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Risk assessment in the international food safety policy arena
Can the multilateral institutions encourage unbiased outcomes?

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Abstract:

Two institutions provide multilateral venues for countries to discuss food safety measures at the international level: the Codex Alimentarius Commission (Codex) and the World Trade Organization. Both institutions encourage their members to base food safety standards on scientific evidence.

In this paper we provide a description of how food safety related scientific evidence is generated and how it is used in the context of risk assessment for international standard-setting at CODEX and in WTO trade disputes. In particular, we discuss the processes leading to policy conclusions on the basis of scientific evidence, with a focus on the interactions involved between private and public sector actors and those between "scientific experts" and others.

We identify weaknesses in the current institutional set-up and provide suggestions on how to improve the interaction between different players at the national and international level so as to strengthen the existing system and increase its cost efficiency.

Key words: Food safety standards, risk assessment, policy capture, Codex Alimentarius Commission, WTO.

JEL codes: **F13, Q16, Q18**

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Introduction

Governments implement food safety measures to control risks inherent in food consumption. National policies which regulate the supply of foods or ingredients to the domestic market are typically based upon product characteristics, including content of risky compounds. Given the global agro-food system, with its increasingly long international supply chains, government food regulations typically cover both food produced within the country and imported food. Because of these linkages between national food safety policy and trade, countries have found it useful to discuss food safety measures at the international level.

Two international institutions provide multilateral venues for such discussions: the Codex Alimentarius Commission (Codex) and the World Trade Organization (WTO). Each of these acknowledges the dual effects of food safety measures, however they have different mandates. Codex activities focus on the role of these measures in the protection of human health, while the WTO focuses on the trade effects of food safety measures. The link between the activities of these organizations is further strengthened by the fact that the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) in the WTO defines the Codex as the relevant standard-setting body for food safety. Because the SPS Agreement stresses the importance of risk assessments in determining whether a food safety measure complies with WTO obligations, the WTO is involved in the interpretation of risk assessment exercises and their results when trade disputes related to food safety measures arise among Members.

Countries have concerns that food safety restrictions on imported products may be implemented in order to protect domestic industry from foreign competition. The reliance in the SPS Agreement on scientific evidence to justify food safety measures that deviate from international standards reflects an attempt to make regulatory policies less vulnerable to political

or economic capture, particularly by import-competing firms. Yet, in practice, private producers are often placed at the centre of the initial stages of the process that leads to risk assessments. Interactions between private and public sector players, thus, appear to be inevitable. It is, therefore, crucial for the system to contain appropriate checks and balances in order to ensure that risk assessment and its interpretation are efficient and reliable.

This paper provides a description of how food-safety-related scientific evidence is generated and how it is used in the context of international standard-setting or trade disputes. Throughout the paper we analyse the mechanisms through which the current institutional relationship between Codex and WTO seeks to control for undesirable influences and we discuss ways to strengthen this control. We also examine whether the multilateral trading system effectively handles scientific evidence and risk assessment and we discuss ways to increase efficiency.

The structure of the remainder of the paper is as follows. In the next section, we provide theoretical background regarding private sector motivation to influence regulatory activities. This is followed by a Section where we describe how food safety risk is determined. In the discussion we pay attention to the role of value judgements at the different stages of risk assessment and thus the potential for private or public actors to influence decisions. Next we discuss how decisions are taken on how to handle risk at the so-called risk management stage and we have a closer look at the relationship between risk assessment and risk management. We then describe how risk assessment and risk management are dealt with in Codex with a particular emphasis on the respective roles of risk managers and risk assessors and the interactions between the two. This is followed by a discussion of how the WTO dispute settlement system handles the issue of risk assessment. A final section concludes.

Background

Food-safety characteristics represent what economists call "credence" characteristics in that consumers are unable to determine food safety characteristics themselves, often even after consumption.[1] In markets for credence goods, producers cannot be expected to give consumers all the information they require because producer and consumer interests do not coincide. Intervention of a third party, typically a government agency, can therefore be justified on efficiency grounds. Government regulatory interventions in these markets aim at providing consumers with the information they need to take appropriate consumption decisions.

[1] The term "credence goods" was first used by Darby and Karni (1973). See Tirole (1993) on the possible roles of private and public sector regulation in markets with information asymmetries.

Interventions can range from simple labelling requirements to outright bans of products considered dangerous. In deciding upon a measure, governments are expected to take the wellbeing (e.g. in terms of health and product prices) of consumers into account, but also the effect a measure potentially has on producer profits.

Whenever governments regulate, interest groups will be tempted to lobby and drive decisions in a direction most convenient for them. Economists have analysed the behaviour of lobbyists, in particular industry lobbies, and use the term "government capture" when referring to a situation where government decisions reflect the interests of particular lobbies rather than the interests of the country as a whole.[2] In the context of international trade and food regulation, government capture is typically perceived as involving import-competing companies asking the government to set standards higher than necessary. This is, arguably, reflected in the SPS Agreement that emphasizes the obligation of importing countries to justify their trade-distorting food regulations scientifically.

Sturm (2006) has shown that exporting companies also may have incentives to influence regulation. In particular, exporting companies are likely to lobby in favour of standards that are lower than the standards the government would set in the absence of private sector pressure. In Sturm's set-up interest groups lobby national institutions and goods that meet national standards can be exported freely. National regulatory policy therefore determines which goods can be exported. In practice, an international "regulator" for food safety issues exists in the form of Codex and the SPS Agreement encourages WTO Member to apply Codex standards. Based on Sturm's (2006) findings it may not be unreasonable to expect that exporters (and importers) try to lobby Codex and influence its decisions.

