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WTO Efforts to Manage Differences in National Sanitary and Phytosanitary Policies

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Abstract

The Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization is the centerpiece of global efforts to restrain governments from imposing non−tariff barriers on trade in foods and other products that could affect human, plant an animal safety. It is designed to prevent proliferation of such non−tariff trade barriers while, at the same time, allowing governments flexibility to impose restrictions for "legitimate" purposes. This article reviews the design of the SPS Agreement and its actual operation during the first five years of the WTO; it focuses on the three formal disputes over application of the SPS Agreement that were prosecuted within the WTO Dispute Settlement system. It argues that it has proved difficult, within the framework of the SPS Agreement, to draw a sharp distinction between legitimate and illegitimate application of SPS policies. Moreover, the article concludes that there is little evidence that attempts to reduce SPS−related non−tariff trade barriers has led to a "race to the bottom" or, generally, a reduction in the stringency of SPS policies in WTO member governments.

KEYWORDS:

INTRODUCTION

One measure of the success of the postwar trading system is that tariff trade barriers have declined sharply. But the reduction in tariffs has exposed the many non-tariff barriers that remain, and in many cases governments have kept protectionism in place by simply shifting from tariff to non-tariff measures. Included in the broad category of non-tariff barriers are differences in technical standards such as labeling requirements and environmental regulations. The focus in this paper is on one subset of these technical barriers: measures for sanitary (animal, including human) and phytosanitary (plant) protection. Such rules include import bans that are intended to prevent pests from moving across borders along with trade goods, fumigation regimes that are intended to kill harmful pathogens, and sundry other systems.

Sanitary and Phytosanitary (SPS) measures often have huge effects on trade; yet managing them is not easy. SPS measures vary across and within nations because preferences and circumstances vary. Simply requiring nations to harmonize the SPS measures to a single standard is neither technically nor politically feasible in the global context. Some nations seek tight protection while others readily consume riskier foods; some pristine environments are vulnerable to pest infestations and require elaborate quarantines for imported products, but other countries are already overrun with pests. It would be difficult to design a single set of international standards that could accommodate such varied preferences and circumstances. Even if that were technically possible it would be politically impossible in the global context because harmonization of standards would transfer political power to international institutions.

The 1994 World Trade Organization (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement") is the most significant global effort to reduce trade distortions caused by differences in national SPS protection policies. The negotiations leading to that agreement rejected harmonization as technically and politically infeasible; instead, the architects of the SPS Agreement sought to strike a balance between the need to accommodate differences in local preferences and circumstances while also barring SPS measures that are merely impediments to trade. The Agreement urges the use of international standards as benchmarks but allows countries to deviate from international standards provided that national SPS policies are based on risk assessment and meet other criteria.

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This paper examines the first five years' operation of the SPS Agreement and explores the three questions raised in the introduction to this book:

(1) Are the rules of the SPS Agreement having an effect on national standards?

(2) Is the Agreement leading to harmonization of national SPS policies or diversity?

(3) Is the Agreement leading to national SPS policies that are stricter ("trading up") or weaker ("trading down")?

The answers will help improve the debate about globalization. International free trade agreements, such as those in the WTO, are designed to promote globalization. International agreements are also often cited as the best remedy for the ills of globalization, such as the fear that fully free trade will lead to a "race to the bottom." The SPS Agreement is one of the few in the are of "trade and the environment" where there is some track record that makes it possible to determine whether agreements are fostering or hindering trade, and whether they are also harmonizing or changing the stringency of national SPS protections.

In brief, I argue that the effect of the SPS Agreement on national regulatory standards has been remarkably small. Benchmarking appears to be having little effect because the SPS Agreement allows countries to deviate from international benchmarks provided that the *process* by which countries set their SPS measures meets certain minimum standards. In particular, the SPS Agreement is requiring that countries establish a "rational relationship" between assessments of SPS risks and the measures that they impose. Moreover, it has required that they impose comparable levels of SPS protection in comparable situations. In practice, these process requirements have been vague and elastic. They have probably led to the use of SPS measures that are less restrictive of trade, but they have had no significant effect on the *level* of SPS protection. Indeed, the SPS Agreement was designed so that it would not require countries to reduce (or increase) their level of SPS protection. In a few cases countries are removing highly restrictive SPS measures, but doing so has had no appreciable effect on SPS protection. The "rational relationship" test is probably leading to more use of risk assessment and greater attention to risk management, which may lead to more diversity in SPS measures and levels but no systematic trend toward tighter or looser SPS measures. Neither "trading up" nor "trading down" is observed.

The SPS Agreement is still young and there are no other global examples of this strategy with which to make useful comparisons. The approach taken here is to examine the major elements of the SPS Agreement and the three international SPS standard-setting processes that are explicitly mentioned in the SPS Agreement (section I). Then I review the major elements and decisions of the three WTO disputes that have concerned SPS measures, which help reveal how the WTO system is interpreting the SPS Agreement (section II). Finally, I explore a few conclusions that emerge (section III).

