

**“Based on science”**

**Stakeholder influence on risk assessment in the context of  
international food standards**

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## **Abstract**

This paper provides a qualitative political economy analysis of risk assessment related to food standards at the national and international level and examines to what extent the evaluation of risks is prone to capture by interest groups and may produce biased results. The paper identifies four stakeholders with respect to risk assessment and divides them into two groups: the producers of scientific evidence –scientific experts - and the users - consumers, producers and governments. The paper also identifies two variables that determine decisions taken with respect to risk assessment – the amount and direction of (primary) research prior to risk assessments and the value judgements taken during risk assessments. Referring to the existing literature on financial conflicts of interest, this paper argues that both variables can be influenced through the funding of specific research or risk assessment projects. As a result, resource constrained developing country governments and consumers are in a disadvantaged position compared to industrialized country governments and producers in relation to international standard setting or international disputes evoking scientific evidence.

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## **“Based on science”**

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## **1 Introduction**

By implementing food safety measures governments can address risks associated with particular hazards to human health and life. The level of risk arising from a particular hazard in a food is a function of the probability and severity of the adverse health effects in exposed populations (Echols 2001). The establishment of food safety measures which are proportionate to a specific risk thus requires an assessment of risks to human health. Food safety measures may also have trade implications if they differ across countries and countries may therefore seek to harmonize standards in order to facilitate trade. But they may also want to maintain differences in order to hinder trade and protect domestic producers from import competition.

Two international institutions deal with food safety measures: the Codex Alimentarius Commission (Codex) and the World Trade Organization. While each of these acknowledges the dual effects of food safety measures, 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 activities of both organizations are thus linked and the WTO's Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) makes explicit reference to the Codex.

The SPS Agreement defines the Codex as the relevant standards-setting body for food safety (Annex A of the SPS Agreement). By explicitly acknowledging the role of the Codex in developing science-based food safety standards, the SPS Agreement created an enduring link between national trade policy in the area of food products and standards-setting at the international level. In addition to the basic acknowledgment of Codex's role in the development of standards, the SPS Agreement strongly encourages countries to harmonize their SPS measures. Article 3.2 of the SPS Agreement states that SPS measures "which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human...life or health and presumed to be consistent with the relevant provisions of this Agreement." Since within the WTO Agreements conformity assessment often arises in the context of dispute settlements the text of the SPS Agreement also establishes a clear role for Codex standards within the context of dispute settlement. Codex standards provide a benchmark against which national food safety policies could be evaluated to determine whether they

address true food safety risks in a reasonable way, or whether they represent a national strategy to protect particular food industries from import competition.

The SPS Agreement allows Members to introduce food safety measures that are more stringent than those proposed by Codex, if there is a scientific justification to do so or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate (Article 3.3). Article 5 adds that sanitary and phytosanitary measures should be based on an assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. The WTO legal texts thus indicate that scientific evidence on hazards and risks and related risk assessments are essential factors for distinguishing a legitimate food safety measure from one that pursues protectionist interests. This focus on scientific principles is intended to provide a buffer against potential incentives for countries to use food safety regulations for protectionist ends. Indeed, food safety measures that intend to address food risks should be intimately linked with the assessment of the risks they intend to address. In contrast, since protectionist intentions tend to be driven by financial considerations rather than concerns related to human health, effective protectionist food regulations could be designed with reference to profit considerations rather than risk assessment.

One implication of the Agreement's reference to risk assessment is that the WTO, a mainly legal and economic body, will in some situations, particularly when measures of WTO Members are in conflict, be involved in the interpretation of risk assessment exercises and their results. The difficulty of this task stems from two characteristics of risk assessments that this paper elaborates. First, risk assessment is a complex concept from both a scientific and an institutional perspective. The latter is the case, because different national and international institutions are involved in risk assessment. Second, the paper postulates that scientific analysis relevant for risk assessments inherently includes subjective elements, which could be subject to interest group capture.

The paper distinguishes among different stages of risk assessment. All stages tend to be carried out by "scientific experts", but the definition of experts differs according to the risk assessment stage and depending on who employs the term. Risk assessments can be carried out in different places and the paper shows that it is possible to identify the stages of risk assessment that tend to be carried out at national or industry levels and those that tend to be carried out at the international level. More importantly, all stages of risk assessment involve value judgements by the experts who carry them out. As a consequence the question arises whether interest groups who want to use food safety measures for protectionist or strategic trade policy reasons can actually influence results of risk assessments and thus the choice of standards. Interest groups may have enhanced potential to influence the risk assessment process, or its interpretation, given the complexity of risk assessment and the diverse groups of actors who contribute to the evaluation of risk.

The structure of the rest of the paper is as follow. Section two introduces the notion of risk assessment and the role it plays in international standard setting and in WTO disputes related to standards. The section also gives a detailed description of the different steps involved in risk assessment processes and of the value judgements that need to be made at different stages. Section three introduces the different stakeholders in decisions with respect to risk assessment relevant for food safety measures. Section four discusses the role of scientific data and risk assessment in the context of standard setting at Codex, focusing on the example of standards concerning food additives.<sup>1</sup> Particular attention will be paid to the selection of scientific experts participating in Codex, their actual activities in the context of Codex and the role of other stakeholders with respect to risk assessment and the risk management based on these assessments. The discussion in section four will show that many relevant activities related to Codex risk assessment still take place at the national level. Section five therefore has a closer look at those activities and the involvement of different stakeholders at that level. Section six discusses the role of scientific evidence and expert involvement in WTO disputes. Finally, section seven concludes with suggestions for policies to buffer food safety evaluations from interest group pressure.

## **2 Risk assessment by whose definition?**

### **2.1 Risk assessment: what is involved**

Risk assessments are typically catalyzed by a question regarding safety implications of particular products. However in situations in which science is rapidly changing, for example biotechnology policy, scientists, policy makers, producers and consumers often disagree on the questions that need to be asked. Societies may find themselves in a situation of not knowing what they do not know about a new technology and therefore knowing neither the questions to ask about the impacts of these new technologies, nor the answers to these questions (Khachatourians 2001). Before analysing how stakeholders can influence the answers that can result from risk assessment it is therefore necessary to analyse how stakeholders can influence the questions that that risk assessment tries to answer. Science plays a fundamental role in defining the unknowns and the direction in which the search for answers needs to take place.

The kind of research needed to define unknowns and directions of further research could be considered to fall under the concept of what is often called "primary research". This type of primary research is carried out by scientists, typically in laboratories, research institutes or universities.

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<sup>1</sup> Codex defines "additives" to mean certain substances intenrationally added to food for a technological pupose in the manufacture, processing, preparation or other facets of getting the food to the market (Echols 2001).

After a threshold level of understanding of the fundamental questions to be asked with respect to the safety of certain products has been achieved, it is possible to move to a more applied stage, the one of risk assessment. The Codex defines risk assessment as a "scientifically based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment, risk characterization." (FAO/WHO 2003, p. 52) National standard-setting organizations do not necessarily distinguish the same steps but for the purpose of this paper it is useful to distinguish different aspects of risk assessment at an earlier stage as this makes it easier to identify those aspects that can be influenced by different stakeholders. Codex defines the four components of risk assessment as follows:

Hazard Identification: identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical, and physical agents which may be present in food.