Codex standards are based on risk assessments by selected international experts who use scientific evidence collected from both public and private sector sources and from all over the world. Decisions based on these risk assessments are made by national delegations, composed of government representatives. Codex standards are thus likely to reflect both political and scientific components and we will delve deeper into the interactions between risk managers (policy makers) and risk assessors (scientific experts) later on in this paper. At this stage we

[2] Capture theory, for instance, posits that larger and older firms use regulation as a political substitute for economic competition, constructing entry barriers against smaller and newer competitors (Stigler, 1975)

only want to refer briefly to the possible implications of private sector involvement in the generation of scientific evidence used for food safety risk assessments.[3]

Private companies are often in a privileged position to influence product risk assessment by government agencies, because they generate and provide relevant scientific data and evidence for particular products of their interest. In particular, producers typically have privileged access to relevant scientific evidence on new food additives or food products. This is the case because they need to understand the characteristics of their products in order to reduce the probability of significant damage claims or reputation loss and thus manage risks which affect their expected profits.[4] A significant amount of scientific evidence relevant for food safety policy is, therefore, generated by producers themselves. For reasons of cost-efficiency it makes sense to use this evidence for public policy purposes.

Producers carry out relevant R&D in-house, as well as finance R&D conducted by independent agencies, like academic institutions. In recent years, ties between industry and academia have often been encouraged by governments in an attempt to increase the effectiveness of public R&D expenditure. There is by now a significant amount of evidence that R&D funding affects R&D processes and outcomes. Financial considerations may, for instance, affect the period during which certain tests are carried out. While long testing phases may provide important insights, they do not tend to give high returns (Waterton, 2005). Several studies of medical research have shown that published studies sponsored by private companies with a stake in the studies' outcome tend to yield pro-industry conclusions (Bekelman et al., 2003; Bekelman et al., 2003). Funding may also affect when research results are published (Krimsky, 2006).

Private sector funding supports a high proportion of the articles published in leading medical and scientific journals (Goozner, 2004) and the academic profession is well aware of a potential problem of conflict of interest. In recent years, many leading peer-reviewed academic journals have therefore adopted policies requiring disclosure of conflicts of interest. Conflict of interest policies also have been high on the agenda in standard-setting bodies. The discussion in the following sections highlights at which stages of the standard-setting process conflicts of interest may interfere with outcomes.

[3] See also Crawford-Brown et al. (2004) on the potential capture of scientific estimation of risk by policy interests.

[4] See WTO (2005) for a more detailed discussion on private sector incentives to control risk.

Risk assessment

Risk assessment identifies the product of the likelihood of the occurrence and the magnitude of the consequences of exposure to a hazard on human health (Fischer et al., 2005). It is often decomposed into four elements (Codex Alimentarius, 2007): hazard identification, hazard characterization, exposure assessment and risk characterization.

(a) Hazard identification and characterization

The first step in risk assessment is the identification of biological, chemical or physical agents, capable of causing adverse health effects and which may be present in a particular food or group of foods.[5] Once a hazard is identified, laboratory experiments evaluate the nature of the adverse human health impacts associated with particular levels of exposure to the identified hazard. This second step is typically referred to as hazard characterization.

When conducting experiments to characterize hazards, scientists choose the design of their experiments, e.g. regarding the level of exposure to be analyzed and the methodology which affect hazard characterization.[6] Experimental design can influence the results of hazard characterization studies. In order to test the effects of a chemical additive on human health, scientists may apply, for instance, short-term oral toxicity tests in rodents, *in vitro* digestibility tests or tests for chronic toxicity and reproductive performance by long-term feeding of the relevant additives to rodents. These different types of tests provide information of a very different nature, and involve different levels of costs and different time frames. Many examples exist of differences in scientific approach leading to differences in the characterization of a hazard. The diverging conclusions of US and Canadian authorities with respect to the safety of fish caught in the Great Lake have, for instance, been related to differences in the methodologies used to assess risk (Harrison and Holberg, 1994).

(b) Exposure assessment

Once the damage that a certain substance can produce is understood in a hypothetical population, exposure assessment provides information on the potential damage it may cause in specific populations. Since dietary intake typically differs across regions and even across countries, a population's mean or median exposure to a certain contaminant is first estimated. A possible next step is to identify individual foods or food groups that contribute significantly to

[5] Definition based on Codex definition (Codex Alimentarius, 2001)

[6] A full characterization of a hazard often requires results of several laboratory studies.

this exposure and to generate distribution curves that help risk managers to identify instances of particularly high concentration of the contaminant (WHO, 2000).

(c) Risk characterization

Hazard identification, hazard characterization, and exposure assessment are integrated in the so called "risk characterization" to estimate the probability of occurrence and severity of an adverse health effect. Scientists examine several studies of hazard identification and characterization at their disposal. They compare the methodologies and results of those individual studies and combine the insights gained with available information on exposure assessment in order to provide answers to the relevant risk management questions.