I. THE SPS AGREEMENT: MAJOR ELEMENTS

The basic obligations for members of the world trading regime have not changed since the first GATT agreement in 1947: members must give equal treatment to exports from all members, and members are barred from discriminating between locally produced and imported

products. Exceptions were allowed for tariffs on specific products, which were "bound" at specific levels. Numerous other "general exceptions" were also allowed for many national policy purposes, such as protection of human, animal or plant life or the conservation of exhaustible natural resources. But those general exceptions—listed in the famous Article XX—were described only briefly. A system of "dispute panels" emerged to handle conflicts. In principle, the dispute panel system could have clarified the scope of Article XX; but in practice any GATT member could block adoption of a GATT panel report and the panel system was often inactive, erratic in operation, and ineffective in major cases.[1] Enforcement that did exist was mainly through reciprocity imposed by GATT members themselves. But the blunt instrument of unilateral reciprocity was poorly suited for working out and applying the complex legal interpretations that would be needed to make Article XX workable. In the early decades of the GATT, tariffs were the largest barriers to trade. The main result from each of the first 6 rounds of negotiations to strengthen the GATT was to revise the list of tariff bindings and reduce the tariff impact on trade. Non-tariff measures remained in shadow.

For the last thirty years, attention to non-tariff measures has grown. The 1979 "Tokyo Round" agreements, which resulted from the 7th round of negotiations, included a separate "standards code" that imposed discipline on technical barriers to trade. But the code, like the GATT agreement, was backed by little enforcement; although all GATT members were bound by the GATT's core rules, they were largely free to pick and choose among "code" rules. The result of the Tokyo Round's "GATT a la Carte," most experts agree, was little effect on lowering technical barriers to trade.

The failures of earlier efforts were addressed head-on in the most recent (8th) Uruguay round of negotiations. By 1986, the year that the Uruguay round began, nearly 90% of US food imports were affected by nontariff barriers to trade, up from only half in 1966.[2] Exporters had a growing interest in taming these barriers. The main legal products of the Uruguay round were adopted in 1994: an updated version of the GATT ("GATT 1994") along with 14 other agreements on textiles, subsidies, technical barriers to trade, SPS measures and other topics. The Uruguay round also produced a stronger dispute resolution procedure and a mechanism that reviews trade policy in all member countries on a regular basis. Together, these agreements form a single, integrated package of obligations that constitutes the core obligations of a new international organization: The World Trade Organization (WTO).[3] Countries were no longer free to pick and choose their free trade commitments.

The most important element of the WTO concerning SPS protection is the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"). The Agreement's central purpose is to promote international trade by limiting the use of SPS measures as disguised barriers to trade. The Agreement's basic rights and obligations (Article 2) underscore that WTO Members have the right to impose SPS measures as necessary "for the protection of human, animal or plant life or health (Articles 2.1 and 2.2)." But the agreement bars countries from using SPS measures as disguised barriers to trade (Article 2.3). These basic rights and obligations are quite general and thus efforts to interpret them have focused on the more detailed provisions of the SPS Agreement (in particular Article 5, which is detailed below). In addition to restraining the SPS policies that countries may develop on their own, the SPS Agreement urges members to implement international standards. Countries that apply international

standards are automatically deemed in compliance with the SPS Agreement. Countries may deviate from international standards if there is scientific justification for doing so.[4]

Thus WTO members face a choice. The Member may simply implement international standards,[5] where they exist. Or, it may deviate from those standards. In order to examine how the Agreement affects the SPS measures that countries implement it is thus necessary to examine both outcomes: (1) how international standards are established, and (2) the exceptions that permit a country[6] to deviate from those international standards. I will address these in reverse order because the exceptions are the most elaborate portion of the SPS Agreement, and all of the disputes involving the SPS Agreement, have focused on how to interpret the exceptions.

Before turning to international standards and exceptions, it is important note that the SPS Agreement includes several important obligations that extend the Agreement's influence beyond simply the setting of SPS levels and measures. In particular, Article 4 of the SPS Agreement requires importers accept the SPS measures of exporters:

> …as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of [SPS] protection. (Article 4.1)[7]

Assuming that exporters have an interest in identifying the least trade restrictive measure, this "equivalence" requirement could automatically ensure that SPS rules are not more discriminatory than necessary. In essence, equivalence could ensure that trade liberalization (which is the central goal of the WTO) is achieved without reducing (or raising) SPS protection.

The Agreement also requires that countries make their SPS policies transparent both through publication and creation of national "enquiry points" that can answer any reasonable question about that country's SPS rules (Articles 5.8 and 7, and Annex B). In addition, the Agreement creates an international "SPS Committee" that meets on a regular basis to consider relevant topics and periodically review the performance of the SPS Agreement (Article 12).

