had been found wanting by the panel on *United States - Customs User Fee* and Argentina had not made any effort to disprove that some importers, perhaps even most, would be assessed a tax that was disproportionate to the cost of any service rendered to them.

(b) Services and Costs Covered by the Tax

3.263 Regarding the nature of the service to be covered by the tax, the **United States** argued that the term "services rendered" in Article VIII meant "services rendered to the individual importer in question".[127] The type of services that may benefit an individual importer had been expansively construed. "Services" included "government activities closely enough connected to the processes of customs entry that they might, with no more than the customary artistic licence accorded to taxing authorities, be called a 'service' to the importer in question".[128] Despite the breadth of this interpretation, some charges had been found to be too remotely connected to any service benefitting imported goods to allow for imposition of the charge (*e.g.*, charges for processing passengers, charges covering

---

[124] Working Party Report on the *Accession of Venezuela*, adopted on 11 July 1990, BISD 37S/43, para. 22.
[125] *Ibid.*, para. 91.
[126] Working Party Report on the *Accession of Tunisia*, adopted on 12 December 1990, BISD 37S/30, para. 38.
[127] *United States - Customs User Fee*, Op. Cit., para. 80.
[128] *Ibid.*, para. 77.

lost revenue from goods exempt from the same fee, and charges for services performed on behalf of goods previously imported).[129] The government imposing the fee had the burden of demonstrating that a service was in fact performed for the benefit of the importer.[130]

3.264 The United States submitted that the leading decision in this area, the report of the panel on *United States - Customs User Fee*, made clear that the term "services rendered" in Article VIII:1(a) meant "services rendered to the individual importer in question". The panel recognized that a flat rate might have a greater impact on low price merchandise, but nonetheless concluded that Article VIII required covered charges to be tailored to the individual services provided. The panel concluded that an unlimited *ad valorem* charge violated Article VIII because such charges exceeded "the cost of [...] processing [...] the individual entry in question". Despite the clear findings of this decision, Argentina in its submission asked this Panel to reach an outcome that was directly contradictory to the report on *United States - Customs User Fee*, that its three per cent *ad valorem* tax on imports was proper even though (a) the charge was not connected to a service to any individual importer but to international trade generally and (b) the charge covered the cost of statistical services for exported goods as well as imported goods. Decree No. 389/95 stated that the tax was intended to raise revenue for the purpose of financing customs activities related to the registration, computing and data processing of information on both imports and exports. While the gathering of statistical information concerning imports may benefit importers, Article VIII bared the levying of any tax or charge on importers to support activities relating to *exports*. GATT precedent indicated that charges on imported products may not be used to finance services benefitting other interests. In a complaint brought against France in 1952, the United States had maintained that the French "statistical and customs control" taxes violated Article VIII:1 since the proceeds of this tax were also used for funding social security benefits to farmers. France acknowledged the infringement and subsequently abolished the tax.[131] That the charge was in fact no more than a taxation of imported merchandise was confirmed by Argentina's representation that it imposed the tax to raise revenue to meet IMF obligations.

3.265 According to **Argentina**, the purpose of the statistical tax was to cover the cost of supplying the corresponding statistical service intended to provide a reliable basis for foreign trade operations. In this connection, it was important to note that the service was not rendered to the individual importer, the specific importer associated with a particular operation, but to foreign trade operators in general and foreign trade as an activity *per se*. Therefore, as the services rendered in this case and in the case on *United States - Customs User Fee* were different, the precedent in the *United States - Customs User Fee* case did not apply.

---

[129] *United States - Customs User Fee*, Op. Cit., paras. 96-112.
[130] *Ibid.*
[131] See para. 98 document SR.9/28.

3.266 Regarding the costs to be covered by the tax, Argentina stated that there was no dispute about the fact that the sums collected by applying the rate in force for the statistical tax should not exceed the approximate costs necessary to maintain the service. Despite the interpretation of the panel on *United States - Customs User Fee*, the cost of the services to which Article VIII of the GATT 1994 referred should include not only the services rendered to the individual importer but also the total cost of the service.

3.267 Argentina stressed that the cost of the services rendered through the statistical tax was not calculated for each individual transaction, nor was such an approach required under Article VIII, which made no provision for aligning the cost of the service rendered with the level of the tax applied for each transaction. Article VIII did not require Members to set fees on a level commensurate with the cost of each shipment, on a case-by-case basis.

3.268 Argentina argued that the cost of a service - in accounting or trade terms - consisted of a direct cost and an indirect cost, both costs incurred by the organization providing the service whenever it was provided. This was even more obvious in the case of the Argentine customs territory, since 52 customs posts and offices had to be kept open permanently. If for any reason the customs services were to exclude indirect costs from the basic criteria used to calculate the cost of the service they provide, those costs would end up being met from within overall tax receipts. As the service provided had direct and indirect costs, it would be difficult to recover those costs by applying a flat fee per individual import operation. If it were necessary to consider the possibility of applying a flat fee per import operation, that fee ought not to be calculated exclusively as a function of the service rendered in connection with each import operation in particular. The calculation of any flat fee or levy would have to take into account the existing indirect costs and not only the expenses directly related with each particular operation.

3.269 The **United States** argued that Argentina had ignored the report on *United States - Customs User Fee*, which rejected the argument that Article VIII's requirements were met if the total revenues generated by a charge approximated the total cost of the government services. The panel in that matter had recognized that a flat rate might have a greater impact on low price merchandise, but nonetheless concluded that Article VIII required covered charges to be tailored to the individual services provided. The panel concluded that an unlimited *ad valorem* charge violated Article VIII because such charges exceeded "the cost of [...] processing [...] the individual entry in question".

3.270 The United States added that, even if one were to reject the reasoning in the *United States - Customs User Fee* report and adopt a *fees collected must approximate actual costs* approach, Argentina's answers to US questions showed it would fail this test as well. Argentina stated that the funds collected from this tax ranged from US$534 million in 1992 up to US$1.143 billion in 1993, again increasing to US$1.2 billion in 1994, down to US$215 million in 1995 and up to US$328.8 million in 1996. Certainly, the costs of collecting statistical informa-

tion, to which these collected funds had to directly relate, could not possibly have shifted so dramatically during the space of five years. Moreover, Argentina had not provided requested documentation to confirm the direct relationship between its *collections* and costs.

3.271 **Argentina** replied that the revenue collected prior to 1995 did not reflect the cost of the services. In 1995 and 1996, the charge collected was therefore reduced and was approximately equivalent to the cost of the services rendered. With respect to the rationale for eliminating the statistical tax in December 1994 as outlined in Decree No. 2777/94, and the rationale and explanation for reinstating it on 22 March 1995, Argentina mentioned that the fiscal situation in December 1994 justified the decision that a statistical service for foreign trade in general could be provided without relying on the revenue derived from levying a statistical tax on imports. The crisis related to the devaluation of the Mexican peso led to special internal policy adjustment measures discussed with the IMF, the World Bank and the BIS, as well as by the private banks. In order to confront this fiscal problem, it was decided to sign an agreement with the IMF. In order to be able to continue providing statistical services for foreign trade in general it was necessary to reinstate the statistical tax on imports. Otherwise it would not have been possible to provide the service or it would have been necessary to obtain funds from other sources which at the time did not exist.

3.272 The **United States** concluded from the above that Argentina had essentially admitted that the purpose of the statistical tax was a "taxation of imports [...] for fiscal purposes" in contravention of Article VIII. Argentina stated that it levied the charge pursuant to requirements imposed by a "grave fiscal problem" caused by the Mexican peso crisis. Argentina further stated that the statistical tax, along with other fiscal enhancing taxes in the IMF package, was necessary "to confront the fiscal problem and to assure the availability of funds necessary to counteract the outflow of funds from our country, and to avoid the consequent damage and cessation of activities of many national financial institutions". By any objective criteria, these rationales for the statistical tax were for "fiscal purposes" as that term was used in Article VIII:1(a).

3.273 Furthermore, the United States noted that Argentina had asserted that the approximate cost of the provision of statistical services totalled US$326 million in 1996. Argentina has simply stated, without any proof - as requested by the Panel and the United States - that its receipts for 1995 and 1996 were roughly equivalent to the cost of the services. This was simply not an adequate response. Argentina had been requested to provide specific evidence and had not produced its own documents.

(c) Inclusion of the Tax in Argentina's Schedule

3.274 **Argentina** argued that, in Schedule LXIV presented by Argentina at the outcome of the Uruguay Round negotiations, the three per cent statistical tax had been bound under the heading of "other duties or charges". In a separate column attached to the Schedule, the three per cent rate was established for each of the

HS headings under which import duties were bound. It thus rejected the claim by the United States that the statistical tax constituted indirect protection for domestic products. At the very least, this assertion required supporting evidence to substantiate trade distortion.[132]

3.275 The **United States** contended that Argentina's reference to the tax in its Schedule comported with the Understanding on the Interpretation of GATT Article II:1(b) which, in order to ensure transparency, required that such charges be recorded in Schedules. The Understanding, though, made clear that including a charge in a Schedule in no way immunized that charge from WTO scrutiny or from being declared in violation of an applicable GATT rule. The Understanding stated that "such recording did not change the legal character of 'other duties or charges'" and "[a]ll Members retain the right to challenge, at any time, the consistency of any 'other duties or charges' with such [GATT 1994] obligations". This was consistent with prior GATT jurisprudence.[133]

2. IMF Commitments and Cross-Conditionalities

3.276 **Argentina** argued that the statistical tax was part of a commitment undertaken by agreement between Argentina and the International Monetary Fund. This commitment obliged Argentina to maintain the statistical tax at a rate of three per cent until it expired in 1998.

3.277 Argentina stressed that the statistical tax was a commitment entered into by Argentina *vis-à-vis* the IMF. At the same time, Argentina had equivalent obligations as a Member of the WTO primarily under Article VIII GATT 1994 and Article V:1 of the WTO Agreement. If the assertions of the United States regarding a violation of Article VIII were true, Argentina would find itself involved in a conflict of cross-conditionalities, since Argentina might find itself in a situation where it would be prevented from fulfilling its IMF commitments if it were

---

[132] Argentina referred to the Panel Report on *United States - Customs User Fee*, Op. Cit., para.120, which provided that "[i]t was not necessary for the Panel to decide whether the 'indirect protection' criterion actually involved a requirement of no adverse trade effects. The Panel concluded that, even if it did, it had not been demonstrated that these *ad valorem* charges had had a trade distorting effect".

[133] The United States referred to the report of the panel on *United States - Restrictions on Imports of Sugar*, adopted on 22 June 1989, BISD 36S/331, para. 5.7, which stated that "the Panel found that Article II:1(b) does not permit contracting parties to qualify their obligations under other provisions of the General Agreement and that the provisions in the United States GATT Schedule of Concessions can consequently not justify the maintenance of quantitative restrictions on the importation of certain sugars inconsistent with the application of Article XI:1". The United States also referred to the Report of the working Party on *Other Barriers to Trade*, adopted on 3 March 1955, BISD 3S/222, para. 14, which provided that "there was nothing to prevent contracting parties, when they negotiate for the binding or reduction of tariffs, from negotiating on matters [...] which might affect the practical effects of tariff concessions and from incorporating in the appropriate schedule annexed to the Agreement the results of such negotiations; *provided that the results of such negotiations should not conflict with other provisions of the Agreement*" (emphasis added by the United States).

obliged to fulfil its WTO commitments. Conversely, the continued implementation of its IMF commitments could place it in a position incompatible with its obligation under the WTO.

(a) Mandatory Nature of the Statistical Tax Under Argentina's Agreement with the IMF

3.278 **Argentina** contended that its commitment with the IMF to maintain that tax at its current level until the end of 1998 was recorded in the Memorandum of Understanding signed in 1995 and formed part of Argentina's public sector financing package. The United States allegation created a conflict of cross-conditionalities which weakened the basic institutions responsible for establishing exchange and trade disciplines. The obligation Argentina assumed in that Memorandum of Understanding involved achieving a specified level of fiscal revenue and not exceeding a certain level of fiscal expenditure in order to reduce the deficit to a specified amount, also defined in the Memorandum, and adopting or maintaining a series of measures, including the statistical tax, in order to attain these fiscal objectives. This commitment meant that in calculating revenue a certain amount was allocated to the statistical tax while in calculating expenditure a certain amount was included for services rendered in connection with foreign trade statistics. If the amount obtained from the collection of statistical tax were not sufficient to pay for the services rendered in connection with statistics for foreign trade operators and it was therefore necessary to use funds from elsewhere in the budget, there would be problems for the entire financing plan to which Argentina was committed. Failure to obtain the revenue envisaged from the application of the statistical tax would lead to the non-fulfilment of the undertaking given to the IMF. The measures included in the Memorandum of Understanding were the product not of an IMF requirement but of the agreement reached with that institution on the basis of fiscal and other measures which the IMF had approved and therefore considered that the Government should adopt in order to be able to achieve the agreed fiscal objectives. The measures of this type listed in the Memorandum of Understanding constituted the IMF's so-called "conditionality" for allowing access to the facilities at the disposal of member countries.

3.279 The **United States** noted that Argentina had acknowledged that the Memorandum of Understanding it had signed with the IMF in 1995 was merely directed towards obtaining a general level of revenue and that it devised the tax as a mechanism for reaching the fiscal target. The United States recalled that Argentina had claimed that two years after the reintroduction of the tax in March 1995, revenues for meeting these fiscal goals remained "scarce". However, Argentina had not stated that the IMF actually required the use of the statistical tax.

3.280 In reply to this, **Argentina** emphasized that the conditions imposed by the IMF were the subject of a "letter of intent" between Argentina and the IMF which referred to the adoption of national economic rationalization plans. Legal writers considered these agreements as "simplified international agreements". In the case

of Argentina, these agreements had become valid upon signature, without the need for subsequent legislative approval. The Memorandum of Understanding was binding on Argentina. This did not mean that the IMF requested application of the statistical tax. The point was that Argentina's commitment to the IMF included the statistical tax. It added that the margin of manoeuvre for achieving the fiscal goal agreed with the IMF was limited. At the time of negotiating the Memorandum of Understanding it would not have been possible for Argentina to increase the fuel tax, because of its recessionary effects, or to increase further the rate of VAT. Even supposing that the initiative to re-establish the statistical tax at three per cent had originated with Argentina, the IMF had to give its approval. From that moment, it became a legal obligation of the Argentine Government towards the IMF, to which it had made commitments equivalent to those it had made as a Member of the WTO.

3.281 The **United States** argued that there was no evidence that the statistical tax had been approved by the IMF, which would be required under the Articles of Agreement of the IMF. Moreover, Article VIII:3 of the Articles of Agreement of the IMF specifically prohibited exchange measures which discriminated and the statistical tax was not levied on imports from MERCOSUR countries. These factors strongly suggested that the IMF had not specifically approved the statistical tax. Indeed, the understanding of the United States was that the IMF recently has urged Argentina to eliminate the statistical tax. The United States invited the Panel to consult with the IMF regarding its position on the Argentine tax.

3.282 Regarding the statement that the IMF had urged Argentina to eliminate the tax, **Argentina** noted that what was being discussed was a revision of the source of fiscal revenue with a view to renewing the agreement on the facilities in 1998. This could in no way be interpreted as implying that the IMF had suggested to Argentina that it should not meet the commitment agreed with the Fund.

(b) Relevance of the Declarations Annexed to the WTO Agreement and of the WTO Agreement with the IMF

3.283 According to **Argentina**, the conflict between WTO and IMF obligations was one of the factors that had motivated the *Declaration on the Contribution of the WTO to Achieving Greater Coherence in Global Economic Policymaking* ("Declaration on Coherence").[134] At the signing of the cooperation agreement with the IMF, the Director-General of the WTO had acknowledged the possibility of the occurrence of such conflicts.