Typically risk assessors must choose how to characterize risks, despite gaps in scientific evidence (Kerr, 2003) and in these cases, risk assessors' value judgement is required. For example, when testing a new food additive there are large numbers of possible human subpopulations upon whom the drug can be tested, defined both by their genetic make up and the possible combinations of food and food additives they may be consuming. In most cases it would be prohibitively costly to conduct tests on all possible sub-populations. Choosing to make inferences from studies on one human subpopulation to another or from animal studies to human populations, involves a value judgment (FAO, 2003).

Risk Management

Once the risk inherent in a hazard has been assessed, a decision is needed on how to handle this risk. The process of weighing different policy alternatives that emerge as a possible consequence of the results from the risk assessment is called risk management. Risk managers (often policy makers) take into account existing risk assessments when considering which policy options to apply to reduce risk in the population. But to evaluate the implications of such policy, risk managers may need to go back to risk assessors, as the latter are better positioned to evaluate risk outcomes.

Given this complex relationship between risk management and risk assessment, the question has often been raised whether risk assessment and risk management *can* and *should* be functionally separated. It has been argued in the literature that public trust in food safety is instilled by the functional separation of components, particularly risk management and risk assessment (Fischer et al., 2005; Frewer and Salter, 2007). Indeed, national institutional set-ups frequently reflect a desire to create a clear separation between the assessment and the management stage. In the EU, for instance, responsibility for food risk assessment is institutionally placed within the European Food Safety Authority (EFSA), and food risk

management is institutionalised within the General Directorate for Health and Consumer Protection (Houghton et al., 2008). Yet, individual EU members have not introduced such a clear institutional separation.

One reason why the distinction between risk assessment and risk management may not be clear-cut, is that risk assessment is not *de facto* free of value-laden or political judgments (Cheyne, 2006). Another reason is that the same individuals in regulatory institutions may have responsibility for both assessment and management (e.g. Jensen et al., 2003 as cited in Houghton et al. 2008). Risk managers also often determine which hazard should be analysed and the hazard identification stage is, therefore, often directly influenced by risk managers. In principle, they also need to interact with risk assessors when evaluating different policy options.

Thus, risk characterization emanating from a risk assessment exercise is likely to be the outcome of a combination of scientific evidence and value judgements and it does intrinsically require the interaction between risk assessors and risk managers. Some have argued, therefore, that the functional separation between risk assessment and management creates the false impression that risk assessment is "neutral" (e.g. Jasanoff (1987)), and that it would be more appropriate to link the two stages more explicitly together (Walker, 2006).[7] In particular, it has been suggested that risk managers should explicitly shape the ways in which risk assessments are constructed and conducted and thus also take responsibility for at least some of the risk assessment value judgements that are implicit in risk assessors' deliberations. In other words, risk managers should determine and publish so-called "risk assessment policies", i.e. the guidelines that risk assessors should follow whenever they need to make value judgements.

Risk assessment and risk management in the Codex

The Codex, a joint body of the FAO and WHO, develops food standards, guidelines and related texts, such as codes of practice to protect health of the consumers and to ensure fair trade practices in the food trade. One of the consequences of the activities of Codex is that differences in the interpretation of scientific data available on consumer health protection are narrowed down, encouraging countries to choose convergent policies (Boutrif, 2003).

To examine the role of scientific evidence in the setting of international food safety standards, it is useful to understand the governance structures of Codex. All Codex member governments are represented at the meeting of the governing body, the so-called Codex

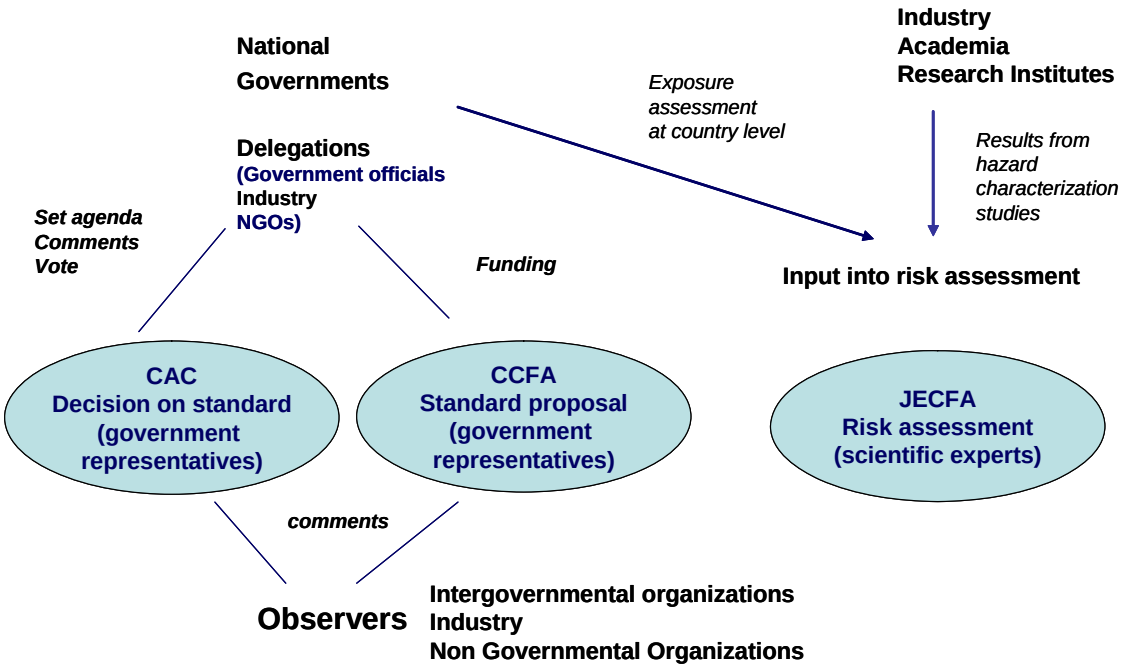
[7] Note in this context the WTO Appellate Body decision in the EC-Hormones dispute rejecting the distinction between risk assessment and risk management (Appellate Body Report, 1998).