Exposure Assessment: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

Risk Characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a give population based on hazard identification, hazard characterization and exposure assessment

Each of these components involves decisions regarding the choice of variables to measure and report. Choices also need to be made concerning the "scientific" method to be applied in each step. Scientists, for instance, have the choice between using "mathematical modelling" or a safety factor approach in the context of risk assessment, with the latter method implying a more important role of qualitative judgements. Harrison and Hoberg (1994) report that in the risk assessment of TCDD (the most toxic dioxin) professionals in the U.S. were more likely to employ a mathematical modelling approach, while scientists in Canada supported the safety factor approach. Jasanoff (1990, 61) recounts the observation of an executive of Dow Chemical that "if one wishes to eat fish caught in the Great Lake, one had better to do it in Canada. The fish is safe across the border, even though the dioxin residues have led U.S. regulators to label it unfit for human consumption" (Jasanoff 1990, p. 61). This example illustrates that the choice of scientific method and other choices made during risk assessment can affect policy conclusions.

Different risk assessments may thus exist with respect to one hazard and these risk assessments may differ in one or a number of aspects including the sample used, the methodology applied and in the precise question analysed. To the extent that different risk assessment come to different results concerning involved risks, surveys of existing risk assessments can shed light on the general messages

that can, if possible, be drawn. Indeed, the surveying of data and studies on risk assessment from different sources plays an important role for international standards-setting. For the sake of this study it is useful to draw the distinction between the activity of assessing risk through the collection and analysis of original data and the one of assessing risk through surveying other research, i.e. surveying risk assessments that have been carried out by others.

## **2.2 Risk assessment in the international context**

Codex terminology incorporates an understanding of the ways that risk assessments fit into overall policy frameworks. Instead of relying on one term (risk assessment), Codex has adopted a multi-faceted approach, including both scientific and political concerns, which emphasizes that risk analysis is composed of three separate activities: risk assessment, risk management and risk communication. The definition of risk management in the Codex is "the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed selecting appropriate prevention and control options." (FAO/WHO 2003, p. 52). Within the Codex framework the first step of risk analysis is to conduct a scientific, quantitative risk assessment. However after the risk is determined, the second step of a Codex risk analysis, i.e. risk management, acknowledges that regulators must make decisions about responses to risks and the level of protection considered to be appropriate.

Codex advises 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" (FAO/WHO 2003, p.42). This implies that risk assessment is something more "scientific" than risk management (risk management refers among other things to the choice of policy instrument, e.g. standard, maximum limit, labelling etc). Nevertheless, Codex's suggestion that the "determination of risk assessment policy should be included as a specific component of risk management", establishes a link between assessment and management. Risk management is clearly prone to capture by different groups, but, given its stated scientific basis, risk assessment has a veneer of objectivity.

The definition of risk assessment used by the SPS Agreement differs from the Codex definition. Article 5 describes the obligations of WTO Members to base their SPS measures on risk assessment "taking into account risk assessment techniques developed by the relevant international organizations." Annex A of the SPS Agreement includes separate definitions of risk assessment for risks assessments

related to foods and beverages and risk assessments for measures focused on other purposes.<sup>2</sup> Annex A(4) defines a risk assessment in the context of foods or beverages as

"the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or 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."

Risk assessment in the context of the SPS thus refers to the assessment of the risk when a specific food safety measure, i.e. a risk management strategy, is already in place. This different focus makes sense taking into account the role of the SPS Agreement. The SPS Agreement discourages WTO Members from using food safety measures to protect domestic producers by requiring a link between the relevant food safety measures and the extent of risk to human life. Codex, instead, focuses on the question whether food safety measures are necessary at all and gives advice on which measures to use. The starting point of risk assessment in the context of Codex is, therefore, a situation without government intervention, i.e. a situation before risk management decisions have been taken. SPS risk assessment, instead, enters the picture after risk management strategies have been introduced.

### **2.3 "Science" at different stages of risk assessment**

To sum up, scientific expertise is required at different stages of the risk assessment process. It is required in order to identify and characterize hazards and in order to obtain knowledge about the risks they involve. This type of information is typically obtained from individual studies carried out on specific population samples. When enough individual studies have been carried out, scientific experts can try to draw more general conclusions from the existing evidence and give advice as to policy measures that may limit the risks inherent to certain hazards. In order to evaluate the effectiveness of different policy measures one may also consider carrying out risk assessments after introduction of the relevant measures. Those assessments indicate the potential of different policies to reduce risk.

Each of the three stages of risk assessment involves value judgements by those responsible for the assessment. Whether, when and how stakeholders can influence these decisions may differ across

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<sup>2</sup> To date only the *EC – Hormones* dispute has considered risks to human life and health related to food, beverages. The on-going dispute between the US, Canada and Argentina and the European Communities regarding biotechnology products may also provide additional guidance on risk assessments in the area of food and beverages.

countries and may be different in the context of national standards-setting, international standards-setting and WTO disputes.

### **3 Stakeholders in risk assessment outcomes**

Risk assessments are carried out in order to provide information about the risks inherent to certain hazards. Different economic players are interested in obtaining that information but for different reasons. Scientific experts tend to carry out risk assessments. They can therefore be considered to be the "producers" of scientific evidence, while three stakeholders – consumers, producers and governments - consume the evidence they provide.

Producers want to enhance their understanding of risks inherent to their products as they affect their expected profits. Perceived or real risks may affect product reputation and thus the prices consumers are willing to pay. In the case of adverse health effects caused by their products producers may face damage claims. Consumers are concerned about food safety and would like to be confident that what the food they consume does not represent a significant risk to their health. Food safety characteristics represent classic credence characteristics in that consumers are unable to determine food safety characteristics themselves, often even after consumption. In markets for credence goods, producers cannot be expected to give consumers the necessary information and intervention of a third party is justified. Government regulatory activities fill this need.

Governments are expected to put in place policy measures that protect consumers but that also take into account producer interests. Governments need information about risks inherent to hazards in order to set appropriate policies. Assuming the government acts like a benevolent social planner, consumer interests enter its calculus differently than they enter the decision making process of companies. As a result governments may be looking for different information on hazards and associated risks than producers.

Two issues need to be kept in mind with respect to governments' policy choices. First, decisions that may be optimal from a national point of view are not necessarily optimal from a global point of view, even if they are based on objective criteria. Rents that domestic companies can extract from foreigners, for instance, in imperfectly competitive markets, enter the domestic welfare calculation with a different sign than the foreign welfare calculations. Health risks to consumer groups abroad may also enter domestic and foreign welfare calculations differently.