3.284 Argentina added that compliance with an obligation assumed *vis-à-vis* the IMF and fulfilment of an obligation arising from GATT 1994 should, according

[134] Declaration on the Contribution of the WTO to Achieving Greater Coherence in Global Economic Policymaking, in *The Results of the Uruguay Round - The Legal Texts*, GATT Secretariat (1994), p.442.

to the Declaration on Coherence, avoid "the imposition on governments of cross-conditionality or additional conditions".[135] Ministers had also recognized:

> "difficulties the origins of which lie outside the trade field cannot be redressed through measures taken in the trade field alone. This underscore the importance of efforts to improve other elements of global economic policymaking to complement the effective implementation of the results achieved in the Uruguay Round. [...] The interlinkages between the different aspects of economic policy require that the international institutions with responsibilities in each of these areas follow consistent and mutually supportive policies".[136]

3.285 Moreover, Argentina added that the *Declaration on the Relationship of the World Trade Organization with the International Monetary Fund*,[137] noted the close relationship between the CONTRACTING PARTIES to the GATT 1947 and the International Monetary Fund, and the provisions of the GATT 1947 governing that relationship, in particular Article XV of the GATT 1947.

3.286 Argentina submitted that these texts and the precedents under Article XV[138] covered, on the one hand, the handling of the balance-of-payments problems which constituted the traditional area of cooperation between the WTO and the IMF and, on the other hand, the obligations arising from Article V:1 of the WTO Agreement and the Declaration on Coherence, which were meant to cover the area of future cooperation. They had to be analyzed from the standpoint of GATT/WTO obligations, inasmuch as they were an integral part of the Uruguay Round Agreements.

3.287 For Argentina, the Declaration on Coherence was one of the agreements in question and had to be considered for the purpose of interpreting the scope of obligations under Article VIII GATT 1994 in relation to Argentina's agreement with the IMF and its impact on fulfilment of the obligations under the WTO. This implied that the Declaration on Coherence constituted an "instrument" agreed between the parties in connection with the conclusion of a treaty, within the meaning of the general rule of interpretation contained in Article 31.2(b) of the Vienna Convention on the Law of Treaties (1969).[139]

3.288 Argentina emphasized that the subsequent practice of the CONTRACTING PARTIES had confirmed this interpretation inasmuch as, in the light, *inter alia*, of the above-mentioned Article V:1 of the WTO Agreement,

---

[135] Declaration on the Contribution of the WTO to Achieving Greater Coherence in Global Economic Policymaking, in *The Results of the Uruguay Round - The Legal Texts*, GATT Secretariat (1994), p.443, para. 5.

[136] *Ibid.*, p. 443, paras. 4-5.

[137] Declaration on the Relationship of the World Trade Organization with the International Monetary Fund, in *The Results of the Uruguay Round - The Legal Texts*, GATT Secretariat (1994), p.447.

[138] See paras. 3.297-3.305 below.

[139] UN Document A/CONF.39/27 (1969), hereafter the "Vienna Convention".

the General Council had approved, at its meeting of 7, 8 and 13 November 1996, the Agreement between the International Monetary Fund and the World Trade Organization ("IMF Agreement").[140] Paragraph 10 of the IMF Agreement specifically accepted and acknowledged the possibility of inconsistency between measures adopted by the parties in the light of one or the other agreement. Argentina therefore concluded that any evaluation that was made of the alleged inconsistency of the Argentine statistical tax had to take into account the existence of a potential conflict of rules which went beyond the framework of a possible bilateral trade dispute.

3.289 The **United States** considered that Argentina was asking the Panel to create a new exception not found anywhere in the body of the GATT or the WTO Agreement and in direct contravention of Article 3 DSU, which provided that decisions of the DSB could not add to or diminish the rights or obligations of WTO Members.

3.290 The United States argued that the several WTO declarations calling for greater cooperation or coordination between the WTO and the IMF, which Argentina cited in support to its arguments may be laudable goals. However, the declarations hardly established concrete exceptions to fixed WTO rules. These declarations imposed no binding obligations on Members, and they certainly did not address the specific issue before the Panel in this matter.

3.291 According to the United States, Argentina had not demonstrated that imposition of the three per cent tax was required or even requested by the IMF. As it appeared that Argentina itself chose to levy the tax as a means to achieving fiscal goals established by the IMF, the United States declared that Members should not be permitted to voluntarily adopt WTO-inconsistent practices to meet IMF commitments of a general nature. To the extent Argentina had done so, its tax was adopted for "fiscal purposes" in direct contravention of Article VIII.

3.292 The United States maintained that the question of whether amendments or exemptions should be made under the WTO Agreement to provide for better cooperation with the IMF was reserved for the WTO Members, not a dispute settlement panel.

3.293 **Argentina** was totally in agreement that amendments or exemptions should be reserved for WTO Members, but it was the United States which has brought this question before the Panel while Argentina was requesting the Panel to rule, in this specific case, on the existence of cross-obligations responsible for a situation which, in the view of the United States, represented the non-fulfilment of obligations *vis-à-vis* the WTO. In other words, it was the responsibility of the Panel to determine whether Argentina should act, as proposed by the United States, and fail to fulfil an obligation to the IMF, on the grounds that the statistical tax was unrelated to the approximate cost of the service. Argentina rejected

[140] Document WT/L/195, Annex I, approved by a decision adopted by the General Council at its meeting on 7,8 and 13 November 1996, document WT/L/194, 18 November 1996.

the possibility that no such relationship existed and also rejected the precedent of not complying with its legitimate international obligations.

3.294 For Argentina, the "*empirical*" method of solving problems as they arise which a special sub-group of the *Working Party on Quantitative Restrictions* had suggested with respect to the interpretation of Article XV[141] meant relying on "practice". In GATT terms, practice had consisted, firstly, in holding consultations with the IMF, consultations which Argentina considered pertinent and indeed requested. Secondly, any response by the IMF should be examined and evaluated in the light of the particular characteristics of the case.

3.295 Argentina further considered that, accordingly, the Panel should consider the subsequent legislative developments. The Declaration on Coherence was an integral part of an international treaty: the WTO Agreement. In the process of converting the provisions of the WTO Agreement, which were "programmatic", into "operational" rules, Argentina had worked together with the other WTO Members on preparing the Agreements between the WTO and the IMF and the World Bank, approved by the General Council at its meeting on 7, 8 and 13 November 1996.

3.296 The case of the Argentine statistical tax constituted an example of cross obligations between the two institutions. The existence of this and other examples was what had inspired the Declaration on Coherence.

(c) Scope of Article XV

3.297 In relation to the declarations and agreements regarding the relationship between the WTO and the IMF, **Argentina** recalled that Article XV:1 of the General Agreement provided that "the CONTRACTING PARTIES shall seek cooperation with the International Monetary Fund [...] with regard to exchange questions within the jurisdiction of the Fund [...] and other trade measures within the jurisdiction of the CONTRACTING PARTIES".

3.298 Argentina noted that, on the basis of this connection between the rules governing the GATT/IMF relationship, which found concrete expression in specific provisions authorizing, for example, the use of exchange controls in accordance with the Articles of Agreement of the International Monetary Fund (Article XV, paragraph 9(a)), the possibility was envisaged of situations where conflicts could arise in respect of legal obligations.

3.299 Thus, According to Argentina, a working party sub-group which looked into whether Article XV, paragraph 9(a) provided exemption from compliance with obligations under GATT, "agreed that it would be preferable not to try to lay down general principles on the relationship between paragraphs 4 and 9 but

[141] See para. 3.299 below.

to leave this question over for empirical consideration if and when particular points arose which had a bearing on it".[142]

3.300 Argentina stressed that the practical upshot of all this was that, for example, when faced with a complaint by Italy against Turkey concerning the establishment of an equalization fund which was financed by the sale of import permits (allegedly in breach of Article II:1(b) GATT), "the Fund had stated that it did not object to the temporary continuance of these practices and would remain in consultation with Turkey on these practices. The complaint was referred to the Panel on Complaints but was withdrawn later".[143] The purpose of this inter-agency collaboration was to encourage the member governments of both organizations to develop coordinated action in their economic policymaking.

3.301 Argentina further argued that, in relation to the scope and application of Article XV, the following had been noted in the Tokyo Declaration of 1973 which launched the Tokyo Round of multilateral trade negotiations:

> "the policy of liberalizing world trade cannot be carried out successfully in the absence of parallel efforts to set up a monetary system which shields the world economy from the shocks and imbalances which have previously occurred. The Ministers will not lose sight of the fact that the efforts which are to be made in the trade field imply continuing efforts to maintain orderly conditions and to establish a durable and equitable monetary system".
>
> The Ministers recognize equally that the new phase in the liberalization of trade which it is their intention to undertake should facilitate the orderly functioning of the monetary system".[144]

3.302 For the **United States**, Article XV did not speak to the imposition of a statistical tax. Instead, Article XV was concerned with exchange arrangements. It was inapplicable to this dispute because the tax in question was not an exchange control measure and bore no direct relationship to exchange issues. Rather, as acknowledged by Argentina, the tax was a charge on imports for the gathering of statistical data regarding Argentina's international trade. To whatever degree exchange controls approved by the IMF may be allowed under Article XV, Argentina's tax clearly was outside the scope of that provision. While Article XV did generally call for cooperation between GATT contracting parties and the IMF, Article XV:4 was careful to state that "[c]ontracting parties shall not, by

---

[142] Argentina referred to the *Working Party on Quantitative Restrictions Relations between the GATT and the International Monetary Fund* Report of the Special Sub-Group, BISD 3S/170, p. 195, para. 8.

[143] Argentina referred to document SR.9/7, as mentioned in *GATT, Analytical Index: Guide to GATT Law and Practice, Updated 6th Edition* (1995), p. 439.

[144] MIN(73)1, Declaration of Ministers approved at Tokyo on 14 September 1973, BISD 20S/19, p. 22, para. 7.

exchange action, frustrate the intent of the provisions of this Agreement".[145] Argentina's tax, though, did just that. Therefore, to suggest that the latitude accorded to Members under Article XV to meet commitments to the IMF in relation to exchange controls extended so far as to permit the imposition of a tax in violation of Article VIII, would necessarily expand the scope of Article XV far beyond what its drafters intended.

3.303 **Argentina** replied that the practice relating to Article XV should not be overlooked or excluded because that Article referred to measures relating to exchange controls. Argentina did not dispute the subject matter of this Article, but considered it to form part of the historical relationship between GATT and the IMF.

3.304 The negotiating effort made by the WTO Members to make "operational" the Declaration on Coherence and the fact that the Argentine case was specifically mentioned during the process constituted palpable evidence that it was not solely a question of "laudable goals". The history of Article XV and the Declaration on Coherence were specifically applicable to the Argentine case, since it was a question of a precedent which had led to the signing of the Agreement between the WTO and the IMF. Argentina had mentioned Article XV as a basis for the Declaration on Coherence, which as mentioned above, it considered applicable in this case as an "instrument" agreed between the parties in connection with the conclusion of a treaty.

3.305 Argentina did not wish to extend the scope of Article XV to this case, but cited the history of the problems relating to the exchange agreements as a stage in the process of WTO/IMF cooperation. If there had not been problems over and above those relating to exchange rates, there would, firstly, have been no need to negotiate the text of the Declaration on Coherence and, secondly, no need to negotiate the subsequent agreements between the WTO and the IMF and the World Bank in order to be able to deal with precisely such situations as the one at issue. Likewise, mention of Article XV of the GATT 1994 when referring to the question of "WTO-IMF relations", did not mean that Argentina intended to make an assimilation between the statistical tax and an exchange measure or some similar measure. Neither did it imply that the statistical tax was a measure which "frustrate[d] the intent" of the Agreement.

[145] The United States added that *ad Article XV* addressed the word "frustrate" in Article XV:4 by permitting infringements of the letter of any Article by "exchange action" so long as "there is no appreciable departure from the intent of the Article". However, in this instance, there was no exchange action. Even if Argentina's statistical tax could be considered as such, the imposition of the three per cent statistical tax was an "appreciable departure" from the requirements of Article VIII. Moreover, the examples in the Ad Note only related to exchange measures consistent with the Articles of Agreement of the IMF.

D. Article 7 ATC

3.306 The **United States** considered that, as they applied to textiles and apparel, Argentina's specific duties and tax on imports were contrary to Article 7 ATC. Article 7 ATC imposed a sweeping obligation on signatories to take whatever steps were necessary to bring their regimes into compliance with GATT obligations as they affected textiles and apparel, and thereby to improve market access for these products. ATC signatories had recognized the acute importance of greater market access for covered merchandise and, through Article 7, had accepted an affirmative obligation to eliminate improper methods of protection. At a minimum, a violation of a provision of the GATT that affected textiles and apparel also constituted a violation of Article 7 ATC. The broad language of Article 7 ATC suggested an even more expansive application. However, given what appeared to be clear GATT violations in this case, the Panel needed only find that such violations, as they related to textiles and apparel, also contravened Article 7 ATC. In agreeing to the ATC as part of the WTO Agreement, Argentina had agreed to "achieve improved access" to its textile and apparel market through lower tariffs and reduced non-tariff barriers. By imposing its specific duties in violation of GATT Articles II and VII, as well as its tax on imports in violation of GATT Article VIII, Argentina had not only violated the GATT but also the ATC.

3.307 **Argentina** was of the view that the purpose of the ATC was to eliminate existing quantitative restrictions with a view to integrating this sector into the rules of the multilateral trading system. Article 7.1(a) ATC referred to compliance with bound tariff rates and the lifting of the quantitative barriers maintained by some countries which Member countries may have notified to the Textile Monitoring Body ("TMB") in accordance with Article 7.2. When the WTO Agreement, including the ATC, entered into force, Argentina was not applying quantitative restrictions under the MFA or any bilateral agreements. Argentina did not maintain quantitative restrictions or non-tariff measures such as customs, administrative and licensing formalities that might give rise to a roll-back obligation, nor had it done so in the past.

3.308 For Argentina, the interpretation seeking to define Article 7 ATC as imposing a legal obligation to open up markets beyond the level of bound tariffs had been rejected by both the General Council and the WTO Ministerial Conference of Singapore.[146] The fact that Article 7 provided that "Members shall take such actions as may be necessary to abide by GATT 1994 rules and disciplines" presupposed the implementation of tariff bindings. The United States' invocation of Article 7 ATC was neither legally nor economically justifiable. The growth of Argentine imports of textiles and apparel during the period 1991-1996 unambiguously demonstrated the openness of the Argentine market and the lack of barriers or obstacles to the entry of those products. Imports of textiles had risen by

[146] Argentina referred to document WT/MIN(96)/2, 26 November 1996, Section IV.

800 per cent between 1991 and 1996. During the same period United States textile imports had risen by a maximum of 50 per cent and those of the EC by 41 per cent.

3.309 The **United States** noted that Argentina appeared tow agree with the United States that if its practices violated GATT obligations, then they also violated Article 7 ATC. However, the United States considered that attempts to narrow this provision's application were inconsistent with its language, history and underlying purpose. India, as a third party to this dispute, had advocated a very narrow interpretation of Article 7 ATC. India had suggested that Article 7 implicated only a limited category of measures, i.e., tariff concessions and quantitative restrictions listed in a Member's schedule which related to textiles and clothing.[147] Applying India's theory, violations of GATT 1994 provisions such as Article I:1 and III:2 would not violate Article 7 ATC, even if they negatively impacted market access for textiles and clothing, so long as they did not relate to a particular tariff or quantitative restriction listed in a particular Member's Schedule.