Alimentarius Commission (CAC). This body meets every two years and has a range of responsibilities, including:

- setting up subsidiary bodies or subordinate working committees;
- reviewing and adopting Codex standards (each country has one vote);
- setting the agenda and future priorities for Codex.

National delegations may propose work on specific food safety issues to specific Codex Committees and deliberations within these Committees help to clarify the scope of the draft standard. In the case of food additives, for instance, the Commission will ask the Codex Committee on Food Additives (CCFA) to prepare a project proposal for the Executive Committee of the Commission to consider. The CCFA will in turn ask advice from the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA is primarily responsible for performing the risk assessments upon which CCFA and ultimately the Codex Commission base their risk management decisions. Chart 1 gives an overview of the functioning of the Codex standard-setting process in the case of food additives. The process is similar for other Codex areas of standard-setting (e.g. contaminants in foods or pesticide residues), but for ease of exposition we will focus in the remainder of this discussion on food additives.

Chart 1: The role of public and private sector actors in the Codex process



a) Setting the stage for risk assessment

The Codex Committee of Food Additives (CCFA) is responsible for the so-called "preliminary risk management activities" that include the determination of risk management priorities and the ranking of hazards for risk assessment. It then asks JECFA to conduct relevant risk assessments. The scope of JECFA risk assessments is thus determined by risk managers, i.e. representatives of national Codex delegations.

JECFA is expected to establish so-called Acceptable Daily Intakes (ADIs), i.e. the level of intake that is considered to be without any danger for human health. JECFA is also asked to provide exposure assessments, i.e. information on the likely intake of the relevant substances via food or exposure to other sources. On the basis of this information, CCFA proposes risk management recommendations to the CAC, typically in the form of "maximum use levels" for the relevant additives. Two questions are of interest in this context: how is the link between risk management options and risk assessment made and how many risk management options are analysed? The Codex Procedural Manual gives indications on both issues (Codex Alimentarius, 2007).

On the first issue the manual states: "Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options."[8] In other words, JECFA may evaluate the risk of different risk management options, but the range of options is determined by CCFA, i.e. by risk managers and thus policy makers. The question arises whether risk assessors could play a more important role in determining the range of possible policy options.[9] Risk assessors are in any case involved in the evaluation of policy options and their involvement in determining a possible policy basket could reduce the potential for capture at this stage of the regulatory process.

On the second issue, the manual foresees that a range of management options should be analysed. It states that "Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health"[10] and that "CCFA may also refer a range of risk management options, with a view towards obtaining JECFA's guidance on the attendant risks and the likely reductions associated with each option." In practice, CCFA has typically requested JECFA to compare only two - rather than a "range of"- policy options. This has, for instance, been the

[8] Codex (2007), p. 114, paragraph 16.

[9] We owe this idea to a suggestion made by Philippe Verger at the WTI workshop on "Food Safety Risk Assessment at the International Level" in Bern, October 3, 2007

[10] Codex (2007) pp. 116/117, paragraph 35.

case for aflatoxins in cereals, aflatoxin M1 in milk and ochratoxin A in cereals. JECFA reports are in these cases unlikely to contain full assessments of the risk implications of other possible risk management policies. Enlarging the range of policy options analysed by JECFA would increase costs, but it would provide policy makers with a more complete assessment of the risk implications of the policy basket at their disposal. Enlarging the scope of JECFA's analysis could also be useful from the point of view of potential WTO disputes on food safety standards as the discussion below will highlight.

b) Risk assessment in the case of food additives

JECFA meets once or twice a year to evaluate substances placed on its agenda. JECFA itself does not carry out any laboratory work and also does not commission work by others. Instead, a call for information, research data and studies on the substances to be reviewed precedes each meeting (Boutrif, 2003). JECFA thus mainly intervenes at the risk characterization stage of the risk assessment process and obtains most of the relevant information on hazard characterization and exposure assessment from external sources in response to its call for information. Manufacturers, for example, are expected to submit all relevant published and unpublished data. Governments, national and international organizations, research institutes, and universities may also submit data (JECFA, 2003). Summarized data are not considered to be sufficient for the full evaluation by the JECFA. Presumably this is one mechanism which shields experts groups from potential biased interpretation of the data by the sponsors.

On the basis of the information resulting from the "call", JECFA experts produce reviews and evaluations when sufficient and appropriate information is available to make an evaluation. Included in the review are data available in the open literature, from private studies, and the toxicological and specification data supplied by the sponsors of the substances. The JECFA's evaluation of food additives normally results in an estimate of the amount of the additive that can be ingested daily over a lifetime without appreciable health risk. Once it has been decided how much of a certain substance individuals can absorb, exposure assessment data are used to establish how much of that agent can be contained in different food types (Jukes, 2000).