Second, governments may be subject to lobbying efforts from different stakeholders. Hayami and Ruttan's model of induced institutional innovation maintains that the combination of demand for change on the part of various interest groups outside the government and the payoffs to policy makers leads to induced policy changes (Hayami and Ruttan 1985). In the case of international standards-setting the development and evolution of food safety standards are the end result of a process in which

stakeholders anticipating potential costs and/or benefits in terms of food safety, food prices, production costs, or protection seek to influence decision makers either at the national or international standards-setting level.

### **3.1 Producers of scientific evidence: experts**

Scientific experts play a fundamental role in national and international standard-setting processes as they tend to be those who conduct risk assessments and often provide the first policy relevant interpretation of the results of risk assessments. As pointed out in Pollak (1998) a first question that arises is "who is an expert" and a next question is how expert perceptions are formed.

The first type of risk assessments identified before, i.e. identification and characterization of hazards and risks, is typically carried out by professionals with a relevant education and in the context of laboratory research either in public (e.g. university, standards-setting body) or private institutions (e.g. company research laboratory). The "expert" definition depends in this case on the relevant employer. Value judgements of experts at this stage of risk assessment may be influenced by a number of motivations including: a desire to push the knowledge frontier further, a desire to obtain recognition in the profession and financial considerations. Recognition by the profession will to a large extent be determined by a scientist's publication record and the attitude of leading research journals towards different streams of research will therefore have an influence on the evolution of primary research.

The source of financing for specific research is likely to influence the questions to be asked in the relevant project. But the source of financing may also influence the findings of research. Indeed, a number of 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. (2001), for instance, combined data from articles examining 1140 studies in the area of biomedical research and found that industry-sponsored studies were significantly more likely to reach conclusions that were favourable to the sponsor than were non-industry studies. A recent study on conflicts of interest in leading medical and scientific journals found that around one fifth of 176 evaluated articles were funded by private firms. This share differed across journals within a range from 5 to 40 per cent (Goozner 2004).

The academic profession is well aware of the problem of how to manage conflicts of interest that can lead to bias in the conduct and publication of scientific research. Many leading peer-reviewed academic journals have therefore adopted policies requiring disclosure of conflicts of interest. Some journals bar conflicted authors from writing reviews or editorials. As the editors of the *Journal of the Medical Association* said in 2001, "Full disclosure ... serves to highlight the potential for bias, but cannot and does not eliminate the conflicts." (See Goozner 2004).

Experts that are called upon by Codex are likely to be chosen from a larger group of experts discussed so far. The selection of experts for Codex risk assessment is based on "consideration of the scientific credentials of the various candidates, with a view towards balancing scientific expertise and other experience". (JECFA 2006). FAO and WHO establish rosters of experts from which individuals would be selected to serve at expert consultations based upon responses to calls for applications, which describe the essential qualifications of the applicants, selection procedures for the roster and other relevant information.

The SPS Agreement does not provide a clear definition of who is an expert. Article 11 only states that panels should "seek advice from experts chosen by the panel in consultation with the parties to the dispute". Parties to the dispute thus have influence in the selection of experts and the list of experts consulted in a dispute is likely to represent a negotiated outcome among Parties in the dispute.

## **3.2 Users of scientific evidence**

### *3.2.1 Producers*

Producers are likely to pursue profit maximization in any context, however the effect on profits of new technologies will affect groups of producers differently. Producers that feel threatened by a new technology will take a risk adverse stance. Inventors are likely to take a more risk tolerant approach, although they have to take into account the possible extent of damage claims in case of severely negative effects of the relevant technology. The willingness to "take risks" stems from the fact that inventors are interested in bringing new products as quickly as possible to the market, in order to be ahead of competitors and also in order to start seeing returns for investments made in research and development.

Many different categories of producers exist within the agri-food economy - including seed companies, producers of commodities, and producers of processed foods – and their concerns with respect to food safety differ. Producers of commodities and processed foods, for instance, often make production choices regarding the introduction of additives that improve the production process. They may, for instance, depend upon inputs such as pesticides or food processing agents both to enhance the efficiency of their production and to enhance quality characteristics of products. If the additives are accepted as safe, the user of the additives will have a competitive advantage. The additives may at the same time create a food safety risk, which acts as a type of externality for consumers. In an unregulated world, producers do not have the incentive to moderate their own use of these additives.<sup>3</sup>

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<sup>3</sup> In reality the likelihood of a company facing damage claims and the extent of these claims will also influence a company's interest in moderating their use of a potentially risk product. These largely depend on the legal systems in place in the countries where the relevant products are sold. Producers' willingness to take risks will therefore also depend on the legal systems in place in their major domestic, or foreign, markets.

Producers that have a comparative advantage in using the additives or that have easier access to the additive, will be in favour of lower thresholds standards for the use of these additives. Other producers may also eventually need to adopt these additives in their production process, in order to remain competitive. Depending on market conditions and their competitive position, however, those who do not have a comparative advantage in using the additives may find it profitable to lobby in favour of higher thresholds for the use of additives.

Based on their profit-making incentives, producers thus may have an interest in influencing policy makers' decisions about how to regulate these externalities. Given the importance of risk assessments for the design of food safety measures, producers thus may have an interest in financing scientific evidence that supports their own economic interests. Producers who favour low thresholds standards for the use of additives will want to minimize the possible risks involved, while incumbents, i.e. those not wanting to use the new additive, may want to exaggerate possible risks.<sup>4</sup> It again depends on the individual market whether one or both types of producers have the means and an interest in financing research that serves their purpose.

### 3.2.2 Consumers

Traditional consumption theory assumes that products are homogeneous and consumers only care about the quantity of product consumed. Alternative models (particularly the economic literature on advertising) have suggested that consumers value qualitative product characteristics, and that consumer valuation of product quality depends upon a combination of search, experience and credence characteristics (Lancaster 1966). In such set-ups consumers are interested in both the price and the quality of products. "Safer" products are often more expensive than "less safe" products and consumers thus face a trade-off between price and quality.

At the theoretical level, Antle (1998a) shows that an individual's demand for risky foods depends on income, prices, the objective risk associated with the food, the perceived risk of the food, the likelihood that an individual will be exposed to the risk, and the individual's susceptibility to the risk. It follows that the market demand functions for foods that pose a health risk depend on income and prices, and also on the factors that determine how individual characteristics, such as risk perceptions and susceptibilities, are distributed in the population of consumers. These factors are likely to include demographics (age, education, etc.) and policy (product labelling, availability of food safety information).

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<sup>4</sup> Goozner (2005), for instance, points out that "The vast majority of industry-funded trials in the literature were "seeding" trials: clinical trials for common but off-label uses of drugs that have already been approved for narrower indications. The idea is to get results published in a wide range of journals so that salespersons can deliver reprints to physicians in those specialities."

Consumer concerns about food safety are thus likely to differ within countries and also across countries. Consumers' opinions about the need for risk assessments is thus likely to differ and also their ideas as to the questions that need to be answered. This and the lack of financial means may explain why consumer organizations, to our knowledge, do not tend to fund risk assessment projects. Consumers' preferences with respect to different food safety measures does not only depend on the risk assessments related to these policy measures but also on the effect of these measures on food prices. Consumers would thus in principle need information from producers on the links between policy measures and prices in order to form their opinion with respect to food safety measures.