3.310 The United States argued that India's interpretation ignored Article 31 of the Vienna Convention and was inconsistent with the text, context, and object and purpose of Article 7 ATC. The proper interpretation of the phrase "the specific commitments undertaken by the Members" was *all* GATT 1994 rules and disciplines which negatively impacted improved market access for clothing and textiles. India's reading of the word "commitments" to mean only specific scheduled concessions was far too limited. The text did not read "specific commitments undertaken by *a* Member", but rather "the specific commitments undertaken by *the* Members". This meant all commitments undertaken by all WTO Members in the single undertaking, at least as they regarded the provisions of GATT 1994. This interpretation was confirmed by the immediate context of the "specific commitments" phrase in Article 7, which stated that "all Members shall take such actions as may be *necessary to abide by GATT 1994 rules and disciplines* so as to: (a) achieve improved access to markets for textile and clothing products through such measures as tariff reductions and bindings, *reduction or elimination of non-tariff barriers*, and facilitation of customs, administrative and licensing formalities".[148] If Article 7 were limited to only "scheduled" tariff and quantitative restriction concessions as India argued, then the non-tariff and non-quantitative references in Article 7.1(a) to (c) would be rendered a nullity.[149] The "schedules" of Members simply did not include references to non-tariff barriers, facilitation of customs, administrative, and licensing formalities, dumping and

---

147 India's arguments are contained in section IV.C below (Third Parties Submissions).

148 Emphasis added by the United States.

149 The United States referred to the Appellate Body Report on *United States - Standards for Reformulated and Conventional Gasoline*, Op. Cit., p. 23, where the Appellate Body stated that an interpreter was not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.

subsidies, or intellectual property rights. Moreover, the fact that Article 7.2 anticipated that Members' actions already may have "been notified to other WTO bodies" other than the TMB suggested a far broader context for GATT 1994 provisions than textiles and apparel.

3.311 The United States contended that, on the contrary, the interpretation of Article 7 ATC advocated by the United States and the EC was consistent with its object and purpose of achieving improved market access for textile and clothing products. While the ATC generally dealt with quantitative textile and apparel restrictions, Article 7 ensured that non-quantitative restrictions such as tariffs, non-tariff barriers, licensing provisions, intellectual property provisions were not used in a manner which undermined market access for all WTO members. An overly-restrictive reading of Article 7 ATC such as proposed by India and Argentina would limit the ability of the TMB (pursuant to notifications received under Article 7.2) to pursue its mandate of collecting and reporting on non-tariff measures having a negative impact on market access for textile and apparel products.

3.312 Finally, the United States contested India’s reference to alleged negotiating history of Article 7 ATC, based on meetings of which no minutes were taken. Article 32 of the Vienna Convention limited the use of preparatory work of a treaty "in order to confirm the meaning" of the text. Since India was not using this "preparatory work" to confirm a particular meaning of the text, nor to demonstrate that the meaning of the text was ambiguous or obscure or that it would lead to a result which would be manifestly unreasonable, there was no basis for the Panel to review or rely on such work.

3.313 **Argentina** considered that the arguments of the United States had been adequately queried by India in its third-party statement, which it fully supported. Also, in relation to the value of preparatory work as a method of interpretation, Argentina stated that preparatory work should serve to confirm the interpretation of a text as such and not to confirm the unilateral interpretation made by a party.

IV. THIRD PARTIES SUBMISSIONS

A. The European Communities

4.1 The **European Communities** noted that Argentina's regime of minimum specific duties on textiles, apparel and footwear had been frequently renewed and amended. The measures applying to footwear had been placed on a different legal basis to those concerning textiles and apparel since 14 February 1997, the date on which Argentina opened a safeguard investigation and decided to impose "provisional" minimum specific duties on footwear. Generally, these decisions in no way altered the nature of the regime of minimum specific duties for textile and apparel products nor the fact that by their nature they could exceed the bound duties. They served to underline however that the complaint had to be considered as directed at the regime, not the individual legal acts imposing the duties which were susceptible to constant change.

4.2 The EC also noted that the new "safeguard" duties were identical in form to the duties they replaced. The safeguard measures were expressly stated in Article 2 of Resolution No. 226/97 to be "provisional minimum specific duties", that is they had exactly the same nature as their predecessors since they applied where the amount of the *ad valorem* duty was less than the specified "minimum duty". Not even their "provisional" nature allowed them to be distinguished since they were no more "provisional" than the previous duties.

4.3 The EC argued that the Panel should not accept the request by Argentina for a preliminary ruling to dismiss the complaint insofar as it related to the footwear duties on the grounds that the duties complained against no longer existed. The provisional safeguard measures which had been adopted soon after the duties on footwear had been repealed operated in exactly the same way as the previously existing duties. The provisional safeguard measures were also clearly intended to replace the previous duties as was evidenced by the reference in the preamble of each of the repealing and safeguard Resolutions to the other Resolution and the simultaneity of their entry into force. The US complaint should be taken to be directed against the regime of minimum specific duties and not against specific legal acts. The reference to specific Argentine legal acts in the US request for the panel only served to describe the features of the measures complained of. If the approach of Argentina were to be followed, then the US complaint against the specific duties on textiles and apparel could also be considered to be inadmissible, since the Argentine measures imposing it had also changed. The fact that the minimum specific duties on footwear were now based on the Argentine legislation on safeguards constituted an attempt to justify the measures as safeguard measures and this justification needed to be examined.

4.4 The EC shared the view of the United States that in imposing its regime of minimum specific duties on textiles, apparel and footwear, Argentina had violated Article II GATT 1994 by allowing duties to be imposed which exceeded its bound tariff rate of 35 per cent *ad valorem*.

4.5 For the EC, any such system created a possibility for duty rates to exceed the bound rate with the probability of this happening increasing as the customs value of the imported product decreased. Argentina effectively admitted this when it insisted on the availability of the challenge procedure in its Customs Code to avoid the payment of excess duty. Such an effect was particularly likely in the present case in view of the method used by Argentina to establish the minimum specific import duty. As this was explained by Argentina itself in bilateral exchanges and during these proceedings, the reason for the existence of the system was that certain shipments of the goods were considered to be imported at particularly low prices which caused injury to the Argentine industry.

4.6 According to the EC, since the prices of products within a tariff heading varied and the price used to calculate the corresponding minimum specific duty was an average or representative price, it was obvious that some imports would be above and some below these prices. Since the duty was calculated at 35 per cent of the "average" or "representative" price, all those products imported at

below the "average" or "representative" price bore a duty of more than 35 per cent *ad valorem*.

4.7 The EC argued that the explanation of the calculation of the duties supplied by Argentina in the form of a table including a list of tariff heading for textile and clothing, average prices used as a basis for the calculation and the DIEM proposed showed some proposed minimum specific duties which were above the amount calculated to be 35 per cent of the "representative price", sometimes by very high margins. The EC referred the Panel to HS tariff lines 5209.52.00, 5309.11.00, 5513.12.00, 5513.22.00, 5514.12.00, 5513.13.00, 5516.22.00, 5516.42.00, 5516.91.00, 5516.93.00, 5606.00.00, 5607.21.00, 5607.50.11, 5607.90.10, 5702.10.00, 5702.20.00, 5702.49.00, 5702.92.00, 5705.00.00, 6102.30.00, 6104.29.00, 6107.92.00, 6116.92.00, 6204.13.00, 6204.19.00, 6207.22.00, 6210.10.00, 6302.92.00, 6306.41.00, 6306.91.00, 6306.99.00, 6310.10.00. For HS Chapter 56 the proposed duties were sometimes over 10 times the 35 per cent limit and therefore equivalent to 300 per cent duties (see, e.g., tariff line 5607.90.10). Even the weighted average duty for the whole of Chapter 56 was above 35 per cent of the "representative prices". A comparison with the latest version of the minimum specific duties imposed by Resolution No. 597/97[150] of 14 May 1997 showed that some of these minimum specific duties of over 35 per cent *ad valorem* of the "representative prices" were still being applied by Argentina.

4.8 The EC agreed with Argentina that the United States bore the burden of proof. However, it could be demonstrated that applied duties would exceed 35 per cent *ad valorem* simply by considering the way in which the duties were calculated. The United States had also given specific examples of tariff positions where the duties exceeded 35 per cent. The EC further considered that Argentina had admitted that some of the examples provided by the United States demonstrated an applied duty in excess of 35 per cent. If further specific examples of how applied duties may exceed the binding under this system were needed, they had been provided by Argentina itself. The examples of administrative appeals by the importer of Company X and by Company Y related to the imposition of minimum specific duties exceeding 35 per cent *ad valorem*.

4.9 The EC agreed with Argentina that Article II GATT 1994 did not impose an obligation on a WTO Member to apply a specific type of duty but only to grant tariff treatment "no less favourable" than that provided in its Schedule. Thus, to the extent that the applied tariffs were lower (e.g., 20 per cent *ad valorem*) than the tariff binding of 35 per cent *ad valorem*, there was some scope for Argentina to apply duties higher than the applicable *ad valorem* rate so long as the applied duties did not in any case exceed the bound rate of 35 per cent *ad valorem.*

[150] *Boletín Official de la República Argentina*, No. 28.650 of 20 May 1997.

4.10 The EC could therefore share the conclusion expressed by Argentina that, for a category of goods with an *ad valorem* applied duty of 20 per cent and subject to the payment of a specific duty of US$3.50, the three following possibilities existed:

Customs Value		*Customs Duty*
more than	$17.50	20 per cent *ad valorem*
between	$17.50 and US$10	$3.50
less than	$10	35 per cent *ad valorem*

4.11 The EC had understood Argentina as admitting that Article II GATT 1994 required that the customs duty imposed on any good subject to the regime of minimum specific duties could not in any case exceed 35 per cent *ad valorem*. The EC thus considered the argument by Argentina that a "mere potentiality" of a WTO incompatibility was not sufficient to found a violation, was misleading and unfounded.

4.12 The EC noted that Argentina had referred to GATT case-law according to which there was no violation if the national measure merely provided for the possibility of a measure being incompatible with WTO rules. Argentina equated "possibility" with "potentiality" and argued that this principle applied in the present case. This parallel was misleading and incorrect. The principle was that laws and regulations of WTO Members which *allowed* taking measures which would be incompatible with the WTO were not themselves violations. The violation only occurred when the authorities of the WTO Member actually used the possibility given to it and took a measure contrary to the WTO. The situation in the present case was different. The customs authorities of Argentina were obliged to impose minimum specific duties even when they exceeded 35 per cent *ad valorem*. Argentina's legislation did not allow them a discretion in the matter. The potentiality invoked by Argentina was merely the fact that the minimum specific duties would not always exceed 35 per cent *ad valorem* but would only do so when the customs value of the good was below a certain level. Since the "potentiality" of a violation of Article II GATT 1994 depended on the *price* of the product, *not on any action by Argentina*, the principle established by the GATT case-law invoked by Argentina was not applicable.

4.13 The EC noted that the Argentine Customs Code (Law No. 22.415) contained an administrative procedure by which an importer could challenge, *inter alia*, the amount of customs duty it was asked to pay. In addition, Article 75.22 of the Constitution of the Argentine Republic of 1994 provided that treaties were hierarchically superior to and therefore prevailed over domestic Argentine laws. Any Argentine judge was able to declare unconstitutional any provision of Argentine law which violated the provisions of an international treaty such as the WTO Agreement which had been ratified by Argentine Law No. 24.425. The implication seemed to be that Argentina's regime of minimum specific duties was contrary to its Constitution. The EC therefore wondered why Argentina had not abolished its system of minimum specific duties or at least introduced a ceiling of

35 per cent *ad valorem* to ensure that it respected the WTO Agreement and Argentina's Constitution.

4.14 For the EC, the challenge procedure described by Argentina, even in conjunction with the principle of the hierarchy of norms, was not such as to bring the system of minimum specific duties into conformity with Article II GATT 1994. Argentina claimed that the importer was entitled, if he introduced a "challenge procedure" to have his goods cleared through customs and placed in free circulation with only the payment of the amount which he considers due, provided that the importer submits a guarantee of payment of the difference, pending the adjudication of his challenge. Argentina further claimed that the procedure was automatic, free and required no legal representation. The examples provided by Argentina demonstrated that this was not the case. According to the EC, the challenges mentioned by Argentina were long and complicated. Argentina had given only two examples but there certainly existed thousands of potential cases. Finally, no indication was given as to the outcome of these challenge procedures. They had been introduced in February and November 1996 and were apparently still pending.

4.15 The EC further argued that, even if it were the case, that a challenge procedure would "simply and automatically" lead to the duty not exceeding 35 per cent *ad valorem* (and this had not been demonstrated), the system would still not be compatible with Article II GATT 1994. The higher duty was imposed by law and the importer was forced to follow a procedure to avoid it. In the meantime he had to bear the costs of the challenge and the provision of a guarantee.

4.16 The EC stated that the transformation of the minimum specific duties imposed on footwear into "provisional minimum specific duties" on 25 February 1997 (date of entry into force) and the initiation of a safeguard investigation constituted a mere change of legal basis and the measures themselves remained the same. The EC therefore considered this change of legal basis to be an attempt by Argentina to justify its measures under the WTO. The safeguard investigation had not been opened, and the provisional measures not imposed, in conformity with WTO Agreement. Accordingly, Argentina's system of minimum specific duties on footwear still violated Article II GATT 1994 just as it did before 25 February 1997.

4.17 The EC's information concerning Argentina's safeguard investigation and provisional measures derived from Argentina's Resolution No. 226/97 opening the proceeding and imposing provisional measures, WTO notification documents G/SG/N/6/ARG/1 - G/SG/N/7/ARG/1 (including Corr. 1) and G/SG/N/6/ARG/1/Suppl.1 - G/SG/N/7/ARG/1/Suppl.1, and the replies by Argentina to questions put by the EC in the course of consultations held under Article 12.4 of the Agreement on Safeguards on 2 May 1997.

4.18 The EC noted that Article 6 of the Agreement on Safeguards set out two preconditions which needed to be met before safeguard measures may be imposed: (i) critical circumstances where delay would cause damage which it would be difficult to repair; and (ii) a preliminary determination that there was clear

evidence that increased imports had caused or were threatening to cause serious injury. In addition, Article 2 (Conditions) of the Agreement on Safeguards, which applied to all measures taken under this Agreement, provided in paragraph 1 that safeguards may only be imposed if products were being imported "in such increased quantities, absolute or relative to domestic production, and under such conditions as to cause or threaten to cause serious injury".

4.19 The EC recalled that Article 2.1 of the Agreement on Safeguards required that products be imported in *increased quantities.* This was not an alternative to the *conditions* of import and therefore had to be satisfied in every case. Argentina's Resolution No. 226/97 and the Argentine notifications to the WTO referred to by the EC in paragraph 4.17 above demonstrated that imports into Argentina of footwear had *decreased* between 1994 and 1995 in both absolute and relative terms. Argentina did not deny this but claimed during consultations with the EC that there had been an increase in imports between 1991 and 1995. Safeguard measures were intended to protect against emergencies and unforeseen circumstances.[151] The EC considered that an increase in imports between 1991 and 1995 could not justify safeguard measures imposed in 1997 where there was a decrease in imports in the most recent period for which data was available (1994 and 1995). Even if it may be justified to provide (as in Article 8 and Annex I of Argentina's Decree No. 1059/96), that information on import data "must be supplied for the last five (5) full years", this was to provide a background against which trends could be established, not in order to measure the injury. The EC considered that Article 5.1 of the Agreement on Safeguards foresaw as a reference period for calculating quantitative restrictions a period of the last three representative years.

4.20 The EC argued that, as regards the second element in Article 2.1, *i.e.* the *conditions* under which the products were imported, the requirement that imports had to have an effect on domestic prices through price-undercutting, price-suppression or price-depression was clearly established. Since Argentina had not conducted this analysis (the notification documents did not present any information on prices), an essential and separate condition for the application of safeguards had not been met. The EC could not accept as an excuse the statement of Argentina during the consultations under Article 12.4 of the Agreement on Safeguards, that price analysis was "difficult" due to the variety of products under consideration, since it would have been possible to restrict the scope of the measures to those products for which it was possible to determine whether this requirement was fulfilled.