The Exceptions

One of the most controversial aspects of the debate over opening trade has been the fear that free trade will force all countries to harmonize their national standards into a straitjacket of international standards. Especially vocal in the development of the WTO rules on SPS protection were governments and interest groups who feared that international standards would be weaker than national SPS policies; the straightjacket, they feared, would require "downward harmonization." In the name of freeing trade, the WTO would require compromising hard won rules that protect consumers and the environment.[8]

Because of this heated debate, fully under way when the WTO agreements were negotiated, the SPS Agreement permits countries to adopt SPS protection policies that deviate from international standards, provided that the Member bases its SPS measures on "scientific principles" (Article 2.2) and can provide "scientific justification" for choosing a higher level of SPS protection (Article 3.3). These general requirements are quite broad and thus, in practice, the

Panels and Appellate Body decisions in the three WTO disputes related to the SPS Agreement have turned to Article 5 for a more detailed description of what qualifies as "scientific" determination of SPS levels and measures.[9]

Article 5 essentially creates five rules that countries must follow when they impose SPS measures that deviate from international standards (or when no international standards exist):

- The country must obtain a risk assessment (Articles 5.1, 5.2, 5.3, and 5.7);[10]
- The SPS measures imposed must be "based on" that risk assessment (Articles 5.1 and 5.7);
- The country must not discriminate or create disguised trade barriers by requiring different *levels* of SPS protection in comparable situations (Article 5.5);
- A country may adopt more stringent measures if scientific information is incomplete, provided that the measures are temporary and a process is established to provide the missing information (Article 5.7). This is one of the few specific applications in international law of what is often termed the "precautionary principle."
- The measures must not be more restrictive of trade than necessary to reach the level of SPS protection that the country desires (Articles 5.4 and 5.6).

As we will see below, the exact meaning of these five requirements is not obvious. However, Article 5 is the linchpin of the SPS Agreement—it puts discipline on SPS protection policies that countries adopt without requiring the politically impossible task of harmonization.

There is a curious tension in Article 5 and other related provisions of the SPS Agreement.[11] Article 5 is mainly concerned with ensuring that countries base their SPS *measures* on risk assessment and that they not adopt measures that are more restrictive of trade than necessary. It is largely silent on the *level* of SPS protection that a country seeks. Indeed, as already mentioned, several provisions of the SPS Agreement underscore that countries are free to set their own level of SPS protection, even if that level of protection is different from the level that would be afforded by international standards (e.g., Articles 2.1 and 3.3). The only provision in the SPS Agreement that specifically constrains the *level* of SPS protection that a country may set is Article 5.5, which requires that countries seek comparable levels of SPS protection in comparable situations.[12] Thus to determine whether a country's level of SPS protection is legitimate one must *look inside the country itself*—at whether the country consistently seeks a particular level of SPS protection. It is possible to interpret the requirements that SPS *measures* be based on a risk assessment (Articles 5.1, 5.2, 5.3 and 5.7) as also a requirement that a country's SPS *levels* also be based on risk assessment. Indeed, how can one assess the risks of SPS measures without assessing the risks associated with the level of protection as well? Levels and measures are two sides of the same coin.[13] This remains a hotly contested issue because it concerns perhaps the most politically sensitive aspect of the SPS Agreement—whether it will encroach on a nation's sovereign right to determine its own SPS protection level.

International Standards

While most of the SPS Agreement is focused on exceptions, its principal objective—stated in the preamble—is to promote harmonization of national standards.[14] The SPS Agreement explicitly urges countries to adopt the standards set in three international processes:

the *Codex Alimentarius* Commission (food safety), the Office International des Épizooties (animal safety, also known as the World Organization for Animal Health) and the various organizations and processes that operate under the International Plant Protection Convention (plant safety). It also empowers the SPS Committee to identify other appropriate standards, guidelines and recommendations; so far the Committee has been silent on that matter.

*The*Codex Alimentarius *Commission*[15]

In the aftermath of the Second World War the European nations created several institutions that were designed to promote trade and cooperation. Their architects hoped that the resulting economic integration would widen and deepen—by focusing on making money, European nations would form a binding political union that would avert future war. The institutions included the European Coal and Steel Community (a predecessor of today's European Union) and the *Codex Alimentarius Europaeus*, established in 1958 to help harmonize methods for testing food safety in Europe. At the same time the World Health Organization (WHO) and Food and Agriculture Organization (FAO), spurred by the European dairy industry, created a committee to harmonize milk standards and thus open trade in milk and milk products. In 1962 WHO and FAO loosely merged these activities into the *Codex Alimentarius* Commission.

The Commission's mandate was to develop and adopt food standards that would allow firms and countries to realize their self-interest: world trade in safe food products. From the outset the emphasis was on participation and consultation, especially with industry; engagement, the *Codex* architects hoped, would lead these stakeholders to harmonize their activities without the need for international enforcement. Thus *Codex* standards are developed by committees of government representatives and stakeholders through an 8-step cycle. Technical committees evaluate evidence and elaborate standards, which are then subjected to the approval of the full *Codex Alimentarius* Commission, which meets every two years. The process is designed to obtain wide input and yield consensus. Participation in the committee and Commission meetings has been open to any stakeholder; yet only rarely have consumer and other public interest groups attended the committee meetings where standards are elaborated. The process is driven by industry, and the vast majority of *Codex* standards attract essentially no attention from other interest groups.