### **3.2.3 Governments**

Governments are supposed to represent the interests of both national producers and consumers, but the weight each group represents in its decisions may depend on their potential to lobby governments. Some have argued that innovators do not have political champions<sup>5</sup>, but this statement can probably not be generalized as it will, among other things, depend on innovators' position in national and global markets. From strategic trade policy analysis it is, for instance, known that governments may have incentives to support national producers in imperfectly competitive markets, be they innovators or incumbents. Governments may therefore take a risk tolerant approach if they support a national innovator and be rather risk averse if they support national incumbents that compete with foreign innovators. This argument implies that governments' attitudes towards risk may differ across sectors and products.

Governments are interested in all the three types of risk assessment discussed in section two and governments in industrialized countries have the means to finance relevant risk assessment. Governments need to make choices as to how to allocate their resources. In particular, they need to spread their funding over early stage risk assessment, i.e. hazard and risk identification and characterization, and risk assessment related to policy measures. Like consumers, governments are also need to obtain information on the links between policies and production costs from producers, in order to make appropriate judgements concerning optimal food safety measures.

### **3.3 Can users of scientific evidence influence scientific experts?**

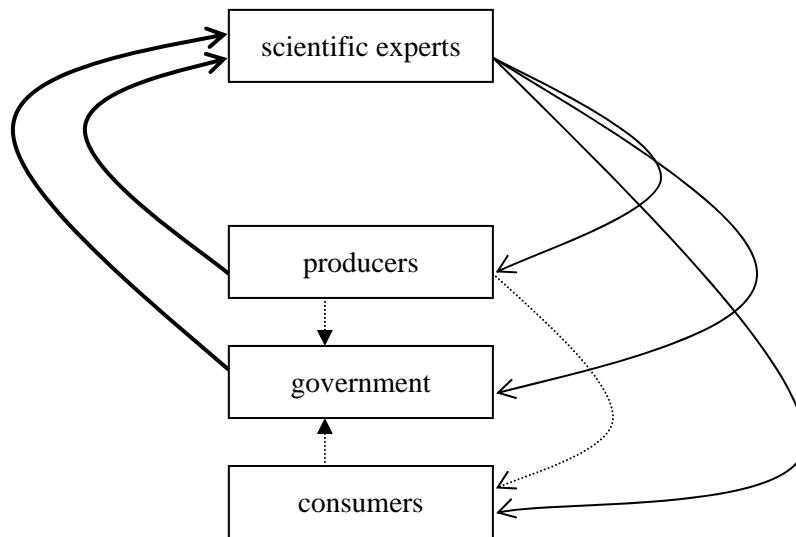
The discussion in section two already indicated that risk assessments involve judgements by those carrying them out, i.e. scientific experts. This section gave some indications as to who can influence those decisions. In order for scientific evidence produced in the context of risk assessments

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<sup>5</sup> Wildavsky (2000, p.49) argues that innovators do not have political champions. "To wipe out tangible benefits people already enjoy – familiar products, traditional jobs, with their identifiable and self-aware constituencies – is politically more difficult to do than to stop something new that is not yet surrounded with a self-productive belt of interest."

to be objective producers of scientific evidence should in their value judgements not be influenced by outsiders and in particular not by users of the scientific evidence. The figure below illustrates the linkages among the different actors in the context of national standards-setting.

**Figure 1:**



Normal arrows indicate the direction of information flows on risk assessments from producers of scientific evidence (experts) to users. The bold arrows indicate the directions of possible financial flows with to fund risk assessments. Both producers and governments fund risk assessments and may therefore be able to influence the questions that are being analysed and, possibly, even outcomes. The dotted arrows indicate another type of information flows, those necessary in order for the government to formulate the need for and design of risk assessments related to food safety measures. The discussions in section two indicate that these types of risk assessments may be particularly relevant for WTO disputes.

The figure illustrates that producers can influence the risk assessments through their allocation of funding and through the information they pass to governments and possibly consumers concerning the effect of policy measures on prices and profits. Governments can influence risk assessments through their allocation of funding, but depend on information from consumers and producers in order to formulate relevant questions. Consumers can only affect risk assessment through the government and even for this they, in fact, need some information related to production variables.

## 4 Codex and scientific evidence

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts, such as codes of practice under the Joint FAO/WHO Food Standards Programme. This Programme seeks to protect health of the consumers and ensure fair trade practices in the food trade, and promote coordination of all food standards work undertaken by international governmental and non-governmental organizations.

### 4.1 The Codex standards-setting process

Codex is governed at the highest level by the Codex Alimentarius Commission (CAC), a body in which all Codex member governments are represented. 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 can intervene at two important stages of the international standards-setting process: they set the agenda for Codex work and they take decisions on standards through a voting system. In other words, governments influence which standards need to be discussed at Codex and thus influence when scientific evidence is called upon. They are also the ones to take decisions concerning international standards on the basis of such scientific evidence.

National delegations thus may propose work on specific food safety issues to specific Codex committees and deliberations within these committees help clarify the scope of the draft standard. For example, discussion in the CCFAC in 1987 on the proposed development of maximum levels for aflatoxin in foods covered the type of targeted aflatoxin, the type of targeted food, and the appropriate sampling method. Through these deliberations the committee decided to develop, as a priority, a maximum level for total aflatoxins in peanuts for further processing. Generating a credible proposal is a resource intensive activity, hence those members with adequate financial resources and technical expertise have a greater capacity to influence the original decision to pursue the elaboration of a standard. Codex Committees are themselves hosted by individual member governments and the committees' activities are to a large extent funded by those host governments. The eight general subject committees are all hosted by OECD countries:

- Food Additives and Contaminants: Netherlands
- Food Hygiene: United States
- Food Import and Export Inspection and Certification Systems: Australia
- Food Labelling: Canada

- General Principles: France
- Methods of Analysis and Sampling: Hungary
- Nutrition and Foods for Special Dietary Users: Germany
- Pesticide Residues: Netherlands
- Residues of Veterinary Drugs in Foods: United States

Once the committees in conjunction with the FAO and the WHO have developed priorities for standard development, and the Commission has decided to elaborate a standard, the Codex follows an eight step process in the elaboration of a standard. The process is initiated when the Commission decides to elaborate a standard. The second step is the preparation of a proposed draft standard. Next, step three, the proposed draft standard is sent to governments and international organizations for comment. In step four, the Secretariat forwards comments to the committee for consideration and possible revision of the draft. The proposed draft standard is sent in step five to the Commission through the Secretariat for preliminary adoption as a draft standard. In step six the draft standard is sent for comment again for comment and then in step seven, the Secretariat forwards comments to the committee. Finally, in step eight, the draft standard is submitted to the Commission through the Secretariat for final adoption as a Codex standard. The draft standards prepared under step two are typically prepared by specialized Codex Committees. These in turn convene experts who are asked to provide independent scientific expert advice on relevant issues, including the assessment of relevant data for the preparation of proposed draft standards.