4.21 The EC also insisted that there was no clear evidence of serious injury. According to Article 6 of the Agreement on safeguards, there had to be clear evidence of *serious injury* or a threat of injury. The notification under Article

[151] See Article XIX GATT 1994.

12.1(a) of the Agreement on Safeguards (initiation of investigatory process)[152] did not contain any evidence of serious injury. The data in the notification under Article 12.4 (imposition of provisional measures)[153] referred only to *critical circumstances*. It was furthermore insufficient to provide "clear evidence" for the existence of serious injury because it only referred to the change in the condition of the domestic industry from 1991 to 1995 which was, in particular because of the duration of the period, irrelevant for assessing the situation of the industry. The notification contained no data on profitability of the domestic industry even though this was required by Article 4.2(a) of the Agreement on Safeguards. In its response to the EC's questions raised during the consultations under Article 12.4 of the Agreement, Argentina admitted that the investigation lacked information on profitability in the sector being investigated. The notification documents did not present any information on productivity of the Argentine industry.

4.22 The EC noted that another element of serious injury for which *clear evidence* would be required was the existence of a *causal link* between the imports and the injury so that injury caused by factors other than increased imports would not be attributed to imports (Article 4.2.(b) of the Agreement on Safeguards). It was stated in Argentina's notification document[154] that the situation of the domestic industry was only *partly* a result of import trends.[155] In its response to the Community's questions during the consultations under Article 12.4 of the Agreement on Safeguards, Argentina had admitted the existence of other factors for the condition of the domestic industry such as the apparent contraction of the Argentine footwear market and a general economic crises in 1995. Additionally, although only imports from non-MERCOSUR countries were subject to the measure, imports from MERCOSUR countries were included in the injury assessment. Imports from non-MERCOSUR countries had, according to a document dated 25 April 1997 submitted by the importer's association CAPCICA to the safeguards investigation, dropped continuously since 1992 to only 4.69 per cent in 1996. This demonstrated that imports from non-MERCOSUR countries could not be the cause of any injury that may exist.

4.23 The EC also criticized the absence of *critical circumstances*. According to Article 6 of the Agreement on Safeguards, the imposition of provisional measures required the existence of critical circumstances where delay could cause damage which would be difficult to repair. The EC considered that this was an additional requirement and the data provided on the condition of the domestic industry alone could not be sufficient to justify the need to impose measures immediately. There was no reference to an imminent danger of severe damage in Argentina's notification documents except the fact that the "mere absence of Minimum Specific Duties would recreate the critical circumstances required for the adoption of

[152] Document G/SG/N6/ARG/1; G/SG/N7/ARG/1, 25 February 1997.
[153] Document G/SG/N6/ARG/1/Suppl. 1; G/SG/N7/ARG/1/Suppl. 1, 18 March 1997.
[154] *Ibid.*
[155] *Ibid.*, p. 2, para. 5.

provisional measures".[156] The EC considered that a WTO Member could not rely on its own acts, such as the removal of the previous minimum specific import duties to establish *critical circumstances* and justify provisional safeguard measures.

4.24 In conclusion, the EC considered that the imposition of a provisional safeguard measure in this case was manifestly unjustified and the regime of minimum specific duties on footwear measures remained contrary to Article II GATT 1994.

4.25 With respect to the alleged violation of Article 7 ATC, the EC shared the view of the United States that, as they applied to textiles and apparel, Argentina's specific duties on imports were contrary to Article 7.1 ATC. There was no basis in that provision for the claim by Argentina that the obligations it created were limited to those matters which Members had notified pursuant to Article 7.2 ATC. On the contrary, Article 7.2 required notification to the Textiles Monitoring Body of all actions taken under Article 7.1 which had a bearing on the implementation of the ATC. Argentina had also violated Article 7.2 ATC by not notifying its measures as required by that provision.

4.26 The EC concluded that the Panel should find that Argentina's system of minimum specific duties for footwear, textiles and apparel, violate Article II:1(a) and II:1(b) of GATT 1994 and those relating to textiles and apparel also violate Article 7, paragraphs 1 and 2 ATC and recommend that Argentina bring its measures into conformity with its obligations under GATT 1994 and the ATC.

B. Hungary

4.27 **Hungary** considered that Argentina's minimum specific import duties often had amounted to more than 35 per cent of the actual value of the affected products, as it was the declared purpose of Argentina when establishing them to impose a duty higher than the ad valorem duty otherwise to be applied. Hungary provided data regarding the evolution for the six most affected Hungarian exports:

Specific Duties in Dollar per Kilogram

Product	*1993*	*1994*	*from 1995*
6201.11.00	-	6.0	16.3
6202.11.00	-	3.9	16.3
6203.11.00	-	16.5	26.2
6203.31.00	-	13.7	26.2
6203.41.00	-	14.0	14.0
6204.31.00	-	13.2	26.2

[156] Document G/SG/N6/ARG/1/Suppl. 1; G/SG/N7/ARG/1/Suppl. 1, 18 March 1997.

4.28 Hungary stated that, due to the introduction and later the drastic increase of level of specific duties, the Hungarian textiles and apparels exports to Argentina had practically ceased to exist.

4.29 Hungary recalled that Article II of GATT 1994 prohibited Members of the WTO from exceeding their bound tariff rates and according treatment less favourable than the terms stipulated in Schedules. In imposing specific duties on textiles and apparel, Argentina had violated Article II by exceeding or having the potential to exceed its bound tariff rate and failing to apply only *ad valorem* duties in accordance with its Schedule.

4.30 Hungary underlined that Argentina had also violated its WTO obligations by imposing a three per cent *ad valorem* statistical tax. Article VIII of GATT 1994 provided that all fees and charges on imports other than tariffs imposed by WTO Members "shall be limited to the approximate cost of services rendered". Argentina's statistical tax violated Article VIII because it bore no relation to the cost of any service rendered to importers.

4.31 Hungary added that by imposing its specific duties on textiles and apparel, as well as its statistical tax on imports, Argentina had also violated Article 7 ATC. Under this provision, Argentina had agreed to "take such action as may be necessary to abide by GATT 1994 rules and disciplines so as to (a) achieve improved access to markets for textile and clothing products through such measures as tariff reductions and bindings, reduction or elimination of non-tariff barriers". Hungary claimed that, as a consequence of the referred measures, the value of the Hungarian textiles and apparel exports had decreased drastically: from US$1.6 million in 1994 to US$0.07 million in 1996.

4.32 In conclusion, Hungary requested the Panel to find that Decree No. 998/95 and Resolution No. 22/97 which imposed specific duties on textiles and apparel, violated Article II of GATT 1994 and Article 7 ATC; that Decree No. 389/95, which applied a statistical tax on imports, violated Article VIII of GATT 1994 and Article 7 ATC. Finally, Hungary requested that the Panel recommend that Argentina bring its measures into conformity with its obligations under GATT 1994 and the ATC.

C. India

4.33 India limited its submission to the interpretation of Article 7 ATC advocated by the United States. In India's opinion, this interpretation could neither be justified on the basis of the language of Article 7, nor with reference to the negotiation history of this provision. The most crucial element in Article 7.1 was the phrase "with reference to the specific commitments undertaken by the Members as a result of the Uruguay Round". In view of this phrase, a Member's obligations with regard to tariff reductions and bindings, reduction or elimination of non-tariff barriers had to be interpreted with reference to the specific commitments undertaken by that Member as a result of the Uruguay Round. Therefore, India totally disagreed with the statement of the United States that "Article 7 imposed a sweeping obligation on signatories to take whatever steps are necessary to bring

their regimes into compliance with GATT obligations as they affect textiles and apparel, and thereby improve market access for these products". The United States could not legitimately argue that through Article 7, Members of the WTO accepted any "affirmative obligation". The obligation in Article 7.1 ATC was limited in scope in the sense that the obligation was with reference to the specific commitments undertaken by the Members. The argument of the United States according to which violation of a provision of GATT that affected textiles and apparel *ipso facto* constituted a violation of Article 7 ATC was not correct. If a WTO Member violated a GATT provision without going back on any specific commitments undertaken by that Member in its Uruguay Round Schedule, in so far as these commitments related to market access in respect of textiles and clothing products covered by the ATC, that Member could be deemed to be violating GATT but not necessarily Article 7 ATC.

4.34 India recalled that Article 7 ATC had been negotiated in the very last hours of the Uruguay Round between the United States, the European Communities, India, Pakistan and Hong Kong. It was no secret that the United States and the EC did not want Article 7 ATC to be interpreted as imposing more obligations on them than what they had accepted through the back-loaded integration process envisaged in the ATC. The phrase "as part of the integration process" appearing in Article 7.1 ATC was supposed to imply that there was no additional obligation for the United States and the EC to remove the MFA-inherited quotas faster than what was envisaged through the back-loaded integration process outlined in Article 2.6 and 2.8 ATC. The phrase "with reference to the specific commitments undertaken by the Members as a result of the Uruguay Round" implied that Article 7 would not be used to make additional demands in respect of tariff reductions, tariff bindings, etc. on countries like India, Pakistan, Argentina, etc. over and above what they had committed themselves to in their Uruguay Round Schedules. In that context, India expressed its surprise that the United States was trying to impose on Argentina an obligation with regard to improved access to textiles and apparel market without linking it in any manner to the obligations undertaken by Argentina in its Schedule. India agreed with the view expressed by Argentina that the central purpose of the ATC was to put an end to the discriminatory quota regime which had dominated the textile and clothing sector for so long and to bring it under the discipline of the multilateral trading system. India also supported the point made by Argentina to the effect that the interpretation which sought to define the wording of Article 7 ATC as a legal obligation to open up markets beyond the level of bound tariffs had never been accepted by the WTO Membership.

V. INTERIM REVIEW

5.1 On 7 October 1997, Argentina and the United States requested the Panel to review, in accordance with Article 15.2 of the DSU, the interim report that had been issued to the parties on 30 September 1997. We carefully reviewed the arguments presented by Argentina and the United States and revised paragraphs 3.15, 3.140 and 3.234 of the Descriptive Part in the light of the comments made by the parties. In response to their comments, we have clarified the wording of paragraphs 6.41, 6.53, 6.67 and 6.71 of the report. We have also made small modifications on other paragraphs.

5.2 Regarding Argentina's argument that it informed the Committee on Market Access that it was not going to change its minimum specific duties, as applied before the Uruguay Round (see paragraph 6.21), we have referred to the relevant argument submitted by Argentina in paragraph 3.67 of the Descriptive Part.

5.3 Argentina also contested that, in paragraph 6.79 of the panel report, the Panel did not address the wider and more fundamental issue of the existence of cross-conditionalities and conflicting obligations that could exist between a Members's commitments to the IMF and under the WTO Agreement. We see no reason to address this wider issue since, in the situation before the Panel, there is no evidence that Argentina was requested by the International Monetary Fund ("IMF") to impose an import tax that would violate the provisions of the WTO Agreement. Moreover, we see nothing in the Agreement Between the IMF and the WTO[157], the Declaration on the Relationship of the World Trade Organization with the International Monetary Fund and the Declaration on the Contribution of the World Trade Organization to Achieving Greater Coherence in Global Economic Policymaking that suggests that we should change our approach.

5.4 The United States has requested that, since we have decided not to reach any conclusion on its claim that Argentina also violated Article 7 of the Agreement on Textiles and Clothing ("ATC"), we limit our discussion on the matter. We have, consequently, adjusted our findings in paragraph 6.87.

VI. FINDINGS

6.1 The United States claims that Argentina's tariffs on imports of textiles, apparel and footwear items violate, generally and in specific cases, the provisions of Article II of the General Agreement on Tariffs and Trade 1994 ("GATT"). The United States also claims that the statistical tax of three per cent *ad valorem* collected by Argentina on imports[158] is in violation of the provisions of Arti-

[157] Annex I to WT/L/195, adopted by the General Council on 7, 8 and 13 November 1996.
[158] See paras. 2.19-2.21 of the Descriptive Part.

cle VIII of GATT. Finally, the United States claims that these violations give rise to an infringement of the provisions of Article 7 of the Agreement on Textiles and Clothing ("ATC").

6.2 Argentina raises a preliminary objection of a procedural nature on the jurisdiction of the Panel to address part of the US claim, challenges the evidence submitted by the United States and asks the Panel to reject the US claims as unfounded.

6.3 This dispute raises, therefore, various legal issues which we have identified and grouped as follows:

A. Argentina's preliminary objection. Should the Panel consider a measure relating to tariffs applied on footwear which was revoked prior to the establishment of the Panel?

B. Article II of GATT. Does the imposition of minimum specific duties by Argentina, which has bound the tariffs at issue at an *ad valorem* rate, constitute a violation of Article II? Does Argentina's tariff system have the potential to violate Article II and is this potential sufficient to constitute an infringement thereof? Has Argentina imposed duties in excess of its bound rate of 35 per cent *ad valorem*? How should we treat the issues raised by the parties with regard to proof and evidence submitted to the Panel?

C. The domestic challenge procedure. Do the constitutional supremacy of international law under the Argentine Constitution and the existence of a domestic procedure to challenge duties imposed in excess of Argentina's bound rates constitute a defense to the claimed violation of Article II of GATT?

D. Article VIII of GATT. What are the criteria for application of Article VIII's limits on charges and fees imposed in connection with importation? Is the statistical tax of three per cent *ad valorem* collected by Argentina on imports in violation of Article VIII of GATT?

E. Article 7 of the ATC. Does a violation of any provision of the WTO Agreement in the textile and apparel sector constitute a violation of Article 7 of the ATC? Has Argentina violated the provisions of Article 7 of the ATC?

A. Preliminary Objection by Argentina

6.4 In its request for establishment of a panel, dated 9 January 1997, the United States claims that the tariffs imposed by Argentina on textiles, apparel and footwear violate the provisions of Article II of GATT. The Panel was established on 25 February 1997. On 14 February 1997, i.e., after the circulation of the US request for the establishment of a panel but before the Panel was established by the DSB, Argentina revoked the specific duties that it had been imposing on footwear.

6.5 On the day that it revoked the challenged footwear duties, Argentina imposed a provisional safeguard measure in the form of specific duties (G/SG/N/6/ARG/1, G/SG/N/7/ARG/1, dated 25 February 1997 and G/SG/N/6/ARG/1 Supp.1, G/SG/N/7/ARG/1 Supp.1 dated 18 March 1997) on footwear and initiated a safeguard investigation.

6.6 In its first written submission, Argentina claims that the Panel does not have jurisdiction to address the specific duties on footwear which were withdrawn before the Panel was established. At the first meeting of the Panel with the parties, Argentina requested a decision on this issue before proceeding to the substantive questions.

6.7 We decided that we would not render a preliminary decision on this issue and invited both parties to submit evidence and arguments on all aspects of the US claims.

6.8 Argentina essentially argues that the specific duties on footwear were revoked before the Panel was established so that, even if the revoked measure is still contained in the terms of reference of this Panel, that claim has become "abstract", pertaining to the illegality of a measure that no longer exists. For Argentina, WTO proceedings cannot be initiated without a specific subject of dispute to which they can apply. In support of its claim, Argentina refers the Panel to Article 19.1 of the DSU, which provides that "where a Panel or the Appellate Body concludes that a measure is inconsistent with a covered agreement, it shall recommend that the Member concerned bring the measure into conformity with that agreement". Argentina stresses that the present tense is used. Moreover, for Argentina, making hypothetical assessments of expired measures would distort the dispute settlement mechanism and amount to making interpretations of the WTO agreements, contrary to the specific provisions of the WTO Agreement.

6.9 The United States argues that the Panel should rule on Argentina's specific duties on footwear since they are contained in the terms of reference of the Panel. In addition, the provisional safeguard duties are essentially the same as those applied as specific duties which were part of the same "regime" of specific duties imposed on textiles, apparel and footwear. In the US view, the safeguard duties have in any case a close factual connection with the duties still in force, in that they apply parallel provisions. Finally, the United States argues that measures similar to those revoked may be reinstated at the expiry of the safeguard measures or should Argentina lose a panel proceeding on such safeguard measures.