The Commission adopts three types of standards: (1) residue standards, which define acceptable levels of pesticides and food additives, (2) commodity standards, which define what qualifies as a particular commodity (e.g., what is a "canned peach" or "bottled water"), and (3) codes of conduct and other guidelines that recommend, for example, good practices in the use of veterinary drugs or methods for risk assessment. To date the Commission has adopted about 3000 standards; I describe the standard-setting process in more detail elsewhere.[16]

So far, only *Codex* standards for residues have been directly involved in WTO disputes over the application of the SPS Agreement. These standards codify a value for an acceptable residue (the "maximum residue level (MRL)") of a food additive or contaminant for a particular food. The standards are set by identifying an acceptable daily intake (ADI) of the residue or food additive in question. Typically ADIs are established by identifying an animal that best

mimics the most dangerous possible human response to the residue or food additive and determining the "no effect" level in that animal. What is meant by "no effect" and how it translates to human effects has not been rigorously defined or quantified. The ADI for humans is set by adjusting for the mass, diet and lifetime of a typical human being compared with the test animal. (In the case of the bovine growth hormones, which will be used as examples here because that WTO case involved a *Codex* residue standard, the typical human is 60 to 70 kg and the diet is generously assumed to be 500 grams of bovine meat per day over an entire lifetime.) The ADI also includes a large safety factor. (In the bovine growth hormone case, the ADIs are 100 times lower than they would be without the safety factor.) A maximum residue level (MRL) is then calculated that would ensure that the ADI is not exceeded. If guidelines for "good practice" in food production would yield residues that exceed the MRL then those guidelines are brought into line.[17] In the case of bovine growth hormones, one expert testified that the MRLs adopted by the *Codex Alimentarius* Commission would result in a cancer risk of between 0 and about one-in-a-million;[18] but that was a guess because the *Codex* system does not have a standard level of risk that guides its standard-setting activities.

Determining ADIs and MRLs is a highly technical process. Experts are needed to review the raw data from scientific studies and to calculate ADIs and MRLs. The *Codex* system has drawn on the recommendations of two joint WHO/FAO committees that are independent of and external to the *Codex* system: the Joint Meeting on Pesticide Residues (JMPR) and the Joint Expert Committee on Food Additives (JECFA). Both provide advice not only to *Codex* but also to many other activities of WHO, FAO and the UN system. In the *Codex*, JMPR and JECFA recommendations are used mainly by the three committees that set residue standards (i.e., MRLs): The Committee on Pesticide Residues, Committee on Food Additives and Contaminants, and Committee on Residues of Veterinary Drugs in Foods.

Commodity standards are more complex and make less extensive use of independent expert information. Instead, they are set mainly through a "bottom up" industry-driven process that codifies what is considered to be good practice for supplying safe food. In the past, commodity standards have been inconsistent—some simple while others define a wide array of food characteristics (size, shape, color). Since 1991 the Codex system has been simplifying and harmonizing commodity standards so that they are less complex and focus on elements that are critical for food safety; in part, this revamping of commodity standards is an effort to make the standards more useful for promoting trade and more relevant to application under the SPS Agreement (which Codex members knew would be a likely outcome of the WTO Uruguay Round by the late 1980s).

Finally, codes of conduct and guidelines are looser and are intended to augment application of the core standards rather than as principal standards themselves; in some cases, such standards have been adopted when agreement was not possible on a commodity or residue standard. If the SPS Agreement is interpreted broadly then these looser norms will have potentially binding application. However, that matter of legal interpretation has not been resolved nor tested in any WTO disputes.[19]

For all three types of *Codex* standards the working committees make recommendations, which they forward to the full*Codex Alimentarius* Commission for decision. To speed its work,

the Commission allows for simple majority voting when adopting a standard. Prior to 1994—when the SPS Agreement came into force—the mere adoption of a Codex standard had no international legal consequences for Codex members. Thus it was rare for *Codex* standards to require a vote because a country could simply ignore an unfavorable standard. Indeed, standards were not binding unless the *Codex* member gave its formal "acceptance." The acceptance process allowed countries to pick and choose which standards they wanted to apply rigorously within their nations. For pesticide residue or food additive MRL standards, a country faced a simple binary choice: accept or not. For more complicated commodity standards, countries could accept the standard "with specific deviations," which gave them the opportunity to unilaterally tune the commodity standard to their own local conditions and preferences.

The combination of extensive consultation in standard-setting, simple majority decision-making, and the acceptance process make it difficult to assess what impact Codex standards have actually had on national food safety standards and trade. The only hard data come from acceptances, which are not impressive. Table 1 shows that by 1993—on the eve of incorporation into the WTO—only 12% of the *Codex* standards had been accepted. Moreover, the pattern of commodity standard acceptances suggests that international standards followed rather than shaped national standards: in industrialized countries, which typically already had elaborate commodity standards in place when *Codex* norms were developed, nearly all acceptances were "with specific deviations."[20] Deviations allowed them to tune international standards to meet existing local standards; when the needed deviation was large the country could choose simply not to accept the international standard.