One of the difficulties that the JECFA faces is that most of the time it is obliged to work on the basis of insufficient data from developing countries, in particular data on exposure (JECFA, 2005). It has therefore been recommended that FAO and WHO seek ways to make calls for data more widely known in developing countries and to directly contact governments and other potential data providers to facilitate the submission of data.

Participants in expert committees, such as the JECFA, are invited in their personal capacity (not as representatives of their respective governments or institutions) and are selected from among well-known scientists and experts (Boutrif, 2003). In this regard Codex expert groups differ from expert groups in other international standard setting bodies. In the International Organization for Standardization (ISO), for instance, technical work on standards takes place in so-called technical committees. Experts participating in these committees represent their "national bodies", the latter being national standard setting bodies affiliated to ISO (WTO, 2005; ISO, 2001). In industrialized countries the relevant national bodies often have the status of private non-profit organization that are to a significant extent financed by industry. In contrast to the situation in JECFA, expert links to the private sector are, thus, rather explicit in ISO technical committees and experts represent national institutions.[11]

The process of selection of JECFA experts is made according to specific rules and procedures set by Codex's Governing Bodies, including the need to take into account the geographic distribution of the origins of these experts and of the representation of the different schools of thoughts on the issues to be discussed. Both the FAO and the WHO establish rosters of experts from which individuals may be selected to serve as expert consultations. These rosters are based upon responses to calls for applications that describe the essential qualifications of the applicants, selection procedures for the roster and other relevant information.

Given the importance of expert input in the development of Codex standards, the way that scientific advice is collected, synthesized and incorporated will determine the neutrality, credibility and reliability of the standard-setting process. JECFA currently applies a conflict of interest policy in which invited experts are required, before participating in meetings, to declare any potential interests associated with the substances that will be evaluated through completion of a standard form adopted by FAO. Experts are asked to indicate in writing any potential conflict of interest on their part or their spouse that may affect their scientific independence.

c) Codex risk assessment: value judgments, co-ordination failures and replication of efforts

It has been pointed out above that the choice of methodology and data used for hazard characterization will affect the results. Researchers carrying out the actual laboratory studies influence, through their choices, the outcome of their analysis. JECFA risk assessment only relies on studies carried out by external laboratories. The scientific evidence used by JECFA,

[11] The German affiliate to ISO, the Deusche Institute für Normung (DIN), for instance, is a private group whose experts are often "on loan" from firms (Casella, 2001).

i.e. Codex, is therefore only as neutral as the evidence generated by R&D with private sector or national public sector funding.

The existing process of generating international risk assessment may also be prone to inefficiencies due to replication of efforts at different stages of the process or to lack of co-ordination. JECFA risk characterization is done on the basis of available hazard characterization studies. The more studies available, the better. Ideally, in those studies the different pieces of a puzzle would be analyzed and, when put together, they would provide a complete picture of the relevant hazard characteristics. But, in practice, hazard characterization studies are typically not coordinated with the aim of providing a picture that is as complete as possible. In particular, there is currently no significant co-ordination of this research effort at the international level. Without co-ordination it is unlikely that the maximum amount of knowledge valuable for risk assessment is obtained with any given level of input.

Replication of efforts may occur because steps are repeated at the national, regional and/or global level. The risk characterization step is based on the maximum available evidence from hazard characterization studies and on information on exposure assessment. It is currently often the case that risk characterization for a given country is carried out by national, regional and multilateral institutions. This is repetitive. International guidelines on how to do risk assessment exist and it would be more efficient to rely on one single level of (international) risk assessment for standard-setting at all levels.[12]

Other inefficiencies, or biases, can occur at the exposure assessment stage due to the specificity of the information needed. Risk characterization requires information on a population's exposure to a certain hazard and this information is often not available for developing countries. The relevant countries are therefore not in a position to carry out their own risk assessment and their level of exposure is not necessarily well reflected in the work done by the Codex.

d) Codex standard-setting: science and politics

In the Codex process, delegations that function as risk managers intervene at the beginning and the end of the standard-setting process. The Codex Alimentarius Commission - and thus the representation of member governments - decides, based on suggestions from the Codex Committees, on the content of the Codex agenda and determines future priorities. Since national delegations influence which hazards Codex discusses, national or regional interests

[12] Suggestion by Philippe Verger at the WTI workshop on "Food Safety Risk Assessment at the International Level" in Bern, October 3, 2007.

may play at least as important a role as public health considerations in determining the Codex agenda. Limitations to the Codex budget imply that the selection of substances for evaluation may require intense negotiation.[13] The overall outcome of this process is a negotiated outcome and thus the result of a mixture of opinions and perceptions of facts (Abdel Motaal, 2004). In this context it is interesting to note that countries with larger delegations often include representatives from industries that might be affected by particular Codex standards (Consumer International, 2000).

The reference in the SPS Agreement to Codex standards is thus in practice a reference to standards based both on science and politics. Codex is very well aware of this relationship between the two spheres and tries to clearly delineate this relationship. In its Procedural Manual, Codex indicates that "there should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest" (Codex Alimentarius, 2007). Nevertheless, Codex acknowledges in the same paragraph that “risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application”. The role of the interaction between risk managers and risk assessors appears to be particularly relevant when it comes to determining the basket of policy options to be analysed by risk assessors, as pointed out above.