6.10 We note first that the terms of reference of this Panel include the specific duties on footwear since the terms of reference simply refer to the US request for establishment of a panel. That request specifically mentioned:

> "Resolution 304/95, 305/95, 103/96, 299/96, Decree 998/95 and other measures which impose specific duties on various textile, apparel or footwear items in excess of the bound rate of 35 per cent ad valorem provided in Argentina's schedule LXIV".

6.11 Panels and their terms of reference are established by the DSB and panels are not authorized to amend unilaterally their mandate. On the other hand, panels have often been required to determine their jurisdiction over a matter (See for instance *United States - Standards for Reformulated and Conventional Gasoline,*[159] *Japan - Taxes on Alcoholic Beverages,*[160] *Brazil - Measures Affecting Desiccated Coconut,*[161] and *EC - Regime for the Importation, Sale and Distribution of Bananas*[162] *("Bananas III")*). As stated by the Appellate Body in *Bananas III*, in another context:

> "142. We recognize that a panel request will usually be approved automatically at the DSB meeting following the meeting at which the request first appears on the DSB's agenda.[163] As a panel request is normally not subjected to detailed scrutiny by the DSB, it is incumbent upon a panel to examine the request for the establishment of the panel very carefully to ensure its compliance with both the letter and the spirit of Article 6.2 of the DSU".

6.12 On several occasions, panels have considered measures that were no longer in force.[164] It appears that in each of those cases, however, there was no objection raised by either party to the panel's consideration of the expired measure. In a recent case, an objection was raised by the respondent to panel consideration of a measure no longer in effect. In that case, the panel stated:

> "6.19 The Panel observed that it has not been the usual practice of a panel established under the General Agreement to rule on measures that, at the time the Panel's terms of reference were fixed, were not and would not become effective. In the 1978 Animal Feed Protein case, the Panel ruled on a discontinued measure, but one that had terminated after agreement on the Panel's terms of reference. In the 1980 Chile Apples case, the Panel ruled on a measure terminated before agreement on the Panel's terms of reference; however, the terms of reference in that case specifically included the terminated measure and, it being a seasonal measure, there re-

[159] Panel and Appellate Body Reports adopted on 20 May 1996, WT/DS2/R and WT/DS2/AB/R.
[160] Panel and Appellate Body Reports adopted on 1 November 1996, WT/DS/8, 10, 11/R and WT/DS8, 10, 11/AB/R.
[161] Panel and Appellate Body Reports adopted on 20 March 1997, WT/DS22/R and WT/DS22/AB/R.
[162] Panel and Appellate Body Reports adopted on 25 September 1997, WT/DS27/R and WT/DS27/AB/R.
[163] DSU, Article 6.1.
[164] See for instance,the *Gasoline* Panel Report at para.6.19; Panel and Appellate Body Reports on *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, adopted on 23 May 1997, WT/DS33/R and WT/DS33/AB/R; Panel Report on *EEC - Measures on Animal Feed Proteins*, adopted on 14 March 1978, BISD 25S/49; and Panel Report on *United States - Prohibition on Imports of Tuna and Tuna Products from Canada*, adopted on 22 February 1982, BISD 29S/91.

> mained the prospect of its reintroduction. In the present case the Panel's terms of reference were established after the 75 per cent rule had ceased to have any effect, and the rule had not been specifically mentioned in the terms of reference. The Panel further noted that there was no indication by the parties that the 75 per cent rule was a measure that, although currently not in force, was likely to be renewed [...] . The Panel did not therefore proceed to examine this aspect of the Gasoline under Article I:1 of the General Agreement".[165]

6.13 As noted earlier, the Argentine measure under consideration was revoked before the Panel was established and its terms of reference set, i.e. before the Panel started its adjudication process. The *Gasoline* panel report would argue in favour of not considering the Argentine specific duties on footwear. Moreover, as noted by the Appellate Body in the *Shirts and Blouses*[166] case, the aim of dispute settlement is not

> "to encourage either panels or the Appellate Body to 'make law' by larifying existing provisions of the *WTO Agreement* outside the context of resolving a particular dispute. A panel need only address those claims which must be addressed in order to resolve the matter in issue in the dispute".

6.14 However, the United States claims that there is a serious threat of recurrence since Argentina could easily reintroduce the previous import measures, and the United States suggests that Argentina is likely to do so because there is only a weak justification for its safeguard measure on footwear. We cannot evaluate the justification or likely duration of that safeguard measure. Moreover, in the absence of clear evidence to the contrary, we cannot assume that Argentina will withdraw the safeguard measure and reintroduce the specific duties measure in an attempt to evade panel consideration of its measures. We must assume that WTO Members will perform their treaty obligations in good faith, as they are required to do by the WTO Agreement and by international law[167]. We consider, therefore, that there is no evidence that the minimum specific import duties on footwear will be reintroduced.

6.15 Consequently, we will not review the WTO compatibility of the specific duties which used to be imposed on footwear and which have, since the establishment of this Panel, been revoked. However, since these specific duties on footwear were in force for a long period until 14 February 1997, and for our understanding of the type of duties used by Argentina, we may, when reviewing the

---

[165] Panel Report on *Gasoline*.

[166] See Appellate Body Report on *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, adopted on 23 May 1997, WT/DS33/AB/R, p. 19.

[167] See Article 3.10 of the DSU and Article 26 of the Vienna Convention on the Law of Treaties (*Pacta Sunt Servanda).*

import regime applied to textiles and apparel, refer to some examples of transactions involving footwear because the type of duties used at the time by Argentina for textiles, apparel and footwear was the same.

B. Article II of GATT

6.16 The United States claims that Argentina violates the provisions of Article II of GATT in two ways:

a) Argentina's application of minimum specific duties to products in respect of which it bound *ad valorem* duties violates Argentina's obligation to maintain *ad valorem* tariffs pursuant to Article II; and

b) The specific duties applied by Argentina will inevitably lead and have in fact led to the imposition of duties in excess of the 35 per cent *ad valorem* tariff rate bound by Argentina pursuant to Article II.

6.17 Argentina argues that an allegation of a "potential" violation of Article II is not sufficient, and that in any case its tariffs do not have the potential and indeed have never exceeded the bound rate of 35 per cent *ad valorem*. It also responds that as long as its applied tariffs do not exceed the equivalent of 35 per cent *ad valorem*, it is free to use any type of duties, including specific duties. Argentina also adds that in its Constitution, international law prevails over domestic law and that it is therefore unconstitutional in Argentina to violate WTO rules. In this context, Argentina further argues that it maintains a domestic mechanism whereby Argentine importers, should they be required to pay duties above Argentina's bindings, can ask any judge to declare such duties to be illegal and unconstitutional, which, it notes, has never happened in the sector of textiles, apparel and footwear.

6.18 Argentina states that the specific duties were determined according to the following methodology[168]:

(a) A representative international price was calculated for each category of product and tariff heading. Since there are no standard international prices for textile and clothing products, the prices prevailing in the major markets were used, mainly the United States market. The use of data concerning these markets was determined in general terms by volume and the representative nature of the markets, and also by the degree of reliability of the statistics.

(b) A specific duty was applied to the representative international prices thus determined, adjusted to put them on a c.i.f. - Buenos Aires basis.

6.19 The various *resoluciónes* (hereafter translated as "resolutions") establishing the minimum specific duty system for textiles, apparel and footwear function

[168] See para. 3.120 of the Descriptive Part.

the same way: they impose minimum specific duties to be used as equivalents to applied *ad valorem* duties[169]. The duty collected is the greater of the applicable specific duty or *ad valorem* duty. For example, this is clear from the first resolution (No. 811/93) assigning specific import duties to textile and apparel imports submitted by the United States[170]:

> *"Aclárase que los derechos de importación específicos que se establecen por el artículo 1 de la presente resolución, operarán como mínimo del correspondiente derecho de importación ad valorem".*[171]

The Annex 1 to this resolution lists the *Derecho Especifico Minimo* (Minimum Specific Import Duty) for a list of *Posición NCE* (Foreign Trade Nomenclature (NCE) Heading). We note that all the following resolutions regarding the minimum specific duty regime imposed on the textile, apparel and footwear sector, were similar. The levels of the minimum specific duties have been adjusted from time to time, but they always have been calculated as described.

6.20 A description of how the DIEM. used by Argentina operates was further explained in a letter sent by Argentina to the United States and submitted by the United States[172]:

> *"El funcionamiento del nuevo sistema de derechos aduaneros (v.g. DIEM), se explica de la siguiente manera. Una vez arribado el producto a zona aduanera, y determinado su precio C.I.F. por unidad (en este caso particular, cada unidad está constituida por un par de calzados), se compara el valor del DIEM vigente con el monto resultante de aplicar del Derecho de Importación Extrazona vigente al producto en cuestión, correspondiendo para la nacionalización del mismo (despacho a plaza) la aplicación del mayor de los montos cotejados. A continuación se gráfica el funcionamiento con dos ejemplos hipotéticos".*[173]

6.21 In its first submission, Argentina states that it has not changed its type of duties but rather that it has simply continued to use specific duties as it did before

---

[169] They are referred to in paras. 2.4 and 2.7-2.21 of the Descriptive Part.

[170] See para. 3.15 of the Descriptive Part.

[171] Resolution No. 811/93, 29 July 1993, Article 3. The English translation for this piece of legislation reads as follows: "It is hereby expressly stated that the specific import duties established by Article 1 of this decision shall operate as a minimum of the corresponding *ad valorem* import duty".

[172] See para. 3.15 of the Descriptive Part.

[173] Letter of the National Director of Industry Affairs explaining the Argentine minimum specific import duties. The English translation of this letter reads as follows: "This new customs system, i.e., DIEM, operates as follows. Once the product has arrived in the customs area and its c.i.f. price has been determined per unit (in this particular case, each unit consists of one pair of shoes), the current value of the DIEM is compared against the amount obtained by applying the current extra-zone import duty to the product in question, and the higher of the two amounts compared will be applied for purposes of inward customs clearance. The two hypothetical examples given below will illustrate how this works".

the Uruguay Round. All that it did in the Uruguay Round, was to bind certain tariffs at 35 per cent *ad valorem*. We asked Argentina whether, in its Schedule, it had reserved its right to continue to impose minimum specific duties up to a maximum *ad valorem* duty of 35 per cent. Argentina responded that it declared the situation to the Market Access Committee but did not refer to any minutes of meetings.[174] No further evidence of any such specifications in the bindings was brought to our attention.

6.22 Article II(1)(a) of GATT reads as follows:

> "1. (a) Each Member shall accord to the commerce of the other Members treatment no less favourable than that provided for in the appropriate Part of the appropriate Schedule annexed to this Agreement".

The issue for the Panel is, therefore, to decide what are the obligations covered by the "treatment no less favourable than that provided for in the appropriate [...] Schedule".

1. The Type of Duties Used

6.23 The United States claims that the type of duties applied by a WTO Member - even below any bound rate - must conform to that specified in the Schedule of such Member. Since Argentina has bound its tariffs at 35 per cent *ad valorem* in its Schedule of Concessions (hereafter called "Schedule"), the United States argues that Argentina may only impose *ad valorem* duties. Argentina responds that as long as the duties it imposes are below the equivalent of 35 per cent *ad valorem*, it can use any type of duties. Therefore, we have to decide whether the imposition of minimum specific duties by Argentina, which has bound the tariffs at issue at an *ad valorem* rate, constitutes a violation of Article II.

6.24 The wording of Article II does not seem to address explicitly whether WTO Members have an obligation to use a particular type of duty. However, the wording of Article II must be interpreted in the light of past GATT practice, as mentioned in Article XVI:1 of the WTO Agreement and paragraph 1(b)(iv) of Annex 1A incorporating the GATT 1994 into the WTO Agreement, and indicated by the Appellate Body in *Japan - Taxes on Alcoholic Beverages*.[175] Issues similar to those presented in this case have arisen on a number of occasions.[176]

---

[174] See para. 3.67 of the Descriptive Part.

[175] "Article XVI:1 of the *WTO Agreement* and paragraph 1(b)(iv) of the language of Annex 1A incorporating the GATT 1994 into the *WTO Agreement* bring the legal history and experience under the GATT 1947 into the new realm of the WTO in a way that ensures continuity and consistency in a smooth transition from the GATT 1947 system. This affirms the importance to the Members of the WTO of the experience acquired by the CONTRACTING PARTIES to the GATT 1947 - and acknowledges the continuing relevance of that experience to the new trading system served by the WTO. Adopted panel reports are an important part of the GATT *acquis*. They are often considered by subsequent panels. They create legitimate expectations among WTO Members, and, therefore,

6.25 In this connection, the Working Party Report on *Rectifications and Modifications of Schedules*[177] stated in 1953:

> "The Working Party also concerned itself with the proposal of the Greek Government to introduce a minimum *ad valorem* rate for certain specific rates and came to the conclusion that such changes could not be considered rectifications to be dealt with by the Working Party, [...] [I]t decided therefore to refer the question to the CONTRACTING PARTIES so that such changes could form the object of consultations and negotiations with the parties having an interest in these items".

6.26 In 1954, the Working Party Report on *Transposition of Schedule XXXVII - Turkey*[178] stated:

> "3. The Working Party has also examined the proposal to change the specific duties in the Turkish Schedule to *ad valorem* duties, in *cases where such a change is not expressly provided for in the Schedule,* in order that the new tariff as regards bound items will conform with the Government's obligations under the General Agreement. A comparison by the secretariat of the proposed *ad valorem* rates with rates which would have resulted, if the conversion had been carried out on certain other bases which were suggested, has indicated that for a considerable proportion of the items the method employed by the Turkish Government has resulted in lower rates than would have been the case if one of those other bases had been used. The Working Party considered the proposals in relation to the provisions of the Agreement and to the practices of the CONTRACTING PARTIES which deal with the modification of schedules. *It was found that there is no provision in the General Agreement which authorizes a contracting party to alter the structure of bound rates of duty from a specific to an ad valorem basis.* (Emphasis added)
>
> 4. The obligations of contracting parties are established by the rates of duty appearing in the schedules and any change in the rate

---

should be taken into account where they are relevant to any dispute. However, they are not binding, except with respect to resolving the particular dispute between the parties to that dispute.[Footnote 30: It is worth noting that the Statute of the International Court of Justice has an explicit provision, Article 59, to the same effect. This has not inhibited the development by that Court (and its predecessor) of a body of case law in which considerable reliance on the value of previous decisions is readily discernible.] In short, their character and their legal status have not been changed by the coming into force of the *WTO Agreement*". See Appellate Body Report on *Japan -Taxes on Alcoholic Beverages*, adopted on 1 November 1996, WT/DS8, 10, 11/AB/R, p.14.

[176] See also John H. Jackson, *World Trade and the Law of the GATT*, Bobbs-Merrill Co. (1969), p. 215.

[177] Adopted on 24 October 1953, BISD 2S/63.

[178] Adopted on 20 December 1954, BISD 3S/127.

> such as a change from a specific to an *ad valorem* duty could in some circumstances adversely affect the value of the concessions to other contracting parties. Consequently, any conversion of specific into *ad valorem* rates of duty can be made only under some procedure for the modification of concessions".