Table 1

Acceptances of the *Codex Alimentarius* Standards
(163 standards x 138 countries = 22494 possible acceptances)

	Developing countries (114 in '93)	OECD countries (24 in '93)	Total
Actual acceptances	2,175	559	2,734
Possible acceptances	18,582	3,912	22,494
Acceptance rate:	12%	14%	12%
Type of Acceptance			
Full Acceptance	1,215 (56%)	100 (17%)	1,225
Acceptance with specific deviations	228 (10%)	252 (45%)	480
Free distribution	732 (34%)	207 (37%)	939
TOTAL	2,175	559	2,734

(100%) (100%)

Source: Compiled by author from 1989 Acceptances, vol 14 of *Codex Alimentarius* Commission; updated 1991 & 1993.

Voluntary standards and the acceptance procedure were designed to give states and stakeholders maximum control over which standards they adopted which, in turn, dampened potential conflicts. Today, after the incorporation of *Codex* into the WTO, standards are no longer viewed as completely voluntary. For purposes of the SPS Agreement, a standard is now considered "adopted" when it has been approved by the *Codex Alimentarius* Commission. The requirement of acceptance, which previously was the way that countries ensured that no *Codex* standard would be imposed against its wishes, no longer plays a role. Because of majority voting rules, in principle the result may be a large number of standards adopted against a country's wishes. Industrialized countries have been especially worried about that outcome because those countries governments are under strong pressure from public interest groups who are worried that*Codex* standards will force the lowering of national food safety rules. In practice, however, *Codex* standards have largely reflected risk management procedures in the advanced industrial countries. They are developed with extensive input from industry, mainly (but not exclusively) in the advanced industrialized countries. The industry's interest has been to ensure that international standards are consistent with national practices—they seek international standards that mirror those already in place in major markets or in "good practice" standards developed by industry associations.[21] Similarly, the large safety margins and the desire to set MRL standards at the "no effect" level reflect the goal of the advanced industrialized countries, which is to set food safety risks as close to zero as is practical. Thus the greater worry, perhaps, should be by developing countries that, if forced to apply *Codex* standards, would be implementing food safety approaches that reflect the preferences of industrialized nations. In practice, however, we will see that the real story is that*Codex* standards are not mandatory and there is no strong pressure for harmonization.

Nonetheless, participants in the *Codex* process think that the standards are more relevant now than they were in the past, and that has increased the level of controversy in the standard-setting process. Floor debates at the *Codex Alimentarius* Commission are common, and a greater fraction of draft standards are now put to a vote at Commission meetings than in earlier years when the *Codex* system was viewed as entirely voluntary. Rising conflict in standard-setting bodies should not necessarily be lamented. It is the byproduct of a shift from a voluntary (often ineffective) system of standards to a scheme that may have more binding impact. Until the application of *Codex* standards through the SPS Agreement touched off the systematic effort to streamline and harmonize the *Codex* system, nobody knew exactly what safety levels *Codex* assured and nobody had tried to assure that *Codex* standards attained a specific level of protection. Probably it is a good sign that countries are paying closer attention to the implications of the standards they are adopting.

One negative aspect of the new controversy in *Codex*, however, is that it greatly slows the process of standard-setting; in some politically charged cases, it has caused gridlock. The result is an absence of timely standards, or broad and meaningless guidelines that are equally useless, in areas where *Codex* otherwise would have been able to adopt standards. That could

lead to less trade and to less effective SPS protection, especially in developing countries. Historically, the one situation in which *Codex* standards have been consistently influential has been when they fill gaps in areas of food law where nations did not already have standards in place. As shown in table 1, developing countries lodged more "full acceptances" of *Codex* commodity standards, but industrialized countries—especially those with the most advanced SPS protection systems—employed principally "acceptances with specific deviations." The explanation for this difference is that developing countries had few SPS measures already in place; when they wanted to raise food safety levels they simply adopted *Codex* standards—the standards were a fluid that filled gaps (when countries let the fluid flow). In the industrialized countries, however, the "acceptances with specific deviations" reflected efforts to adjust international standards to the already existing local ones.

The worry is that as markets open the number of gaps—especially in countries where administrative capacity is low—will grow, at least in the short term until countries catch up with the process of national risk assessment and management. International standards could thus play an especially important role in opening trade to new markets, new products and new methods of SPS protection. Examples currently on the agenda of the World Trade Organization include genetically modified organisms (GMOs), labeling, and a scheme for more consistent implementation of SPS measures known as hazard analysis and critical control point (HACCP). However, if nations are gridlocked in *Codex* because they fear binding application in the WTO they won't have adequate international standards to guide their efforts to address new SPS threats and new opportunities for improved SPS protection.

In sum, what began as a voluntary body has been transformed into a very different purpose. Conflicts that should have affected the standard-setting process—such as different views on the acceptable level of risk for products, food additives and residues of veterinary drugs and pesticides—were latent in the *Codex* system but have now developed fully. In the three Commission sessions that have been held since the SPS Agreement was concluded (1995, 1997 and 1999)—the Commission's work is increasingly mired in controversy because it is now viewed as more relevant to trade.