#### **4.2 The role of experts in the Codex standards-setting process**

In the case of food additives, for instance, the CAC will ask the Codex Committee on Food Additives and Contaminants (CCFAC) to prepare a risk management proposal for the CAC. The CCFAC 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 CCFAC and ultimately CAC base their risk management decisions. Expert groups, like JECFA, are not officially part of the Codex Alimentarius Commission structure, but are managed jointly by the FAO and WHO.

JECFA normally meets twice a year with individual agendas covering either (i) food additives, contaminants, and naturally occurring toxicants in food or (ii) residues of veterinary drugs in food. The membership of the meetings varies accordingly, with different sets of experts being called on depending on the subject matter. Note that JECFA only exists during these meetings. It is not a body that continuously works on risk assessment and carries out own research. Instead the role of expert committees is to provide Codex with a risk assessment based on a review of all the published scientific evidence on a particular matter (Consumer International 2000). In preparing its review, the expert

committee is expected to follow the "guidelines for the preparation of working papers on the intake of food additives for JECFA". These guidelines explain in detail how information from published and unpublished studies should be presented. JECFA is, for instance, expected to provide the following type of information: date of study, assumptions/model, (estimated) intake of relevant substance, country where study is carried out and resulting acceptable daily intake (ADI). Table 1 gives an example of a table that may be produced in such a report.

Codex expert committees thus produce reviews of primary research and risk assessments carried out at the national or regional level. Risk assessment activities at the national and/or regional level thus play a crucial role for international standards-setting and will be discussed in more detail in the next section. The table also illustrates that different national studies come to very different conclusions concerning the Acceptable Daily Intake (ADI).

The data used by expert groups providing scientific advice to the Codex are submitted from outside sources, after the expert groups put out calls for data. In the context of food additives for example, manufacturers are responsible for submitting all relevant published and unpublished data. Governments, national and international organizations, research institutes, and universities may also submit data (JECFA, 2003).<sup>6</sup> Summarized data is 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.

**Table 1: Estimates of intake of sulfites based on 'poundage' data.  
(Reproduction of Table 3 in Codex, 2001)**

Country	Date	Assumptions	Estimated intake of sulfites (mg/kg bw per day)	% ADI <sup>a</sup>
Finland	1994	Population, 5.1 million	0.067 <sup>b</sup>	10
Spain	NR	Not consumed by 15% of population <3 years	0.48	70
United Kingdom	1984-86	Population, 56 million	1.6	230
United States	1987	Population, 244 million	Mean, 0.38	50
			90th percentile, 0.77	110

NR, not reported

a JECFA ADI, 0-0.7 mg/kg bw

b The report indicates that data on use in potatoes is missing; the effect of the inclusion is unknown.

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<sup>6</sup> All entities that submit data to the expert groups for evaluation are referred to as sponsors.

Regarding the potential for subjective influences on data, the two main issues raised in a recent FAO/WHO consultative process were source and relevance of data. The report noted that while many data are derived from industry sources, expert committees differed substantially with respect to whether they accepted this data. Ultimately the report recommended that general guidelines for the inclusion/exclusion of data used by expert panels were needed.

### **4.3 Expert group selection at Codex**

Expert group selection is one aspect of the risk assessment process which would be prone to capture by interest groups, depending upon the national representation of experts, but also possible industry representation. Continuing the example of the JECFA, both the FAO and the WHO contribute to the selection of members for this expert group. The selection of members is based on consideration of the scientific credentials of the various candidates, with a view towards balancing scientific expertise and other experience. FAO and WHO establish rosters of experts from which individuals would be selected to serve at expert consultations based upon responses to calls for applications, which describe the essential qualifications of the applicants, selection procedures for the roster and other relevant information. A recent expert group for the JECFA composed of 34 individuals, for example, included 17 individuals working for universities and 15 national scientific institutes or agencies. FAO and WHO meet the costs of experts' attendance at JECFA meetings (JECFA 2005). A summary of the meeting, including details of recommended thresholds for additives and contaminants set by the Committee, is published within a few weeks. Detailed conclusions of JECFA meetings, reflecting the view of the Committee as a whole and describing the basis for conclusions, are subsequently published. A minority report may be included as an annex in situations where consensus is not achieved.

Expert rosters are established for a period of four years and experts are selected from those rosters for each meeting. Experts attend meetings either in the capacity of members or they assist the Secretariat with preparatory work before the meeting. Also in the latter case they tend to participate in the meeting. Table 2 gives information on the nationality of experts included in three FAO rosters for the JECFA. Developing countries are clearly underrepresented on these rosters, in particular the roster for experts on "exposure assessment of food chemicals". The strong presence of EU and to a lesser extent US experts is also noteworthy. The last two columns of the table give information on the experts that actually participated in one of the recent JECFA meetings and the preparations for the meeting. Meetings are prepared by the so-called "Secretariat" and apparently the secretariat does not only draw experts from the rosters. The table shows that not a single developing country representative participated in the preparation of the 64th JECFA meeting in 2005 and less than one fourth of the actual members of that JECFA meeting came from developing countries.

**Table 2: Geographical distribution of JECFA experts**

	FAO Roster of Experts for the JECFA (2002-2006)			Participants to 64th JECFA meeting, Rome, February 2005	
	Food Additives, contaminants and natural toxins	Exposure assessment of food chemicals	Residues of veterinary drugs (added to 2003 roster)	Members	Secretariat
<b>OECD</b>	<b>30</b>	<b>15</b>	<b>13</b>	<b>13</b>	<b>29</b>
Canada	3	1	1	0	2
Mexico	1	0	0	1	
United States	6	3	3	3	5
Japan	2	1	0	1	2
EU(15)	16	6	6	6	16
UK	8	1	0	3	3
Netherlands	0	1	1	0	4
Sweden	3	0	0	0	2
other EU(15)	5	4	5	3	7
other OECD	2	4	3	2	4
<b>non-OECD</b>	<b>14</b>	<b>4</b>	<b>9</b>	<b>3</b>	<b>0</b>
Africa	2	0	4		
Asia	4	1	1	1	
Europe	2	1	0	0	
Latin America	5	2	2	1	
Middle East	1	0	2	1	
<b>Total</b>	<b>44</b>	<b>19</b>	<b>22</b>	<b>16</b>	<b>29</b>

Source: FAO rosters of experts downloaded from [http://www.fao.org/ag/AGN/jecfa/experts\\_en.stm](http://www.fao.org/ag/AGN/jecfa/experts_en.stm) in May 2006 and JECFA (2005b)

Developing countries are not only underrepresented in terms of experts but also in terms of data being analysed by experts. At its 64<sup>th</sup> meeting JECFA welcomed the fact that a greater than usual number of countries had provided information in response to the call for data, but noted that data for developing countries were sparse or lacking altogether (JECFA, 2005b). The Committee therefore recommended that FAO and WHO were to seek ways to make calls for data more widely known at both technical and policy levels in developing countries and to directly contact governments and other potential data providers to facilitate the submission of such data to the Committee.