6.27 The Working Party Report on the *Fourth Protocol of Rectifications and Modifications*[179] reached similar conclusions in 1955 :

> "1. One question could not be solved by the interested parties and was referred to the Working Party. Among the rectifications requested by the Austrian Government were those relating to Items 140 to 144 of the Austrian Tariff which were being made under the authority of the Note to these items included in the Austrian Schedule XXXII which granted the Austrian Government freedom to change the specific into *ad valorem* rates. The Austrian Government felt that it would not be impairing the value of the concessions if it retained beside the *ad valorem* duty the old specific rate as a minimum rate.
>
> 2. *The Working Party took the view that such changes would constitute modifications of Austria's obligations and that it could not recommend their acceptance as rectifications*. Such modifications could only be inserted in a protocol of rectifications and modifications after negotiations authorized by the CONTRACTING PARTIES in accordance with the proper procedures. The Austrian delegation, therefore, did not further insist on the insertion in the Fourth Protocol of Rectifications and Modifications of the specific minimum rates in Items 140 to 144". (Emphasis added)

6.28 In 1984, the report of the *Panel on Newsprint*[180] described GATT practice as follows:

> "50. [...] [U]nder longstanding GATT practice, *even purely formal changes in the tariff schedule of a contracting party*, which may not affect the GATT rights of other countries, *such as* the conversion of a specific duty to an *ad valorem* duty without an increase in the protective effect of the tariff rate in question, have been considered to require negotiations". (Emphasis added)

6.29 The most recent panel report to consider this issue, *Bananas II*,[181] concluded as follows:

---

[179] Adopted on 3 March 1955, BISD 3S/130.

[180] Adopted on 20 November 1984, BISD 31S/114.

[181] Panel Report on *EEC - Import Regime for Bananas*, DS/38/R, 11 February 1994, not adopted (*Bananas II*). Although the Panel Report on *Bananas II* was never adopted, the Appellate Body stated clearly, in its Report on *Japan - Taxes on Alcoholic Beverages* at p.15, that although they

"134. [...]The Panel then considered whether the introduction of a specific tariff for bananas in place of the *ad valorem* tariff provided for in its Schedule constituted 'treatment no less favourable' in terms of Article II. The Panel observed that while the bound *ad valorem* tariff was related to the value of bananas, the new specific tariff was based on the weight of bananas. Any change in the value of bananas per ton therefore led to a change in the *ad valorem* equivalent of the specific tariff. Since the value of bananas was unpredictable, the *ad valorem* equivalent of the specific tariff could also not be foreseen. The Panel noted in this context that the *ad valorem* equivalent of the 850 ECUs per ton specific tariff on bananas presently exceeded by far 20 per cent *ad valorem*. As to the 100 ECUs per ton specific tariff, the Panel also noted that the EEC had neither argued nor submitted any evidence that this tariff could never exceed 20 per cent *ad valorem*; according to the complainants, the 100 ECUs per ton specific tariff had already exceeded the equivalent of the bound 20 per cent *ad valorem* tariff after 1 July 1993. The Panel consequently found that the new specific tariffs led to the levying of a duty on imports of bananas whose *ad valorem* equivalent was, either actually or potentially, higher than 20 per cent *ad valorem*.

135. The Panel considered that the actual levying of a duty in excess of the bound rate clearly constituted a treatment of bananas less favourable than that provided for in the EEC's Schedule of Concessions. The Panel then proceeded to examine whether also the mere possibility that the specific tariff rate applied by the EEC might be higher than the corresponding bound *ad valorem* rate, rendered it inconsistent with Article II. *The Panel recalled the importance of security and predictability in the application of tariffs bindings. It noted that previous panels and working parties had emphasized that tariff bindings justify reasonable expectations about market access and conditions of competition. The CONTRACTING PARTIES had consistently found that a change from a bound specific to an ad valorem rate was a modification of the concession* [...] . The Panel [...] concluded that, in determining whether treatment accorded by a tariff measure was no less favourable than that provided for in the Schedule, it had to take into account not only the actual consequences of that measure for present imports but also its effects on possible future imports. *This followed from the principle recognized by many previous panels that*

---

have no legal status, the reasoning of an unadopted panel report can provide useful guidance to a panel and be, therefore, relevant. In this context we consider the reasoning of the panel in *Bananas II* to be relevant and useful to the present dispute.

> *the provisions of the General Agreement serve not only to protect actual trade flows but also to create predictability for future trade*". (Emphasis added)

6.30 The *Bananas II* panel report clearly recognizes the past GATT practice and can be read as concluding that the imposition of specific duties when only *ad valorem* duties are bound is sufficient to establish a violation of Article II.

6.31 We note that the past GATT practice is clear: a situation whereby a contracting party applies one type of duties while its Schedule refers to bindings of another type of duties constitutes a violation of Article II of GATT, without any obligation for the complaining party to submit further evidence that such variance leads to an effective breach of bindings. The fact that Argentina claims that it is simply following its past practice of using specific duties would not seem to be relevant, since it made *ad valorem* tariff concessions on the products in question and thus created an obligation for itself to impose such type of duties. As a guarantee for predictability and to ensure the full respect of the negotiations under Article II, GATT practice has generally required that once a Member has indicated the type(s) of duties in specifying its bound rate, it must apply such type(s) of duties. Accordingly, faced with such a variance in the type duties applied by Argentina from that reflected in its Schedule, we consider that we do not have to examine the effects of that variance on possible future imports. Indeed, such a variance undermines the stability and predictability of Members' Schedules.

6.32 We, therefore, find that Argentina, in using a system of specific minimum tariffs although it has bound its tariffs at *ad valorem* rates only, is violating the provisions of Article II of GATT and that the United States does not have to provide further evidence that the resultant duties exceed the bound tariff rate. Such a variance between Argentina's Schedule and its applied tariffs constitutes a less favourable treatment to the commerce of the other Members than that provided for in Argentina's Schedule, contrary to the provisions of Article II of GATT.

2. The Application by Argentina of Specific Minimum Duties

6.33 The United States also claims that the system of minimum specific duties applied by Argentina will necessarily lead to, and in fact has led to, the imposition of duties in excess of the tariff rate of 35 per cent *ad valorem* bound by Argentina pursuant to Article II of GATT. The US submission on those claims can be divided into three parts:

- First, the United States argues that the way the minimum specific duty system is implemented necessarily leads to breaches of Argentina's bindings.
- Second, the United States submits a series of tables and charts to demonstrate that, based on the average transaction value of imports and the average level of duties collected, duties well above the 35

per cent *ad valorem* of the import price have been collected by Argentina on many items.

- Third, the United States submits a series of customs documents identifying examples where, it submits, specific duties in excess of 35 per cent *ad valorem* were imposed and paid by importers.

Argentina contests the authenticity and the relevance of the evidence, and the arguments submitted by the United States.

(a) Burden of Proof and Nature of the Evidence Required

6.34 Before we look at the parties' arguments and evidence, we address the issue of the burden of proof and the nature of the evidence required in GATT/WTO panel proceedings. As noted above, Argentina has objected to much of the evidence submitted by the United States.

6.35 Concerning the issue of what one may call the "burden of proof", the Appellate Body has confirmed the GATT practice whereby

a) it is for the complaining party to establish the violation it alleges;

b) it is for the party invoking an exception or an affirmative defense to prove that the conditions contained therein are met; and

c) it is for the party asserting a fact to prove it.

6.36 In the *Shirts and Blouses*[182] case, the Appellate Body stated:

> "We agree with the Panel that it was up to India to present evidence and argument sufficient to establish a presumption that the transitional safeguard determination made by the United States was inconsistent with its obligations under Article 6 of the ATC. With this presumption thus established, it was then up to the United States to bring evidence and argument to rebut the presumption".

6.37 We consider that when the Appellate Body refers to the obligation of the complainant party to provide sufficient evidence to establish a "presumption", it refers to two aspects: the procedural aspect, i.e., the obligation for the complainant to present the evidence first, but also to the nature of evidence needed. In the present case, we consider that it was for the United States to raise a presumption that Argentina did violate the provisions of Article II of GATT. Then, it is for Argentina to provide sufficient evidence to rebut the said presumption. When, however, Argentina is claiming a specific affirmative defense, such that its national challenge procedure can be used to correct any alleged violation of GATT rules, it is for Argentina to raise first a presumption that such system operates in a way that there is, in effect, no infringement of GATT/WTO rules.

[182] Appellate Body Report, p. 13.

6.38 The concept of "presumption" may need some elaboration. A presumption is an inference in favour of a particular fact and would also refer to a conclusion reached in the absence of direct evidence.[183]

6.39 For international disputes it seems normal that tribunals, in evaluating claims, are given considerable flexibility. Inference (or judicial presumption) is a useful means at the disposal of international tribunals for evaluating claims. In situations where direct evidence is not available, relying on inferences drawn from relevant facts of each case facilitates the duty of international tribunals in determining whether or not the burden of proof has been met. It would therefore appear to be the prerogative of an international tribunal, in each given case, to determine whether applicable and unrebutted inferences are sufficient for satisfying the burden of proof. In this respect, the International Court of Justice, in some cases, found it difficult to assert stringent rules of evidence.[184]

6.40 Another incidental rule to the burden of proof is the requirement for collaboration of the parties in the presentation of the facts and evidence to the panel and especially the role of the respondent in that process. It is often said that the idea of peaceful settlement of disputes before international tribunals is largely based on the premise of co-operation of the litigating parties. In this context the most important result of the rule of collaboration appears to be that the adversary is obligated to provide the tribunal with relevant documents which are in its sole possession. This obligation does not arise until the claimant has done its best to secure evidence and has actually produced some *prima facie* evidence in support of its case. It should be stressed, however, that "'discovery' of documents, in its common-law system sense, is not available in international procedures".[185] We shall, therefore, follow these general rules when addressing, for instance, the request of the United States to Argentina for production of documents and the fact that Argentina did not do so.

(b) Minimum Specific Duties Necessarily Lead to Breaches of Argentina's Bindings

6.41 The United States submits that the way the minimum specific duties were initially determined by Argentina, i.e. on a "representative international price" based essentially on the US market price, will always lead to breaches of the bound tariff rate of 35 per cent for those exports which are priced sufficiently

---

[183] This would appear to be in conformity with the ordinary meaning of the words. See *Black's Law Dictionary*, 6th Edition, West Publishing (1991); Raymond Guillien and Jean Vincent, *Lexique de termes juridiques*, Dalloz (1981); and other similar dictionaries.

[184] See Keith Highet,"Evidence and Proof of Facts" in *The International Court of Justice at a Crossroads*, Transnational Publishers, Inc. (1987), p. 355 and Mojtaba Kazazi, *Burden of Proof and Related Issues*, Kluwer (1996).

[185] See Mojtaba Kazazi, Op. Cit. and, for further discussions on the rule of collaboration, George Scelle, *Yearbook of International Law Commission* (1950), vol.II, p.134 and other references in footnote 184 above.

below such average price. The United States submits the example of soccer shoes which are subject to a specific minimum duty of US$3.50 and an applied *ad valorem* duty of 20 per cent. For shoes imported at a value of US$5.00, the minimum specific duty assessed of US$3.50 represents a duty of 70 per cent *ad valorem*. Indeed, all shoes imported at a value below US$10.00 would be subject to an *ad valorem* duty above 35 per cent[186]. In other words, every time a good is imported at a price below the "representative international price", the specific duty - which is set on the basis of what Argentina thought the "price should be" and, as argued by Argentina, to counteract the problem of underpriced imports - would be superior to the normally applicable *ad valorem* duty, and possibly above the bound rate of 35 per cent *ad valorem*. For the United States, the purpose of such minimum specific duty scheme is to impose duties in excess of the 35 per cent *ad valorem* collected on the effective import price because, allegedly, goods are often imported into Argentina at prices below the representative international price so that the bound rate of 35 per cent was not sufficient. The United States further argues that for at least 32 HS headings, the specific duty was set at a rate even greater than 35 per cent of the so-called "representative international price" and referred the Panel to its chart showing on the basis of calculations made by Argentina, the above mentioned instances of violations[187]. Later the United States submitted an additional list of 104 categories of HS lines which demonstrated that the *ad valorem* equivalents of the specific duties, even when applied on US export prices, were above 35 per cent.[188]

6.42 Argentina's response is three-fold. First, it argues that the minimum specific duty was always set so as to be below 35 per cent *ad valorem* of the representative international price of any such item. Thus, if imports were priced at the representative international price, there would be no problems. Second, for Argentina, the US allegations are too general, hypothetical and theoretical and, therefore, not relevant and that the Panel should not consider such "hypothetical" situations without evidence of specific transactions where breaches occurred, since otherwise the dispute settlement system would be abused with frivolous claims. For Argentina, a potential violation would constitute an infringement only if trade was affected and refers the Panel to the *Tobacco*[189] case where, according to Argentina, the panel refused to sanction mere possibility of violations. Third, Argentina argues that, because of its Constitution under which international law is supreme and overrides any domestic law, in the hypothetical case in which a customs official would make a mistake and require the payment of a duty above 35 per cent, the importer has access to a domestic mechanism to challenge such

[186] See paras. 3.113 and 3.117 of the Descriptive Part.
[187] See para. 3.110 of the Descriptive Part.
[188] See para. 3.168 of the Descriptive Part.
[189] Panel Report on *United States - Measures Affecting the Importation and Internal Sale of Tobacco*, adopted on 4 October 1994, DS44/R.

customs determination. We shall return to this last defense raised by Argentina in Section 3 below.

6.43 We understand that the specific duties were set based on representative international prices. In these circumstances, when the specific duties are set so as to be equivalent to a 35 per cent *ad valorem* rate, it is certain that every time a good is imported at a transaction value below the representative international price, the specific duty level will be more than 35 per cent *ad valorem* of the transaction value. In the case of specific duties set so as to be equivalent to a tariff rate of less than 35 per cent, if a good is imported at a transaction value sufficiently below the representative international price used to set the duty, the bound rate of 35 per cent *ad valorem* will also be exceeded. For example, if the representative international price of a product is US$100.00 and the specific duty is set at US$20.00 to reflect an *ad valorem* equivalent of 20 per cent, if the product is imported at a price below US$57.00, the effective *ad valorem* rate will always exceed 35 per cent. Thus, in many cases, it seems clear that the specific duties at issue will necessarily result in a duty in excess of the 35 per cent bound rate when the customs value of a product is below the representative international price for such product.

6.44 We note that customs duties are normally to be imposed on the transaction value of imported goods as defined in the Agreement on the Implementation of Article VII of GATT 1994 (“Customs Valuation Agreement"). The transaction value is defined as "the price actually paid or payable for the goods when sold for export to the country of importation". Obviously, if the customs value declared by the importer does not represent the price actually paid, the Argentine authorities may take action to counteract a false declaration through, for example, revisions of the customs value declared in specific cases and even criminal prosecutions. However, neither the Customs Valuation Agreement nor any other provision of the WTO Agreement allows the breach of tariff bindings made under Article II of GATT on the grounds of a general suspicion that declared customs values are sometimes understated. We note, therefore, that mechanisms to counteract alleged underpricing[190] practices are not justifications for Article II violation.

6.45 In respect of the Argentine argument that the US claim should not be considered because it addresses only a potential violation - in support of which it refers to the *Tobacco* panel report - we note that the Argentine measures, the specific duties, are mandatory measures. Argentina admits that its customs officials are obligated to collect the specific duties on all imports. GATT/WTO case law is clear in that a mandatory measure can be brought before a panel, even if such

[190] Throughout the panel process, the terms "underpricing" and "underinvoicing" have been used interchangeably. In the present Panel Report we shall refer to "underpricing" without prejudice to the parties’ rights and obligations and without addressing any legal distinctions between the two terms.

an adopted measure is not yet in effect, and independently of the absence of trade effect of such measure for the complaining party:

> "[T]he very existence of mandatory legislation providing for an internal tax, without it being applied to a particular imported product, should be regarded as falling within the scope of Article III:2, first sentence".[191]

We are also of the view that the *Tobacco* panel report merely confirms this principle.

6.46 Moreover, in *Bananas III*[192], the Appellate Body confirmed that the principles developed in *Superfund*[193] were still much applicable to WTO disputes and that any measure which changes the competitive relationship of Members nullifies any such Members' benefits under the WTO Agreement.