The Codex also acknowledges that risk assessment involves value judgements and instructs CCFA to establish relevant risk policy guidelines in the context of its preliminary risk management activities. CCFAC, nowadays split into CCFA and CCCF (Codex Committee on Contaminants in Foods), has developed such guidelines, but it has been argued that the degree of compliance has been partial and fragmentary (Millstone et al., 2008).

Risk assessment in WTO Disputes

While the SPS Agreement acknowledges the right of Members to implement food safety measures which are more demanding than Codex standards, the SPS Agreement requires that

[13] Another reason to be concerned about Codex budgetary constraints is the increasing pace of innovation. In order for the Codex standards to remain validly based on current scientific knowledge, they must be routinely reviewed (Boutrif, 2003). Delays in updating standards at Codex increase the probabilities of disputes among WTO Members on SPS measures and thus the probability that the WTO dispute settlement system has to deal with new scientific evidence. The section on risk assessment in the WTO Agreements discusses why this is not a desirable outcome.

Members base these more stringent measures on science.[14] If other WTO Members challenge these more stringent measures through the WTO dispute settlement system, the Member applying the higher requirement would need to provide scientific justification for these measures. Thus, there is, inherent in the analysis of SPS disputes, the need for a framework for integrating science into the legal analysis of dispute cases.

The institutional framework of the WTO dispute settlement process will influence the interpretation of relevant science in the context of parties' claims in the dispute process. While the legal text of the SPS Agreement defines the obligations of importing countries in terms of justifying their trade-distorting SPS measures, the institutional mechanisms for introducing scientific analyses into the legal disputes will determine the extent of flexibility that importers have with respect to deviating from international standards. In this way, the dispute settlement process balances the opposing interests of importing and exporting countries. The obligation of importing countries to justify their domestic food safety measures scientifically may be moderated depending on the flexibility inherent in the standard of review. Over time the jurisprudence associated with the SPS Agreement has developed guidance regarding the role of science and risk assessments in interpreting Members' rights and obligations. The recent Appellate Body report on *Canada/U.S.- Continued Suspension* expands the jurisprudence on the SPS Agreement through its examination of 1) the selection and treatment of expert inputs into the dispute process and 2) the standard of review relevant for responding parties in defence of their choice of measure.

Expert selection and treatment of inputs from experts has been a component of all SPS disputes. Over the course of the first decade of the existence of the SPS Agreement, defending parties in SPS disputes have produced increasingly sophisticated risk assessments to support their positions. The demands on the Panels to be able to interpret these assessments, at least to be able to put the conclusions of the assessments in the context of their deliberations regarding legal rights and obligations, has increased proportionately. The text of the SPS Agreement

[14] To be more precise Article 3.3 of the SPS Agreement acknowledges that Members may introduce more stringent measures, 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 accordance with the relevant provisions of paragraphs 1 through 8 of Article 5". Article 5 of the Agreement sets out Members' obligations with respect to the assessment of risk and the determination of the appropriate level of sanitary or phytosanitary protection.

encourages Panels to call upon scientific experts to help with their deliberations and notes that the selection of experts should be carried out in consultation with the parties to the dispute. [15]

Typically, Panels start their selection process by soliciting suggestions of scientists from the international standard-setting bodies.[16] The list of proposed experts is then circulated to the parties for comment and the parties can state any compelling objections to a candidate. Where an insufficient pool of experts is identified, the parties may be invited to suggest potential experts. In practice it can be quite difficult for parties to achieve a consensus on the experts who should be invited to provide advice to the Panel. For instance, in the context of the disputes related to hormone-treated beef, scientists who had participated in JECFA risk assessment processes were apparently perceived to be biased in favour of the Codex standards. The EC also raised these types of concerns in the context of expert inputs in *Canada-US—Continued Suspension* from particular JECFA experts. The Appellate Body report *Canada-US—Continued Suspension* concluded that:

> In the consultations with experts, the Panel asked Drs. Boisseau and Boobis to evaluate the European Communities' risk assessment and they did so using JECFA's evaluations as a benchmark. This is problematic in this case because the European Communities' risk assessment called into question the validity of JECFA's evaluations and explicitly stated that it would not follow them. In the light of this, it was improper for the Panel to consult with Drs. Boisseau and Boobis, who were directly involved in JECFA's evaluations.
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> WTO Appellate Body, *Canada/US – Continued Suspension*

While allowing, or even requiring, the exclusion of particular experts with links to the Codex food safety evaluation process may be one way in which the WTO dispute system mitigates potential bias, the population of food safety risk assessors for particular compounds may be quite limited and eliminating experts who have worked within the Codex system could reduce the options to zero.

The Panel prepares specific questions for the experts and provides the parties with opportunity to comment on the proposed questions or suggest additional questions. Experts are

[15] Article 11.2 of the SPS Agreement notes that "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."

[16] In one case, EC-Hormones, the Parties to the dispute were each allowed to nominate one expert to be consulted by the Panel.

provided with relevant parts of the parties' submission on a confidential basis and are asked to respond to questions in writing. These written responses have been included in the reports of each of the six SPS disputes. Parties are also free to include their own scientific experts on their delegations and to submit scientific evidence produced by their own experts. The experts chosen by the Panel are invited to meet with the Panel and the parties to discuss their written responses and to provide further information. The possibility is given for parties to question the experts after the experts have provided their oral comments and responses to questions from the Panel. This type of questioning, while not exactly a process of cross examination as it would be conceived in a formal court setting, allows parties and panellists to check validity and competence of the experts.