Given the importance of expert input in the development of Codex standards, clearly the way that scientific advice is collected, synthesized and incorporated will affect the ability of interest groups to influence the outcomes of scientific evaluations. In response to calls for clarification of these processes, the FAO and the WHO recently organized a consultative process (including e-form, consultations within the FAO and WHO and expert meetings) to examine the procedures and mechanisms for the provision of scientific advice to Codex Committees (FAO/WHO, 2004). The Working Group highlighted several areas for discussion including selection and effectiveness of experts, data, processes and procedures, communication of scientific advice. It concluded that it is

important to consider experience in risk assessment at both the national and international levels, as well as their knowledge of food safety issues. It was noted that the selection criteria should be transparent, especially with how to deal with potential conflict of interest. Experts should provide information on various affiliations, financial interests, government service, etc. In addition experts are obliged to inform the Secretariat of any attempts to contact them.

#### **4.4 Risk management decisions and stakeholder influence at Codex**

Because the Codex operates as multilateral institutions with country consultation and multilateral negotiations integrally linked throughout this eight step process, obviously the resulting standards represent negotiated outcomes. As Abdel Motaal (2004) notes there are several difficulties with the notion of "multilateral scientific consensus" in the context of the WTO's reference to Codex standards as benchmarks for determining intent of trade restrictive measures. First, a negotiated outcome is, by definition, the result of a mixture of opinions and perceptions of facts and hence cannot be considered to be the only plausible account of science. In addition, the "multilateral scientific consensus" negotiated through the Codex process leaves room for "other legitimate factors" to be taken into consideration in the setting of Codex standards, therefore there is the explicit recognition that standards may be affected by other factors than strictly scientific evaluations of risk.

Risk management decisions should be based on risk assessment, but take into account a range of other factors, including the impact of food safety measures on trade. In its 15<sup>th</sup> Procedural Manual the Codex Alimentarius Commission (CAC) specifies that "While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers" (paragraph 27; Risk Analysis Policy). Paragraph 28 of the Risk Analysis Policy section stipulates that "decisions should be based on risk assessment and take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade". "In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects." (paragraph 30).

After a rather lengthy consultation process a revised version of a draft standard is submitted to voting by the CAC. A range of different observers, including consumer organizations, industry representatives and international organizations can attend CAC meetings and can submit comments and proposals during the consultation process.

Codex members alone, i.e. representatives of national governments, are responsible for decision-making which strives to be one the basis of consensus. However, the rules permit voting and

should a vote be requested each member has one vote. CAC members can vote in favour or against the proposed standard, but the CAC can also take the decision that scientific data are insufficient or incomplete in which case it will not proceed to elaborate a standard.

Information on Codex observers illustrates the possibilities of different stakeholders to influence the consultation process. According to Consumer International (2000) in 1997, the Codex approved list of 111 observer organizations (excluding intergovernmental organizations) comprised 104 industry funded groups, six health and nutrition foundations and one broad-based international consumer group- Consumer International.

Member country delegations may also comprise observers from the country, possibly giving national observers a more direct influence on delegations' voting behaviour. According to Consumer International (2001) the policy and practice with respect to the composition of national delegations differs significantly from one member to another, and even varies from one committee to the other. At the 1997 Codex committee on food labelling, for instance, the USA delegation comprised 8 government officials, 3 public interest NGOs and 10 industry funded groups. Other members, like the UK, are reluctant to include observers in their delegations and have stated that the proper place for all non-governmental groups to participate is through their international organization.

## **5 Relevant decisions taken at the national level**

While there has been a trend over the past decade for national governments to adopt a more comprehensive coverage of food products and to address consumer confidence issues, countries continue to handle risk assessment and management decisions differently within their food regulatory system. As Josling, Roberts and Orden (2004, p 104) point out while "countries are increasingly adopting science- based regulations, ...they can still differ widely on the role of science and scientist in regulatory decisions." This section considers, in a general way, the role of scientific evidence and risk assessment within national food safety standards-setting.

### *5.1.1 Setting the stage: primary research and first risk assessments*

Primary research tends to take place in universities and research institutes that receive private or public funding or a combination of both. Risk assessments are also carried out in these institutions, but in addition they are carried out in industry laboratories and by national standard-setting bodies.

The share of public and privately funded research in total research tends to differ across countries. Also the amount of funds dedicated to research differs across countries. Industrialized countries tend to spend more on R&D than developing countries do. In 2003, total R&D expenditure represented 3.2 per cent of GDP in Japan, 2.6 per cent in the United States, 1.95 per cent in the European Union (EU15), 0.95 per cent in Brazil and 0.4 per cent in Argentina. China's R&D

expenditure represented 1.2 per cent of its GDP in 2002 and India's R&D represented 0.85 per cent of GDP in 2000 (WTO 2006). The business sector accounted for around 60 per cent of total R&D funding in OECD countries in 2003. In developing countries the role of the private sector tends to be lower. It was, for instance, 40 per cent in Brazil in 2003 and 23 per cent in India in 2000. The role of private investment may also differ across sectors.

The difference between public and private research and development investments related to agriculture specifically in developed and developing countries is striking. A study based on data from the Agricultural Science and Technology Indicators (ASTI) project of the Consultative Group on International Agricultural Research indicates that in developed countries the private sector expenditures on agricultural research and development make up more than half of total national spending. In contrast, in developing countries the private sector accounts for less than ten per cent of total expenditure in this area.

**Table 3: Public and private expenditures on Agricultural R&D, circa 2000**

	Expenditure (Millions 2000 international dollars)			Share (%)		
	Public	Private	Total	Public	Private	Total
Developing Countries	12 819	869	13 688	93.7	6.3	100
Developed Countries	10 191	12 577	22 767	44.8	55.2	100
Total	23 010	13 446	36 456	63.1	36.9	100

*Source: Pardey et al. (2005) based on data from ASTI, available at <http://www.asti.cgiar.org>*

It has been suggested before that producers may have the possibility to influence scientific evidence through private funding of research activities. Although one would expect that publicly financed research is free from such influence, this is not necessarily the case. In many countries industry and academia have become more and more entwined in recent years often as a result of government policies encouraging ties between academia and industry. In the UK, for instance, the 1993 White Paper shifted the emphasis of publicly funded research from pure to applied and encouraged ties between industry and universities (New Scientist, 26 February 2005). Every scientist could become an entrepreneur by patenting a discovery and spinning off a company to exploit it. Industry and university links were already strong in the US at that period and other industrialized countries followed the same strategy.

Risk assessment, in the sense of the collection and analysis of relevant data, tends to take place in a national or, in the case of the EU, regional context. This may be explained by the fact that the permission to market new goods needs to be obtained from national authorities and that permissions often depend on risk assessments. Relevant authorities often have their own research centres in which risk assessments are carried out. The U.S. Food and Drug Administration (FDA), for instance, operating through its Centre for Food Safety and Applied Nutrition, develops and applies food legislation, from horizontal measures to detailed approvals, including pre-market approvals, if appropriate (Craddock 2001). Acting as an agency, it is advised by its own scientists, as well as by other advisory committees. The FDA employs over 9,000 people and has 2,100 scientists working for it in a large number of specialist laboratories. It has full legal responsibility for its decisions and is thought to undertake 90% of its scientific work in-house (Randall 2001).