> "Article III:2, first sentence, cannot be interpreted to protect expectations on export volumes; it protects expectations on the competitive relationship between imported and domestic products. A change in the competitive relationship contrary to that provision must consequently be regarded *ipso facto* as a nullification or impairment of benefits accruing under the General Agreement".[194]

We consider that this principle is also appropriate when dealing with the application of the obligations contained in Article II of GATT which requires a "treatment no less favourable than that" provided in a Member's Schedule. In the present dispute we consider that the competitive relationship of the parties was changed unilaterally by Argentina because its mandatory measure clearly has the potential to violate its bindings, thus undermining the security and the predictability of the WTO system.

6.47 We find, therefore, that the United States has established a presumption that the very nature of the minimum specific duty system maintained by Argentina violates the provisions of Article II of GATT and that, as shown above, this presumption has not been rebutted by Argentina.

(c) Evidence Based on Average Calculations

6.48 The United States filed various charts and tables in an effort to prove that based on the average import price of certain products in relation with the total amount of duties collected, one can only conclude that, on many occasions, duties above 35 per cent *ad valorem* must have had been collected. More specifically, the United States submitted:

---

[191] Panel Report on *United States - Taxes on Petroleum and Certain Imported Substances*, adopted on 17 June 1987, BISD 34S/136, para. 5.2.2.
[192] *Bananas III*, Appellate Body Report, Op. Cit., p. 106, para. 252.
[193] *Superfund*, Op.Cit., para 5.1.9.
[194] *Ibid.*

a) A first set of two charts which identify 118 HS categories of textiles and apparel in which Argentina's specific duties, on average, are greater than 35 per cent *ad valorem*. The United States mentions that it requested from Argentina the data on which the charts are based for the purpose of performing those calculations. The listed specific duties constitute more than 35 per cent of the average of transaction prices of merchandise imported in each category. The United States submits that the exhibit makes plain that, at the least, all merchandise having a lower actual value than the average are subject to duties above 35 per cent *ad valorem*. The data was then broken down into product sectors and demonstrated graphically in another exhibit. For the United States, that exhibit reflects how high, in *ad valorem* terms, Argentina's specific duties are with respect to a variety of textile and apparel groupings, ranging on average from 40.9 per cent to 56.2 per cent. The United States also adjusted its calculations contained in these two first exhibits to take into account a new Argentine Resolution, No. 597/97, which provides five stages of modifications of specific duties in certain categories. Applying the Argentine data to the new duties, the United States submits that the duties collected are still in excess of 35 per cent, on average, with respect to 72 line items.

b) A second set of tables contains calculations performed by the United States from data that had been provided by Argentina to the European Communities during their consultations. For the United States, the information contained in that document is particularly reliable, since it was created by Argentine officials who used Argentine customs data to calculate the *ad valorem* equivalents for 35 textile line items. The document consists of four pages and covers four different types of information: EC imports to Argentina in 1995; EC imports in the first seven months of 1996; all other imports during 1995; and all other imports during the first seven months of 1996. The document identifies, for each line item the total kilograms of textiles imported, their total value, the average c.i.f. value, the specific duties charged, and the *ad valorem* equivalent. Argentina's calculations show that for 4 out of the 35 line items, the EC imports during 1995 and 1996 exceeded 35 per cent *ad valorem.* For the rest of the world, the bound rate exceeds on average in 1996 for 22 out of the 35 textile and clothing categories and, for 26 out of 35 for 1995. Many of the average percentages for the rest of the world for 1995 and 1996 are well over 50 per cent *ad valorem*. Since the prices of products within each of the 35 HS tariff headings vary, some imports are above and some were below the average prices. However, given the large number of HS categories with an average greater than 50 per cent, the United States submits that there necessarily are many individual transactions well above 35 per cent *ad valorem*.

6.49 Argentina argues that as these tables are based on averages they do not constitute evidence of effective transactions. More specifically, the main counter-

argument that Argentina raises against the probative value of the first set of charts and tables is that they are based on data provided to the United States for another purpose: they were given so that the United States would realise the discrepancy between Argentine import prices and US export prices for the same items, which suggests serious underpricing. Another list was submitted to the United States so that it could note the minor trade importance of this issue for US textiles exports. These data were not supplied in order for the United States to determine the average duties collected on imports and such data could not be used for the latter purpose. Argentina also contests the probative value of such calculations because of unacceptable margins of error based on the fact that the data were rounded up to the nearest thousand, a claim contested by the United States, which points out that the numbers were rounded to tens or hundreds of dollars and that such rounding up does not make any difference for transactions worth more than US$10,000. Regarding the second set of charts and tables, Argentina submits that they do not originate from Argentina and that such data was not provided to the EC during the consultations, and that it had specified during the consultations that these data were irrelevant for the purpose of assessing the level of duties imposed on imports.

6.50 Argentina also argues that since the United States based its calculations on net weight whereby Argentina's statistics had been established using gross weight, all the US calculations were erroneous. In response, the United States provided further tables where the levels of duties were readjusted to take into account distortions of two to fifteen per cent due to the difference between net and gross weight. These new tables showed that in many instances duties well above 35 per cent *ad valorem* were collected. The United States referred the Panel to the second set of charts and tables received from the EC and prepared by Argentina, which is based on net weight and therefore could be used to assess whether the specific duties collected on imports were effectively above the 35 per cent *ad valorem*. Finally, to the Argentine claim that Argentina did not keep "net" weight data, the United States filed a copy of the 1983 issue of the INDEC statistical yearbook which made clear that the Argentine authorities did collect net weight data. Argentina did not inform the Panel of any change in this regard.

6.51 As Argentina did not provide any affirmative evidence to the contrary, we consider that this US evidence provides reliable information that, on a tariff line basis, duties above the bound rate of 35 per cent *ad valorem* have been imposed. We agree that, if an average calculation shows duties above 35 per cent, this is evidence of a sufficient number of transactions which were subject to duties imposed above the 35 per cent *ad valorem*. The United States was able to demonstrate that Argentina had imposed and collected duties on the effective price of the import transactions at levels well above the bound rate of 35 per cent *ad valorem*. In our view, the fact that the data was prepared by Argentina for other purposes is not relevant and the United States responded adequately to Argentina's arguments questioning the data. Thus, the US evidence based on averages confirms our finding in paragraph 6.65.

(d) Evidence Based on Specific Transactions

6.52 At the first meeting of the Panel and following our request, the United States provided the Panel with nine (9) examples of transactions where it claimed that duties above 35 per cent *ad valorem* were collected on imports on textiles, apparel and footwear items. The arguments of the parties on these particular shipments are further detailed in paragraphs 3.169 and following of the Descriptive Part of the present Panel Report.

(1) A shipment on 9 May 1996 of U.S. carpets in HS category 5703.20 with a c.i.f. value of US$56,271.90, i.e., the imposition of specific duties of US$20,531, or a 36 per cent *ad valorem* equivalent.

(2) Imports on 4 April 1996 of three types of U.S. carpets in HS Category 5703.30, for which the imposition of specific duties resulted in the payment of duties of 40, 60 and 67 per cent *ad valorem*.

(3) Footwear imports produced in Indonesia indicating a total c.i.f. value of US$15,722.53 and a total specific duty of US$10,560.00, i.e. the specific duties constituted an *ad valorem* equivalent of 67 per cent.

(4) Footwear imports produced in Indonesia indicating a total c.i.f. value of US$23,046.20 and a total specific duty of US$14,476.00, i.e. the specific duties constituted an *ad valorem* equivalent of 63 per cent.

(5) Footwear imports produced in Indonesia indicating a total c.i.f. value of US$7,444.33 and a total specific duty of US$4,809.60, i.e. the specific duties constituted an *ad valorem* equivalent of 65 per cent.

(6) Footwear imports produced in Indonesia indicating a total c.i.f. value of US$94,846.13 and a total specific duty of US$56,909.70, i.e.the specific duties constituted an *ad valorem* equivalent of 60 per cent.

(7) Footwear imports produced in Indonesia indicating a total c.i.f. value of US$30,690.17 and a total specific duty of US$19,576.20, i.e.the specific duties constituted an *ad valorem* equivalent of 64 per cent.

(8) Woven cotton fabric imports indicating a total c.i.f. value of US$19,384.01 and a total specific duty of US$7,087.61, i.e.the specific duties constituted an *ad valorem* equivalent of 37 per cent.

(9) A shipment of U.S. carpet resulted in payment of specific duties of US$1775.00 on a c.i.f. value of US$2811.58, i.e. the imposition of the specific duties resulted in a duty equivalent to 63 per cent *ad valorem.*

6.53 Argentina challenges the validity of these invoices because the name of the importer and all relevant data that could help identifying the importer or the exporter were deleted. The US response is that it has to protect the confidentiality of the persons involved in these transactions. Argentina claims that this information would be very useful in its attempt to deal with the immense import underpricing problem it faces. In this context, Argentina suggests that the difference between the US average export prices and the specific invoice prices for some of these items was such that it affected the probative value of the US evidence. For these imports, Argentina also argues that all invoices related to footwear items

should be excluded if the Panel does not review the specific duties imposed on footwear items. Argentina also opposes consideration of the imports from Indonesia, stating that only imports from the United States are relevant to the present case. On the ninth example, Argentina submits that the amount is very small, and emphasizes that the transaction value is said to be US$1.90 although in 1995, the year of the transaction, the average price for exports from the United States to Argentina in the same tariff heading had a unit value of US$2.79. Finally, Argentina generally argues that the evidence submitted by the United States is not the best evidence, and, therefore, is not reliable. However, we note that Argentina does not challenge the accuracy of the amount of duties imposed.

6.54 At the end of the first meeting of the Panel, the United States argued that the best evidence was in possession of Argentina and therefore requested Argentina to produce all relevant customs forms involving imports in HS line-items 5407.81 (woven synthetic fibre fabric), 5703.20 (carpets), and 6110.30 (man-made fibre sweaters) for the period January-September 1996. The United States said that it chose these three categories in part because Argentine customs data showed that the average duty paid for these three groups of imports from the United States was 99, 43 and 56 per cent, respectively, during the period January-July 1996. Argentina did not produce these documents.

6.55 Just a few days before the second hearing of the Panel, the United States sent to Argentina some 90 additional invoices and customs documents as further detailed in paragraph 3.179 of the Descriptive Part of this panel report. The documents purport to show examples in which Argentina applied duties in excess of its 35 per cent *ad valorem* tariff binding. At the beginning of the second hearing Argentina requested the Panel to disregard this evidence as untimely. We note that the rules of procedures of panels do not prohibit the practice of submitting additional evidence after the first hearing of the Panel. Until the WTO Members agree on different and more specific rules on this regard, our main concern is to ensure that "due process" is respected and that all parties to a dispute are given all the opportunities to defend their position to the fullest extent possible. In light of the difficulties faced by Argentina in responding to this evidence on such a short notice, we decided to accept this additional evidence on the understanding that Argentina would have a period of two weeks to provide further comments on these additional invoices and customs documents. Argentina informed the Panel that it would not be submitting any further comment.

6.56 The United States submitted additional evidence of invoices of shipments during 1996 and 1997 which involved seventy-eight instances where Argentina applied duties in excess of 35 per cent *ad valorem*. The United States used one of these invoices[195] to demonstrate its points but argued that all other invoices were similar and added that if requested it would provide additional comment on the other invoices.

[195] See para. 3.179 and following of the Descriptive Part.

6.57 Argentina raises a series of objections to this evidence:

- most of these invoices concern import transactions for which customs clearance was carried out manually; consequently these invoices suffer from a number of formal defects which ultimately invalidate the substantive arguments they are intended to support;
- most of these invoices represent only part of a larger shipment for which the customs documentation has not been supplied.
- concerning the specific invoice used by the United States during its demonstration, Argentina argued that the legal basis indicated for determining the *ad valorem* duty applied to the goods and the legal basis on which the three per cent statistical tax was levied were erroneous;
- the values declared are considerably lower than the average export prices of like goods originating in the United States in 1996;
- the alleged importer's registration number and tax identification number (CUIT) as well as the import registration number, and the name and registration number of the customs agent, had been shaded out;
- the goods concerned are of Italian origin in all cases but one;
- there is no receipt from the *Banco de la Nación* of payment of duties which represents the last step in the customs clearance procedure for imported goods;
- there is no evidence of import duties actually paid to Argentine Customs by importers;
- all of the transactions occurred in 1997 except one.

We note that Argentina does not deny that the amounts of duties so indicated were those effectively imposed, it simply claims that it was for the United States to prove that full payment was made to the Customs Authorities.

6.58 We do not consider that the fact that the United States submitted copies of customs documents affects their probative value. The United States did try to obtain the original copies in Argentina's possession. Before an international tribunal, parties do have a duty to collaborate in doing their best to submit to the adjudicatory body all the evidence in their possession. In the absence of the originals, and after careful examination and consideration of the evidence, we consider that the copies submitted by the United States constitute sufficient evidence to allow us to make the conclusions we have reached.

6.59 Argentina claims that it is facing a serious problem of frequent underpriced imports and that it needs the names of the parties involved in the said transactions in order to try to defeat such illegal practices. We note the difficulties faced by Argentina but we must also limit ourselves to the claims presented to us. We also note that a claim of underpricing practices is not a legal defence to alleged violations of Article II of GATT. The WTO Agreement offers specific

means for the importing country to redress such practices. We note also that it is often the practice in disputes such as this one, for a party to protect commercial in-confidence information such as the names and other information of the private entities involved. Finally, after reviewing all the evidence and arguments of the parties, we consider that the underpricing arguments raised by Argentina (referred to in paragraph 6.53 above) do not affect the probative value of the US evidence.

6.60 Argentina claims that invoices representing imports from Indonesia and Italy are not admissible since the complainant in the present dispute is the United States. The issue before the Panel is whether Argentina's measures lead to the imposition of duties above its bound rate of 35 per cent *ad valorem*, irrespective of the source.

6.61 The fact that Argentina challenged the admissibility of the customs documentation submitted by the United States on the basis that some of the customs clearance were carried out manually, or that there were cases where the wrong resolution[196] was used and that many of the sets of documents were incomplete does not, in our view, affect the probative value of the evidence provided by the United States. Argentina did not question the rate of duty applicable and the way the amount of duties payable was calculated. Argentina also alluded to the possibility of fraud. Although the Panel understands the difficulties faced by Argentina, in a dispute over the application of Article II of GATT, these points made by Argentina are not relevant. Therefore, we consider, after review of all the evidence and arguments and the fact that Argentina did not present any convincing evidence to the contrary, that there is a presumption, within the meaning given to it by the Appellate Body, that these documents are official and reflect the amount of duties actually imposed. Moreover, we note that customs stamps and signatures can be found on many of these documents. Many of these stamps and signatures were from Argentine customs authorities and a number of these forms had a stamp "*Oficializado - Firma y Sello Despachante de Aduana*" on them.

6.62 Concerning Argentina's claim that there is no evidence of actual payment of the said duties, we recall that we are not faced with a domestic recourse for reimbursement of overpayment. The alleged violation, and the obligation under Article II, is to not impose duties above the bound rate and Argentina does not deny that for each of the 78 examples there is a reflection of the calculation of specific duties in excess of 35 per cent equivalent *ad valorem*.

6.63 Finally, Argentina raises the fact that most of the transactions referred to in the set of invoices submitted a few days before the second meeting of the

[196] We note also that the level of the specific duties imposed pursuant to the resolution in force at the time of the importation and that of the expired resolution referred to on the customs clearance were identical and that the amount of duties payable for this imported item under both resolutions were also identical.

Panel[197] relate to transactions that took place in 1997 implying that these should not be admissible since they took place after the consultations were initiated. In the present dispute, the purpose of the panel process is to try to understand the way the Argentine tariff system functions. The examination of, amongst other elements, some applications of this tariff system is done in this perspective. In our view, these 1997 transactions based on the resolutions and other legislation at issue, further confirm the evidence submitted by the United States for transactions that took place in the preceding years. This is also why we have looked at the invoices related to footwear imports before 14 February 1997. We recall that we are looking at specific transactions in order to assess whether the Argentine resolutions and regulations, as revealed in their application, are inconsistent with Article II of GATT. For this reason, we consider that these examples of 1997 transactions are relevant for our understanding of the effective functioning and application of the minimum specific duty system on textiles and apparel and constitute admissible and relevant evidence for the present dispute.