The Office International Des Épizooties (OIE)

The Office International Des Épizooties (OIE) is an intergovernmental body established in 1924 with the purpose of protecting animal health. It serves as the umbrella for numerous commissions that prepare codes, protection strategies, and manuals. Some commissions work on specific diseases (e.g., fish diseases or foot and mouth disease); others work on problems of specific geographical regions. The OIE periodically revises the *International Animal Health Code*,[22] which applies to mammals, birds and bees; it is also the model for a separate *International Aquatic Animal Health Code*.[23] Both codes include the requirement that countries analyze and manage risks of diseases that are transmitted across borders via international trade and give special attention to adopting measures for controlling diseases that have minimum adverse effects on trade. As with the SPS Agreement itself, the codes also require that countries make their risk analysis transparent and be able to justify their import decisions. In short, the codes thus provide a basis for establishing quarantines and other sanitary measures and for adjusting the severity of the measures according to the economic risks. However, the

requirements only strictly apply to diseases listed in each code; the lists are incomplete and thus offer only a starting point—countries are free to identify other diseases and regulate risks associated with them as well.

In addition to the codes, the OIE also produces guidelines for disease testing and surveillance programs and serves as a clearinghouse for current information on particular diseases (e.g., outbreaks). The work of these commissions is approved by the International Committee, the OIE's main decision-making body. The OIE is also the umbrella for numerous other collaborations help develop reference standards; various working groups promote debate that could lead to standards in areas such as biotechnology and wildlife. As of December 1999, 155 countries were members of the OIE.

International Plant Protection Convention

The International Plant Protection Convention (IPPC) entered into force in 1952 and was amended in 1979. It is intended to promote international coordination of measures necessary to limit the spread of plant diseases. The IPPC obliges countries to identify, assess and manage risks to plants, including risks from plant pests that are carried through international trade. "Guidelines for Pest Risk Analysis," developed within the framework of the IPPC, provide detailed information on how to assess and manage pest risks and require that countries develop import restrictions for protecting plant safety in conjunction with a broader plan for risk management.

The Convention requires nations to create official plant protection organizations that perform inspections, conduct research and disseminate information. (Most countries would have such organizations in place even without the Convention.) As with the SPS Agreement, it requires that countries adopt phytosanitary measures only to the extent necessary for phytosanitary protection. Countries must use the least restrictive trade measures, avoid unnecessary delays during inspection and quarantine, and ensure that phytosanitary measures are transparent.[24] The IPPC probably aids coordination of national plant protection policies—although some of that would occur anyway among those countries that want to coordinate—but it has not engaged in detailed standard-setting to the degree of the *Codex Alimentarius* Commission or the OIE.

II. THE SYSTEM AT WORK: THREE CASES

A full-blown assessment of how the SPS Agreement has affected the use of SPS measures should focus country-by country, measure-by measure. That is impractical. The number of trade measures that could be affected by SPS disciplines is potentially huge. So far, only a small fraction has been subjected to international scrutiny. Many changes to national SPS policies will be time consuming to implement; yet only four years have passed since the WTO agreements went into effect on 1 January 1995.

Thus the approach here is to examine the three WTO dispute settlement cases that have concerned SPS measures: the European Community's ban on imports of bovine meat produced with growth hormones ("EC meat hormones"),[25] Australia's ban on imports of fresh and frozen salmon ("Australian salmon")[26] and Japan's ban on imports of numerous varieties of fruits and nuts ("Japanese fruits and nuts").[27] These cases reveal how the SPS Agreement has been interpreted to date and thus are the most instructive means available for beginning to assess the impact of the SPS Agreement.

Prior to the WTO the dispute settlement procedure had few teeth and was, in essence, voluntary. Any GATT member could block adoption of a dispute panel report and thus block the formal remedies that might help to achieve compliance with trade rules and resolve the dispute. In practice the system was not completely anarchic, but nonetheless it was severely hobbled. The WTO system is more elaborate, has stronger tools at its disposal, is governed by strict timetables that help keep disputes from dragging out over years, and is less vulnerable to dissent. The WTO's Dispute Settlement Body (DSB) manages the process that begins with consultations and other efforts to resolve the dispute. If they fail then the DSB convenes a panel of three experts (the "Dispute Panel") to hear the arguments of the parties and third-parties, consult experts, interpret the relevant WTO obligations, and issue a report with rulings. Either party may appeal the rulings; three members of the standing seven-person Appellate Body reviews such appeals and issues a report with final rulings. The DSB must decide whether to adopt Panel and Appellate Body reports; only a consensus of WTO members may block adoption. (To date, no Panel or AB report has ever failed adoption.) Once the final report is adopted the offending country must comply within a "reasonable period of time."[28]

Formal disputes are important not only because they often address important trade barriers themselves but also because they create interpretations of the law, focus expectations on how the WTO system will handle possible future disputes, and deter other violations. If disputes demonstrate clear discipline and a credible threat to dismantle trade barriers then countries will be more likely to remove illegitimate SPS measures on their own. There is significant evidence that the extended effect may be significant—beyond the three measures that have been the subject of formal disputes, the SPS Agreement has been a "broader catalyst" that has induced some nations to remove illegitimate SPS measures.[29] Moreover, as with any properly functioning enforcement system, well-handled disputes can deter countries from imposing illegitimate SPS measures in the future. These extended and deterrent effects can be extremely important multipliers of the effect of individual disputes, but they are also difficult to assess. More work is needed to extend the results of this study—which focuses on three cases—to the systematic effect of the SPS Agreement.