Some authors (e.g., Pauwelyn 2002) have suggested that it would be more effective to have the scientific experts provide a consensual, rather than an individual, opinion to questions posed by the Panel. This would alleviate the need for the Panel, typically composed of non-scientists, to weigh the opinions of various scientific experts in order to find common ground. The appointment of an expert review group, Pauwelyn argues, would avoid the pitfall of the Panel getting the science wrong in the process of seeking common ground, or of being caught in a situation where contradicting views of scientists leave them unable to find a common ground. However the expert group risks introducing an element of inefficiency to the process, particularly if the group included Codex experts in which case the Codex positions would be replicated at the WTO dispute settlement stage. Furthermore, to the extent that parties to a WTO dispute base their arguments on different scientific bases, the Panel requires access to diverse scientific opinions in order to draw conclusions.

An alternative approach for handling diverse scientific evidence on risk, would be, as argued above, to encourage the Codex risk assessors to propose and evaluate a larger range of food safety measures. This could have the advantage of increasing the probability that countries choose to base their domestic measures on JECFA risk assessments. The potential downside to this approach is that it may reduce the chances of Codex members to agree on one global standard with corresponding economic losses due to the increased complexity of the global food regulatory environment.[17]

Since parties may present risk assessments in the process of arguing their case in front of the Panel, it may fall upon the Panel to consider whether the documentation provided in fact represents an evaluation of the risks inherent to the issue at hand. While a Panel might be

[17] Codex standards are voluntary. Codex' contribution to global harmonization has therefore always depended on the good-will of member countries to adopt these standards.

tempted to seek to evaluate science on the basis of inputs from experts and parties, the Appellate Body in *Canada/US – Continued Suspension* clarified that this is not its proper role. Rather the Appellate Body noted:

> [R]eview power of a Panel is not to determine whether the risk assessment undertaken by a WTO Member is correct, but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.
>
> WTO Appellate Body, *Canada/US – Continued Suspension*

The Appellate Body further provided guidance on the standard of review for SPS cases, identifying a standard of review which provides greater flexibility to Members imposing SPS measures by, for example, re-affirming the relevance of divergent minority views. These conclusions appear to reinforce the rights of importing countries to implement SPS measures that deviate from international standards, again contributing to the balance between the potential biases of importing and exporting countries.

The jurisprudence elaborated in the Appellate Body report on *Canada/US – Continued Suspension* also for the first time opened the question of how to evaluate the sufficiency of scientific evidence, particularly in the context of the implementation of provisional measures. These types of provisional measures are provided for in Article 5.7 of the SPS Agreement, which states

> Where relevant scientific evidence is insufficient, a Member may provisionally adopt SPS measures on the basis of available pertinent information, including that from the relevant international organizations.

In previous disputes where the issue of provisional measures was considered, the benchmark for determining whether there was sufficient evidence was if the "body of available scientific evidence does not allow...the performance of an adequate assessment of risks" (Appellate Body, *Japan—Apples* para 179). In the context of the *Canada/US—Continued Suspension*, the Appellate Body concluded that in situations where Members select a measure more stringent than the international standard the existence of the international standard does not necessarily imply that sufficient science exists to justify their higher requirement. Specifically, the Appellate Body held that:

> Where the chosen level of protection is higher than would be achieved by a measure based on an international standard, this may have some bearing on the scope or method of the risk assessment.[18] In such a situation, the fact that the WTO Member has chosen to set a higher level of protection may

[18]We noted earlier that, at the oral hearing, the United States and Canada recognized that the acceptable level of risk may sometimes play a role, albeit a limited one, in respect of the risk assessment.

> require it to perform certain research as part of its risk assessment that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard.
>
> WTO Appellate Body, *Canada/US – Continued Suspension*, para 685

Furthermore, the Appellate Body ruled that scientific evidence which was sufficient to justify a particular international standards, might not be sufficient " to perform a risk assessment where a Member chooses a higher level of protection" (para 694). The discussion in previous sections of this paper suggests reasons why such situations may occur, indeed, be the case. Codex expert groups, e.g. JECFA, typically analyse a reduced set of policy options based upon inference from a range of hazard characterization and exposure assessment studies. Even when there is sufficient science to conduct a risk assessment of a specific finite set of options this does not imply that the same body of evidence would be sufficient to conduct a risk assessment of a different policy option.

The Appellate Body also disagreed with the Panel regarding how a change in scientific evidence regarding risks would alter the determination of whether available scientific evidence was sufficient to evaluate these risks. The Appellate Body set a lower threshold test than the Panel, requiring "new evidence from qualified and respected source" that "puts into question the relationship between the pre-existing body of scientific evidence and the conclusion regarding the risks" and "casts doubts as to whether the previously existing body of scientific evidence still permits a sufficiently objective assessment of risk" (Appellate Body, *Canada/US—Continued Suspension*, para 703). These rulings arguably provide greater flexibility for importing countries to adopt domestic measures which deviate from international standards by expanding the situations in which Article 5.7 may be invoked to justify a provisional measure.