6.64 We consider, therefore, that Argentina has not rebutted the presumption raised by the United States to the effect that Argentine customs officials have imposed duties, which in many cases are well above 35 per cent *ad valorem*, contrary to Argentine tariff bindings and contrary to GATT Article II. Argentina's arguments do not affect the admissibility and reliability of the evidence submitted.

6.65 In the light of the foregoing, we find that the United States has provided sufficient evidence that Argentina has effectively imposed duties on imports of textiles and apparel above 35 per cent *ad valorem*, that indeed the total amount of duties collected annually on these items leads to the conclusion that duties above 35 per cent *ad valorem* on the average transaction value have been imposed on the same items, and that in any case, as we found in paragraph 6.47 above, the very nature of the minimum specific duty system imposed in Argentina on the items at issue will inevitably lead, in certain instances, to the imposition of duties above 35 per cent *ad valorem*. In addition, the fact that Argentina is using minimum specific duties while they bound their tariffs according to an *ad valorem* type of duties, is inconsistent with its Schedule and with the requirements of Article II of GATT. Therefore, we consider that minimum specific duties imposed by Argentina on textile and apparel imports constitute a treatment of those imports that is less favourable than that provided for in Argentina's Schedule and contrary to Article II of GATT.

3. The Domestic Challenge Procedure

6.66 Argentina denies the legitimacy of the US claims, but in the event that the Panel should agree with the United States in respect of those claims, Argentina

[197] See para. 3.179 of the Descriptive Part.

argues that its domestic challenge procedure is a defense against any claim that it has violated Article II of GATT. Argentina notes that under Article 75.22 of the Argentine Constitution, international law takes precedence over domestic legislation. Therefore, any judge in Argentina has the power to declare, at the request of an interested party, the unconstitutionality of any measure adopted in breach of rules contained in an international treaty, such as the WTO Agreement. Subsequent domestic law cannot annul an international treaty, as such law is lower in rank. Should an importer be victim of domestic legislation or regulations that would violate the provisions of the WTO Agreement, including Article II of GATT and the Argentina's Schedule, Argentina argues that the importer should simply trigger the domestic challenge procedure which is quick and free. Furthermore, all Argentine judges are obligated to recognise the supremacy of WTO rules over an inconsistent Argentine measure such as one imposing duties above the bound rate.

6.67 In our view, this argument has two main flaws. First, although under the Argentine Constitution the WTO Agreement takes precedence over any domestic regulations in Argentina, Argentina states that its customs officials have no discretion and must impose the minimum specific duties even if found to be above the bound rate of 35 per cent *ad valorem* and notwithstanding the fact that such imposition violates the WTO Agreement and the Argentine Constitution.

6.68 Second, Article II of GATT imposes an unconditional obligation on a WTO Member to offer to other Members treatment not less favourable than that provided for in its Schedule. A Member violates this obligation, regardless of whether that Member provides a remedy for such violation in its domestic legal system. Notwithstanding how efficient such domestic court system may be, until the court system acts the Member is in violation of its WTO obligations. Moreover, it is not certain that the violation will ever be corrected since such correction is conditional on a decision by the Argentine importer or the holder of the clearance documents to initiate a domestic action. The inevitable delay and uncertainty in such procedure are fundamentally at variance with the WTO principles and the aim of GATT/WTO tariff bindings which are to provide predictability and security for international trade.[198] We agree with the statement concerning the purpose of the commitments made in tariff bindings as stated in *Bananas II:*[199]

---

[198] There is a general rule of international law that a state cannot plead provisions of its own law (or deficiencies in that law) as a defence to a claim against it for an alleged breach of its obligations under international law. Thus, in the *Free Zones of Upper Savoy and the District of Gex*, the Permanent Court of International Justice said: "It is certain that France cannot rely on her own legislation to limit the scope of her international obligations". (1932, PCIJ, Series A/B, case No.46, p.167). A WTO Member cannot offer as a defence to a claim of violation of a WTO agreement, that its internal system provides for a remedy to such violation to certain individuals, either national or foreign, and that no violation of WTO has therefore taken place.

[199] *Bananas II*, Op. Cit., para. 6.29 of the present report.

> "135. The Panel recalled the importance of security and predictability in the application of tariffs bindings. It noted that previous panels and working parties had emphasized that tariff bindings justify reasonable expectations about market access and conditions of competition. [...] The Panel [...] concluded that, in determining whether treatment accorded by a tariff measure was no less favourable than that provided for in the Schedule, it had to take into account not only the actual consequences of that measure for present imports but also its effects on possible future imports. This followed from the principle recognized by many previous panels that the provisions of the General Agreement serve not only to protect actual trade flows but also to create predictability for future trade".

6.69 Consequently, we do not accept Argentina's defense that its national challenge process is such as to ensure that Argentina does not and will not violate its obligations pursuant to Article II of GATT.

C. The Statistical Tax

6.70 Argentina maintains an *ad valorem* tax of three per cent on imports, without a minimum or maximum charge, to cover the cost of providing the statistical service intended to provide a reliable basis for foreign trade operators.[200] According to Argentina, this service is not rendered to any individual importer, or to the specific importer associated with a particular operation, but to foreign trade operators in general and foreign trade as an activity per se.[201]

6.71 The United States claims that this statistical tax is in violation of Article VIII of GATT. Argentina responds that its statistical tax is permitted under Article VIII. For Argentina, Article VIII should permit the collection of costs not only for the services rendered to the individual importer for a given transaction but also for all costs (direct and indirect) incurred in providing the services. Argentina adds that this three per cent tax is bound in its GATT 1994 Tariff Schedule under the heading "Other Duties and Charges". Although it states that a similar tax has been in place since 1989[202], Argentina argues that this statistical tax is now part of an overall "package" of fiscal commitments it has undertaken with the International Monetary Fund ("IMF"). Consequently, Argentina argues that its obligations under Article VIII should be interpreted to take into account the existence of a potential conflict of rules which goes beyond the framework of a possible bilateral trade dispute.

6.72 This issue subsumes three questions:

---

[200] As further described in paras. 2.19-2.21 of the Descriptive Part.
[201] See para. 3.266 of the Descriptive Part.
[202] See para. 2.19 of the Descriptive Part.

a) Is an *ad valorem* statistical tax of three per cent imposed on imports compatible with Article VIII?

b) What effect, if any, does Argentina's relationship with the IMF have on the answers to the above question?

c) Does the fact that this tax was bound as such in Argentina's Schedule exempt Argentina from the requirements of Article VIII?

1. Article VIII of GATT

6.73 Paragraph 1(a) of Article VIII of GATT provides that

> "[a]ll fees and charges of whatever character [...] imposed by Members on or in connection with importation or exportation shall be limited in amount to the approximate cost of services rendered and shall not represent an indirect protection to domestic products or a taxation of imports or exports for fiscal purposes".

Article VIII:4(e) makes it clear that fees and charges relating to "statistical services" fall within the scope of Article VIII.

6.74 The meaning of Article VIII was examined in detail in the Panel Report on *United States - Customs Users Fee*.[203] The panel found that Article VIII's requirement that the charge be "limited in amount to the approximate cost of services rendered" is "actually a dual requirement, because the charge in question must first involve a'service' rendered, and then the level of the charge must not exceed the approximate cost of that'service'".[204] According to the panel report, the term "services rendered" means "services rendered to the individual importer in question".[205] In the present case Argentina states that the service is not rendered to the individual importer, or to the specific importer associated with a particular operation, but to foreign trade operators in general and foreign trade as an activity per se.

6.75 An *ad valorem* duty with no fixed maximum fee, by its very nature, is not "limited in amount to the approximate cost of services rendered". For example, high-price items necessarily will bear a much greater tax burden than low-price goods, yet the service accorded to both is essentially the same. An unlimited *ad valorem* charge on imported goods violates the provisions of Article VIII because such a charge cannot be related to the cost of the service rendered. For example, in the *Customs User Fee* report, the panel examined the consistency with Article VIII of 0.22 and 0.17 per cent *ad valorem* customs merchandise processing fees with no upper limits. The panel concluded that "the term 'cost of services rendered'. . . in Article VIII:1(a) must be interpreted to refer to the cost of the customs processing for the individual entry in question and accordingly

---

[203] Adopted on 2 February 1988, 35S/245.
[204] *Customs Users Fee*, Op. Cit., para. 69.
[205] *Ibid.*, para. 80.

that the *ad valorem* structure of the United States merchandise processing fee was inconsistent with Article VIII:1(a) to the extent that it caused fees to be levied in excess of such costs".[206]

6.76 The Report of the Working Party on *Accession of the Democratic Republic of the Congo*[207] is also relevant to the present dispute:

> "Members of the Working Party pointed out that the statistical tax of three per cent *ad valorem* applied by the Congolese authorities on imports was not commensurate with the service rendered and was contrary to the provisions of Article VIII:1(a). The representative of the Congo recognized that this tax exceeded the cost of the service, and explained that the surplus revenue from the tax would be employed toward improving the service. His authorities were prepared to consider the adjustment of the statistical tax, in the light of the provisions of Article VIII as soon as they were in a position to afford it. The Working Party took note of this statement and invited the Government of the Democratic Republic of the Congo to re-examine its present method of application of the statistical tax and to report to the CONTRACTING PARTIES on the possibilities of bringing the tax into line with the provisions of Article VIII:1(a)".

6.77 Argentina's statistical tax is levied on an *ad valorem* basis with no ceiling. As described in paragraph 6.70 above, Argentina's tax is clearly not related to the cost of a service rendered to the specific importers concerned. The tax as assessed on many goods is not in proportion to the cost of any service rendered. The tax purportedly raises revenue for the purpose of financing customs activities related to the registration, computing and data processing of information on both imports and exports. While the gathering of statistical information concerning imports may benefit traders in general, Article VIII bars the levying of any tax or charge on importers to support the related costs "for the individual entry in question" since it will also benefit exports and exporters.[208]

6.78 As to Argentina's argument that it was collecting this tax for "fiscal" purposes in the context of its undertakings with the IMF, we note that not only does Article VIII of GATT expressly prohibit such measures for fiscal purposes but that clearly a measure for fiscal purposes will normally lead to a situation where the tax results in charges being levied in excess of the approximate costs of the statistical services rendered.

6.79 In addition, although it does not argue that it is required to impose this specific tax in order to meet its commitments to the IMF, Argentina argues that the tax should be found to comply with Article VIII, if necessary through a less

---

[206] *Ibid.*, para. 86.
[207] Adopted on 29 June 1971, BISD 18S/89, para. 5.
[208] See *Customs User Fee*, Op. Cit., paras. 84-86.

strict application of the requirements of Article VIII of GATT than was adopted in the *Customs Users Fee*. We find no exception in the WTO Agreement that would excuse Argentina's compliance with the requirements of Article VIII of GATT. Moreover, we see nothing in the Agreement Between the IMF and the WTO[209], the Declaration on the Relationship of the World Trade Organization with the International Monetary Fund and the Declaration on the Contribution of the World Trade Organization to Achieving Greater Coherence in Global Economic Policymaking that suggests that we should interpret Article VIII as argued by Argentina.

6.80 Consequently, following the GATT practice on the subject matter, we conclude that Argentina's statistical tax of three per cent *ad valorem*, in its present form, is in violation of Article VIII:1(a) of GATT to the extent it results in charges being levied in excess of the approximate costs of the services rendered as well as being a measure designated for fiscal purposes.

2. Effect of Including Statistical Tax in Tariff Schedule

6.81 Argentina argues that its three per cent statistical tax was included in its Schedule LXIV and is therefore not in violation of GATT rules. The provisions of the WTO Understanding on the Interpretation of Article II:1(b) of GATT 1994, dealing with 'other duties and charges', make clear that including a charge in a schedule of concessions in no way immunizes that charge from challenge as a violation of an applicable GATT rule. The Understanding provides:

> "1. In order to ensure transparency of the legal rights and obligations deriving from paragraph 1(b) of Article II, the nature and level of any 'other duties or charges' levied on bound tariff items, as referred to in that provision, shall be recorded in the Schedules of concessions annexed to GATT 1994 against the tariff item to which they apply. It is understood that such recording does not change the legal character of 'other duties or charges'.
>
> [...]
>
> 5. The recording of 'other duties or charges' in the Schedules is without prejudice to their consistency with rights and obligations under GATT 1994 other than those affected by paragraph 4. All Members retain the right to challenge, at any time, the consistency of any 'other duty or charge' with such obligations.
>
> 6. For the purposes of this Understanding, the provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply".

[209] Annex I to WT/L/195, adopted by the General Council on 7, 8 and 13 November 1996.

This provision is consistent with GATT and WTO jurisprudence dealing with conflicts between non-tariff provisions included in the Member's Schedules and general GATT and WTO rules.[210]

6.82 Therefore, we consider that the fact that Argentina's statistical tax is included in its Schedule is not a defence to its inconsistency with the provisions of Article VIII of GATT.

6.83 Consequently, for all the reasons mentioned above, we find that the Argentine statistical tax of three per cent *ad valorem* is inconsistent with the provisions of Article VIII of GATT in that it is not "limited in amount to the approximate cost of services rendered".

D. Article 7 of the ATC

6.84 The United States claims that because Argentina has violated Articles II and VIII of GATT with respect to textiles and apparel, it has also violated Article 7 of the ATC. The United States claims that a violation of any provisions of any of the WTO agreements in the sector of textiles and apparel would necessarily constitute a violation of Article 7 of the ATC.

6.85 Argentina's response is two fold: First, Argentina argues that since it has not violated any provision of any of the WTO covered agreements, it cannot be said to violate Article 7 of the ATC; second, Argentina claims that the provisions of Article 7 are only applicable to the measures notified pursuant to Article 7. Since it has not notified and does not maintain any quantitative restrictions or non-tariff measures and it has respected its tariffs reduction commitments, Article 7 is not applicable.

6.86 The parties and third parties have entered into long and well-argued debates as to whether Article 7 covers only actions and obligations covered by the ATC, i.e., quantitative restrictions, or whether the purpose of Article 7 is to ensure that measures other than quantitative restrictions such as tariffs, non-tariff barriers, licensing provisions and intellectual property provisions are not used in a manner which undermines market access in the textile and apparel sector for all WTO Members.

6.87 We have decided to exercise judicial economy and not address the US claim related to the ATC. Such decision is consistent with the findings of the Appellate Body report in the *Shirts and Blouses* case.[211] We do not see how a finding on Article 7 of the ATC would help the parties to resolve their dispute. It would not provide Argentina with any further guidance as to how it should reform its measures found to be inconsistent with the provisions of Articles II and VIII of GATT. Indeed, even if we found that the Argentine measures also vio-

[210] See Panel Report on *United States - Restrictions on Imports of Sugar*, adopted on 22 June 1989, BISD 36S/331 and *Bananas III*, Op. Cit.
[211] *Shirts and Blouses*, Appellate Body Report, *op. cit*., DSR 1997:I, 323 at 338-341.

lated the provisions of Article 7 of the ATC, such finding would add nothing to the conclusions we reached concerning the violations of Articles II and VIII of GATT. Accordingly, we consider that a finding on Article 7 of the ATC is not necessary, nor useful for the present dispute.

VII. CONCLUSIONS

7.1 In the light of the findings above, we conclude that

(a) the minimum specific duties imposed by Argentina on textiles and apparel are inconsistent with the requirements of Article II of GATT;

(b) the statistical tax of three per cent *ad valorem* imposed by Argentina on imports is inconsistent with the requirements of Article VIII of GATT.

7.2 The Panel *recommends* that the Dispute Settlement Body request Argentina to bring its measures into conformity with its obligations under the WTO Agreement.