The discussion here will present the basic facts and arguments in the cases.[30] In the next section I will suggest the major issues and conclusions that should be drawn when examining the whole system: The SPS Agreement, the international standard-setting bodies, and these three cases.

EC meat hormones[31]

The first case concerns an EC Directive, imposed in 1981 and strengthened in 1988 and 1996, to ban imports of meat from farm animals that had been administered natural or synthetic hormones. Exceptions were allowed for hormones that are used for therapeutic purposes but not for hormones used to promote growth in cows. American, Canadian and other beef producers used hormones to accelerate growth that reduced costs and yielded higher quality (leaner) meat. The United States had challenged the EC ban under the Tokyo Round "code" on technical barriers to trade, but the EC had blocked formation of an expert panel to examine the dispute. The conflict festered and became symbolic of why the voluntary Tokyo round codes and non-mandatory dispute settlement were incapable of imposing discipline on non-tariff barriers to trade.

At issue was whether the EC ban, which concerned 6 hormones, was compatible with the SPS Agreement. In 1995 the *Codex Alimentarius* Commission adopted standards (by narrow majority vote) for 5 of the 6 hormones in the dispute. The standards were based on the work of the Codex Committee on Veterinary Drugs in Foods and the recommendation of JECFA, which had reviewed the scientific evidence related to hormones twice. The *Codex* standards did not impose MRLs for the three natural hormones in question (oestradiol-17ß, progesterone and testosterone) because naturally-produced residues would far exceed the additional residue caused by "good practice" use of these hormones for promoting growth in cows. For the other two synthetic hormones (trenbolone and zeranol, which mimic the biological activity of natural hormones) the MRLs adopted were far below the residue that would be expected if good veterinary practices were followed. There were no *Codex* standards for melengestrol acetate (MGA), a synthetic hormone administered as a feed additive that was included in the EC ban.

The EC argued that the SPS Agreement explicitly allows WTO Members to adopt standards that are stricter than international norms if those standards are based on an assessment of risks. Every risk assessment of these hormones had shown that growth hormones applied according to good veterinary practices would result in no significant harm to humans—those assessments included two major reviews by JECFA (1988 and 1989) and at least two reviews commissioned by the EC itself.[32] The EC argued that although those studies suggested that there was no objective risk, numerous highly publicized incidents since the early 1980s during which hormones entered European food markets had made European consumers wary of beef.[33] A ban, the EC argued, was necessary to restore confidence in the market.[34]

The WTO Dispute Panel ruled against the EC on three grounds. First, it argued that the EC's measure was illegal because more permissive international standards existed for five of the hormones. The Panel interpreted Article 3.1 of the SPS Agreement, which declares that "…Members shall base their sanitary or phytosanitary measures on international standards" as a requirement that SPS measures *conform* with international standards.[35] In perhaps its single most important ruling on SPS-related issues the WTO Appellate Body explicitly overturned this interpretation, preferring instead the more common-sense definition of "based on:" a measure can be based on international standards without conforming with those standards. Instead of conformity, the Appellate Body pointed to Article 3's fundamental purpose: to promote the use of international standards while allowing countries to deviate from those standards if those deviations conform with Article 5 which pertains to the use of risk assessment.[36] This approach of the Appellate Body, although obviously more consistent with the purpose of the SPS Agreement than

the narrow interpretation imposed by Dispute Panel, was nonetheless a watershed—it removed a legal interpretation that could have resulted in international standards becoming the feared straitjacket.

Second, the Dispute Panel and Appellate Body also ruled that the EC measure was not based on a risk assessment as required in Article 5 of the SPS Agreement. The Panel and Appellate Body found that for five of the hormones that the EC had obtained assessments of some risks—in particular, a 1982 Report of the EC Scientific Veterinary Committee (the "Lamming Report") and two reports (in 1988 and 1989) by JECFA.[37] The Appellate Body underscored that risk assessments need not be based entirely on research in the physical sciences; nor must risk assessments examine only quantitative risks. However, the EC measure failed because the EC had not applied risk assessment techniques to the particular risks that the EC claimed were the basis of its SPS measures (an import ban). All of the valid risk assessments showed that "good practice" application of growth hormones was safe. The EC had argued, however, that a ban was necessary because misuse of hormones could cause excessive risks; the Appellate Body concluded that the EC had not actually presented an assessment of such risks.[38] Not only is there a procedural requirement to *obtain* a risk assessment; also, the Appellate Body declared: "The requirement that an SPS measure be 'based on' a risk assessment is a substantive requirement that there be a *rational relationship* between the measure and the risk assessment."[39] Because the EC failed to examine the risks its measure failed the "rational relationship" test, but the AB never explained the exact contours of would pass or fail.