The question remains whether these new rulings, by shifting the role of science in the standard of review, achieve the desirable equilibrium between the interests of importers and exporters. It could be argued that by increasing the flexibility of importing countries to invoke provisional measures, the latest AB report increases the possibility of food safety measures being used as protectionist devices. The proposal made in this paper, i.e. to encourage JECFA/CCFA to propose a larger set of policy options, each based on proper international risk assessment, could represent a way to limit this increased flexibility. WTO Members who do not wish to apply the policy option the CAC finally adopts, would have the alternative to use one of the other policy options analysed by JECFA risk assessors. In other words, it would be easier for Members to find policies that meet their "appropriate levels of protection" (ALOP) and that are also based on international risk assessment. At the same time, it would be harder for Members to justify policies that fall entirely out of the range of policies examined by JECFA.

Conclusions

Members of the WTO, through application of the SPS Agreement, are encouraged to base their food safety measures on Codex standards. Codex standards are based on scientific evidence and WTO Members need to provide scientific evidence to justify requirements that deviate from Codex standards. The focus on science is intended to provide a buffer against potential incentives for countries to use food-safety regulations to distort trade. However, as discussed above, both importing and exporting countries may be subject to domestic interest group pressures in the context of their food safety regulations, with import-competing firms favouring higher standards and exporting firms favouring lower standards. Furthermore, risk assessments include subjective elements which may allow for biases to be introduced.

In this paper a description is provided of how food-safety-related scientific evidence is generated and how it is used in the context of international standard-setting and trade disputes. The paper examines whether the current institutional set-up is effective in terms of buffering food-safety policy from undesired political influence or influence from private interest groups.

As discussed above, scientific evidence used for food-safety risk assessment is not necessarily neutral. Scientific studies require value judgements and there are reasons to believe that value judgements made by scientists are not independent of the source of funding for their research. Academic journals are increasingly aware of this and have introduced conflict of interest disclosure policies. National and international standard-setting bodies are also aware of this and there has been a tendency to introduce more sophisticated conflict of interest disclosure policies for the experts who evaluate scientific evidence in the context of their risk assessment. These moves are laudable and should be encouraged. Another area in which improvement is possible is with respect to the source of information used in Codex scientific committees, like JECFA. JECFA reports indicate where scientific studies they refer to have been published, but it is not always visible from those references how the relevant studies have been financed. Information on the country and/or the industry that has provided funding could increase transparency and instil trust. Another suggestion that has been made in the context of biomedical research is to rate studies used for risk assessment, in particular those that are unpublished.[19] Such a rating system might avoid the problem of weaker studies unduly influencing non-specialists, for example the legal experts who may be confronted with having to interpret scientific evidence in the context of WTO disputes.

[19] See Krimsky (2006). Along those lines, Crawford-Brown et al. (2004) refer to the importance of policy measures to be based on high quality research, in particular when the possible consequences of basing policy on inaccurate science are significant.

Codex standards are the outcome of multilateral negotiations based upon a risk assessment. It is important to communicate this fact to the public and thus signal that scientific evidence is only one of the determinants of Codex international food safety standards, albeit a very prominent one. The possible trade-offs between economic and political interests on the one hand and public health interests on the other hand, could become more tangible if the outcome of a Codex risk assessment was a "menu of policy options". Existing Codex procedures already allow for this and we encourage the increased use of this practice. We also propose that risk assessors play a more important role in defining the range of policy options to be analysed. One advantage of the suggested set-up could be that countries deviating from the internationally agreed standard may chose one of the other options analysed by the Codex risk assessors. This would possibly make national standard-setting less costly by alleviating the need for duplicative efforts. Also, if it were to come to a WTO dispute, WTO panellists could directly use Codex documents to compare different policy options, which would facilitate their task.

Risk assessors in national and international institutions hardly ever work in an environment of complete scientific evidence and they decide how to assess risks despite gaps in scientific knowledge. Several national institutions have adopted so called "risk assessment policies" that establish rules or default reasoning that risk assessors are supposed to use when taking such decisions. Codex guidelines also foresee the establishment and use of such policies, but in practice they do not appear to be applied consistently. We believe that the advantage of a consistent and thorough use of such policies could facilitate the work of WTO Panels. In particular, it would become easier for panelists to identify where risk assessments presented by parties to the dispute differ from those made by JECFA experts and to understand why this may be the case.

Given the increasing attention being paid to the effects of SPS measures on international food trade and the rapid technological change in the area of agriculture and food supply, there will be a sustained need for scientific guidance in this area. It is in the interest of the international community to fully support the work of the Codex, in particular in terms of funding. Financial constraints should not be such that potentially important risk assessment work cannot be funded or that the reviewing of existing standards in the light of new scientific evidence gets delayed. The more severe the financial constraints on Codex, the more likely it is that the priorities of Codex will be determined by political weight rather than by public health concerns, because the agenda setting in Codex is in the hands of policy makers. The more severe the financial constraints on Codex, the more likely that it will fall behind on relevant issues in the food-safety agenda and that WTO Panels will have to deal with scientific evidence not yet discussed within the context of Codex. It is also worthwhile to consider the possibility

of broadening the role of Codex. The scientific committees of Codex, for instance, could take a role in co-ordinating global research on particular substances and commission scientific studies that could be useful in enhancing risk assessors' understanding of particular substances.

Within the current legal set-up that creates a direct linkage between the WTO and Codex it is in the interest of those involved to have a strong Codex with an efficient and transparent set-up and with an adequate budget. In the absence of such characteristics, disagreements among nations on the risk aspects of food-safety policy will cause the burden to be shifted towards the WTO dispute settlement.

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