The European Food Safety Authority, instead, only had a team of 70 scientists and support staff in 2004, which represented around 50% of the total head count. EFSA staff supports the work of the so-called Scientific Committee and Expert Panels. The Panels are made up of leading independent scientists coming from all over Europe and even in a few cases from beyond Europe, and were appointed following an open call for expression of interest. The Scientific Committee coordinates the work of the Panels, proposes common methodology and guidance in carrying out risk assessments, and addresses transversal issues common to all Panels (for instance, exposure assessment).

The possibility of scientific experts being subject to conflicts of interests has been an issue in recent political debates in the United States. A compromise provision to the FY2006 Agriculture/FDA appropriations bill provides for advance notice when scientists with conflicts of interest serve on FDA advisory committees. The bill foresees that consumers concerned that drug, device and food manufacturers have corrupted the FDA's advisory committee process will have 15 days notice when the FDA wants to put scientists with conflicts of interest on one of its 30 advisory panels. Simultaneous publication of the waivers granted to scientists, along with their conflicts, gives the public additional information for evaluating whether their participation may taint the proceedings.

### *5.1.2 National position in Codex decision making process*

In theory the position that a member country of Codex takes should reflect view of domestic stakeholders. Many countries have sophisticated communication strategies which they use to provide and receive information from their national stakeholders. However the ability and willingness of countries to incorporate views of stakeholders will differ. For example, developing countries may be more reluctant than developed countries to involve the private sector in consultations related to standards-setting, due to concerns about private sector. While this lack of connection may limit the ability of the private sector to unduly influence the national position, it also can lead to policy makers who are uninformed about the ways in which particular international standards might influence sectors

and groups within the national context and constrained in their ability to effectively negotiate within the context of Codex.

Who participates in Codex meetings will also influence outcomes of standards setting deliberations. Delegations to Codex vary in size and also reflect the ability of member countries to incorporate stakeholder views into national positions on standards. At a recent meeting of the CCFAC, the size of the delegations of those countries attending ranged from one to nineteen (FAO/WHO 2005). For countries represented by only a few people, these people are typically public officials. Countries with larger delegations often include representatives from specific industries which might be affected by particular Codex standards. From the developing country's perspective financial resources constrain their ability to participate in Codex standards-setting meetings, and this limitation is exacerbated by their limited ability to influence the process, through, by example providing scientific and technical data for discussion as mentioned before.

### *5.1.3 The decision to apply or deviate from Codex standard*

Countries will also differ in the ways they develop a national response to international standards. Standards could be considered a tool with respect to broader development objectives but evaluating the appropriateness of various options depends upon market access considerations, benefit cost analysis, implications for competitiveness in the long-term, and possible spillover effects with other sectors of the economy (World Bank 2005). Often developing countries adopt a reactive position with respect to standards which does not benefit them in the long run. Furthermore, some countries may adopt legislation which is based upon a Codex standards, but can not be effectively enforced at the national level.

At the national level countries can decide whether or not to apply the Codex standard. This decision will be influenced by whether or not a country agrees with the Codex consensus of the risk, whether the country prefers to seek a lower level of risk in the domestic context and whether the country can effectively implement measures to achieve this level of risk (As noted above, some countries may choose to officially adopt standards through legislation, but may be unable to effectively monitor compliance with these standards). Given the rights of countries under the SPS Agreement, a country could adopt a Codex standard without generating its own evidence and risk assessment to justify this adoption, even if the measure has an impact on trade.

A country might adopt a standard which is lower than a Codex standard because domestic consumers would prefer to have less expensive food than food which satisfies an incrementally higher safety criteria or because domestic producers are not producing for export markets which require compliance with the higher Codex standard. In this situation, foreign exporters who have to meet the Codex standard in their home market may find it difficult to export to the low standard country. Deviations from Codex standards towards lower standards may thus have an impact on trade flows,

yet the SPS Agreement contains no explicit reference to a measure that results in a lower level of sanitary protection than that found in the international standard. Article 3:3 in its second sentence could be an implicit reference to these measures, since it refers to a "different" level of protection (Echols 2001). A challenge could be made on behalf of exporters from another Member, who could argue that the lower level of sanitary protection, compliance with which entails lower costs for local producers, is an infringement of Article 2:3's mandate against discrimination and disguised protectionism.

As noted in an earlier section, the SPS Agreement also acknowledges the right of countries to implement standards which would achieve a lower level of risk than that implied by international standards. However, in this case, due to potential trade distorting impact of these decisions on imports into the country, the SPS Agreement also requires that countries provide evidence, in the form of a risk assessment, which justifies their adoption of these more stringent measures. This requirement links a country's risk assessment to whether they can be found in violation of the SPS Agreement and hence requires that disputes concerning SPS measures evaluate the nature of scientific justification for higher standards. To be more precise, Article 3 of the SPS Agreement notes that "Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist...Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations are...presumed to be consistent with the relevant provisions of [the SPS Agreement]."

Even though the SPS Agreement acknowledges countries' right to implement standards which achieve higher lower levels of risk than those implied by international standards, it could be argued that the existence of the SPS Agreement has made it more difficult for WTO Members to do so. Codex standards are voluntary standards and Codex members are not obliged to comply to them (Abdel Motaal, 2004), nor do Codex rules foresee that members have to justify any deviation. WTO Members instead who deviate from a Codex standard towards a more stringent standard can be challenged by other WTO Members in the context of the WTO dispute settlement system. In such a case the country applying the higher standard would need to prove that it has a scientific justification for doing so.

## **6 SPS Disputes and the expert process**

WTO dispute panels function like tribunals. Usually panellists are chosen in consultation with the countries in dispute. If the two sides to a dispute cannot agree, the WTO director-general may appoint them. Panels typically consist of three experts from different countries who examine the evidence provided by the parties. Panellists for each case can be chosen from a permanent list of well-qualified candidates, or from elsewhere. They serve in their individual capacities. The panel has the responsibility of considering all the facts relevant to the dispute at hand. In the case of SPS disputes,

this includes consideration of often complex scientific information.<sup>7</sup> However, the panel is not expected to have scientific expertise, but rather can call upon scientific experts to inform their deliberations. The WTO dispute settlement process has called upon experts to inform the deliberation of all panels considering SPS disputes to date.<sup>8</sup>

Given only the text of the SPS Agreement as guidance, the transparency of the expert selection process in SPS disputes is perhaps debatable, particularly given that the process in all disputes to date has been confidential during the course of the proceedings. Nevertheless, the procedure may be made public upon the adoption of the panel report by the WTO membership if the panel decides to include these procedures in the report. While there is no obligation for panel reports to publish details of the interactions with scientific experts, all panel reports to date which have sought expert advice relating to SPS disputes have included a description of the expert procedure, copies of responses to written questions by the experts, and a transcript of the meeting between the experts and the panel.<sup>9</sup>

The *EC – Hormones* dispute was the first SPS dispute and therefore set the precedent for future panel procedures with regard to scientific expertise in these areas. Subsequent disputes followed similar procedures. With respect to the composition of the expert group, initial lists have been generated based upon recommendations by international organizations including the Codex Commission secretariat, the World Organization for Animal Health, the International Plant Protection Convention and the International Agency for Research on Cancer. Experts were contacted and those experts indicating a willingness to participate in the process were asked to provide a brief curriculum vitae. These CVs were circulated to the parties for comment. Parties were provided the opportunity to comment and to state objections they might have with regard to any individual. In the *EC – Hormones* case parties were invited to nominate one expert and the panel selected two additional experts from the list. In subsequent disputes the panel selected experts in consultation with the parties.

After the selection of the experts, the panel prepares specific questions for the experts and provides the parties with opportunity to comment on the proposed questions or suggest additional

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<sup>7</sup> 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."

<sup>8</sup> As of 2006, panel reports had been adopted in four SPS disputes: US and Canada's complaint against EC's prohibition of meat from animals treated with growth-promoting hormones (*EC – Hormones*); Canada's complaint against Australia's import restrictions on fresh, chilled or frozen salmon (*Australia - Salmon*); US complaint against Japan's "varietal testing" requirement for fresh fruits (*Japan - Agricultural Products*); and US complaint against Japan's restrictions on apples due to fire blight (*Japan - Apples*). The dispute concerning the US, Canada, and Argentina's complaints against EC on approvals of Genetically Modified Organisms is ongoing at this time.

<sup>9</sup> See *EC – Hormones* p. 113, *Australia – Salmon* p. 94; *Japan - Agricultural Products* p. 73 and *Japan – Apples* p. 87.

questions. Experts are 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 each of the four SPS disputes. Parties are also free to include their own scientific experts on their delegations and to submit scientific evidence produced by their own nationals. Experts are invited to meet with the panel to discuss their written responses and to provide further information.

International standards-setting organizations also play a role in SPS dispute proceedings. These groups may provide recommendations for experts, suggestions for technical resources which will facilitate the understanding of the panellists of scientific information. In addition, standards, recommendations and guidelines developed by these groups are considered as the benchmark against which evidence from the parties is measured.

Historically the WTO dispute proceedings have been held in private sessions, however in 2005 a WTO dispute proceedings was open to the public. The first, and to date only, dispute which has conducted its meetings publicly is the continuation of the *EC – Hormones* dispute, in which the European Communities is challenging the continued suspension by the United States and Canada of obligations in the *EC – Hormones* dispute. The panellists agreed to open their proceedings with the parties in September 2005 at the request of the parties. The closed circuit broadcast was observed by WTO Members and the general public at WTO Headquarters in a location separate from the room where the proceedings actually occurred. While the decision to make the proceedings of this case public does not necessarily imply that this will be the policy across all future disputes proceedings, it increases the likelihood that parties will make similar requests in future cases. The potential public nature of future SPS dispute proceedings will likely affect the incentives that experts have in accepting to participate in them and hence could alter the future composition of the expert groups.

While parties may present risk assessments in the process of arguing their case in front of the panel, it is clear that the scientific evaluation underpinning risk assessments does not occur within the WTO SPS dispute proceedings. Nevertheless 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. Regardless of lack of scientific expertise of panellists, in the case of SPS disputes they have been called upon to consider highly technical information. While input from scientific experts in response to particular questions from the panel and the parties to the dispute can facilitate the panels interpretation of technical matter, some groups have raised questions as to whether it would be useful for panels for SPS disputes to include individuals with scientific, as opposed to legal or economic, training. One problem with this suggestion is that it is not always clear at the time of the initiation of dispute proceedings whether a dispute will turn on SPS issues. Often this is a decision made in the process of panel deliberations, indeed this decision is often made after the panel has been composed.

## 7 Conclusions

The emphasis put by the WTO SPS Agreements on scientific evidence as a basis for food safety standards and the trend for Codex to set international standards only when "enough" scientific evidence is available, increases the pressure to produce scientific evidence to back up national and international standards. National governments and industry will feel obliged to produce scientific evidence supporting their own interests, with the aim to either obtain agreement on an international standard close to their national interests or to show that there is enough contradicting evidence to undermine a standard that is suggested by others and not in the national interest.

Scientific evidence produced by industries at the national level plays a fundamental role for risk assessment at both the national and international level. As a result industries and countries who are more easily able to access and produce technical expertise hold a privileged position when it comes to international standards-setting or international disputes related to standards. In other words, wealthy actors are in a better position to influence standards-setting at the international level. Consumer organizations and poor countries seem to be disadvantaged when it comes to influencing the scientific evidence playing a role for risk assessment. This bias in access to expertise implies that countries with limited resources who nonetheless prefer a higher standard than the Codex standard will be less able to defend their case in a WTO dispute, regardless of whether their measure is intended to address purely food safety goals. Of course, this does not imply that countries would be forced to consume unsafe food. Rather, it implies that they could adopt the Codex standard, but that this would still be sub-optimal from the point of view of their domestic food safety preferences. In practice, the parties in SPS disputes within the WTO have been primarily developed countries and the expert process has highlighted that even among countries with similar resources perspectives on food safety and environmental health diverge substantially.

In order to address these problems, the Codex has begun to develop policies to enhance the ability of developing countries to participate in international standards setting. Trust fund support, training activities and strategic allocation of meetings to limit costs of participation can all contribute to increased participation by developing countries. At a more fundamental level, mechanisms to address the lack of scientific infrastructure in developing countries are critical to address the potential biases introduced when data submissions to expert committees of the Codex are dominated by developed countries submissions.

Given the increasing attention being paid to the impacts of SPS measures on international food trade and the rapid technological change in the area of agriculture and food supply, there will be the sustained need for scientific guidance in this area. Consumer suspicions about interest group capture of risk assessment can lead to the rejection of new, potentially beneficial, technologies. Ensuring that the scientific evaluation of food safety risks is buffered to greatest possible extent from interest group

pressure will strengthen the confidence of consumers and enhance access to beneficial technologies. One obvious way of doing this and that has been discussed in this paper, is to strengthen conflict disclosure policies for scientific experts involved in risk assessment at the national and international levels. Strengthened conflict disclosure policies for scientific journals should also be encouraged. Another way to address the problem of bias could be to provide funding to consumer organization that allows them to produce or commission scientific advice and to provide more funding to international research institutes. The discussion in this paper also suggests that increased ties between universities and industry may increase the bias of research being industry rather than consumer friendly. These two stakeholders do not always have conflicting interests but in the context of food safety, situations of conflict may occur and governments need to be aware of this. This paper therefore supports the idea of continued or even increased public involvement in independent fundamental research related to food safety and in independent risk assessment.

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