For the sixth hormone (MGA) no valid risk assessment existed and thus, by definition, the EC measure was not "based on" a risk assessment.[40]

Third, the Panel found that the EC had violated Article 5.5 of the SPS Agreement by demanding different levels of SPS protection in comparable situations. Notably, the EC allowed carbadox and olaquindox to be used as antimicrobial feed additives that promoted the growth of pigs; yet the EC banned the use of hormones as growth promoters in cows although the hormones resulted in similar (or lower) risks to humans. The Appellate Body overturned that decision by declaring that the SPS level required by a country would be incompatible with Article 5.5 if it failed *each* of the following three tests: (1) the country did not require comparable levels of protection in comparable situations, (2) the failure to apply comparable measures in comparable situations is arbitrary and unjustifiable, and (3) the such measures result in discrimination or a disguised restriction on international trade.[41] The Appellate Body found that the EC had, indeed, applied different SPS levels in comparable situations and thus failed the first test.[42] The EC ban also failed the second test because the EC could not justify this difference in treatment. But the Appellate Body argued that the third test— whether "arbitrary or unjustifiable" differences in SPS levels harmed trade—was most important, and the complainants provided insufficient evidence that the EC measure failed that test. Allowing carbadox and olaquindox as feed additives on the one hand while barring hormones for promoting growth in cows on the other was not by itself evidence of a disguised barrier to trade. The Appellate Body concluded that the "architecture and structure" of the EC Directives was not the purpose of the EC rules that created this incongruous situation. The EC applied the same level of SPS protection (with a ban on hormones as growth promoters) equally to imports and domestic production. Nor had the United States or Canada submitted adequate evidence that the

different treatment had resulted in "discrimination or a disguised restriction on international trade."[43]

In sum, the Panel viewed the SPS Agreement as requiring strict adherence to international standards and sharply limiting a nation's right to determine its SPS levels and measures. The Appellate Body, which is more attuned to the political and social context in which the SPS Agreement and the WTO operate, gave importers much greater autonomy in setting SPS policy. Whereas the Panel found three main reasons to rule against the EC, the Appellate Body endorsed only one—the EC's failure to base its SPS measures on a risk assessment.[44]

Having lost the case the European Union has not complied. Politically, it would be extremely difficult for some democratically elected governments in Europe to reverse course and let hormone-treated beef on the market. If some countries are strongly opposed then it will be difficult for any European country to open its borders to these products as borderless trading within the EU would expose all to hormones. So, rather than comply the EU has been subjected to retaliatory tariffs by Canada and the U.S. In an effort to compensate for lost exports, the EU is negotiating preferential access for hormone-free beef from North America to the European market. However, it has taken a long time to certify the mechanisms that will be used to guarantee that exports are truly hormone-free; moreover, disputes have erupted over the level of concession that will be needed to offset the loss of the hormone-treated market.

Australian salmon

This dispute, the second involving SPS measures to result in a Panel decision, concerned an Australian regulation dating from 1975 that bans imports of fresh or frozen salmon in order to prevent 24 fish-borne diseases from spreading into Australia's pristine environment. Many of the diseases could adversely affect trout, which are vital to Australian sport fishing and tourism as well as Australia's small trout aquaculture industry. And the diseases could also harm the Atlantic salmon aquaculture farms, first established in 1986 in Tasmania, that export high value salmon to world markets and also sell their product on the local Australian market. To combat the threat, Australia required heat treatment for all imports from regions where fish might become infected with the diseases.

The Office International des Épizooties (OIE) listed two of these 24 diseases in the *International Aquatic Animal Health Code* category of fish diseases that are particularly dangerous threats for spreading. Such transmissible diseases "are considered to be of socio-economic and/or public health importance within countries and that are significant in the international trade of aquatic animals and aquatic animal products."[45] The OIE also listed four of the diseases in a category of fish diseases that are less well understood but potentially dangerous. For diseases on either list, OIE "Guidelines for Risk Assessment" require countries to undertake analysis to examine the "disease risks associated with the importation" and to tailor particular import controls to the real world situations in the country.[46] The remaining diseases were not listed by OIE and thus no special OIE guidelines were applicable.[47]

Canada, a major exporter of fresh and frozen salmon, challenged Australia's regulation. Canada did not dispute that Australia had the right to preserve a pristine environment—that is, in the jargon of the SPS Agreement, Australia had the right to determine its own "appropriate level of SPS protection." Canada argued that the quarantine was arbitrary because Australia did not apply similarly strict quarantine measures against other practices that could also spread disease in Australia. Australia had allowed imports of frozen herring bait fish and live ornamental fish that could much more easily transmit many of the 24 diseases into Australian waters, but it barred Canadian salmon. Bait fish are, by design, disposed directly into Australian waters where disease could easily pass to other fish. Ornamental fish often escape their ponds and aquaria; when they die they may be disposed without care for the risk of transmitting diseases to other fish in Australian waters. In contrast, headless and eviscerated fresh or frozen salmon from Canada had low incidence of the diseases and could transmit the disease into the Australian fish population only through a long and implausible chain of events.[48] None of the several existing risk assessments supported the Australian argument. As the EC argued in the Meat Hormones case, Australia maintained that although the risks were low, it could not be certain that headless eviscerated fish would not spread disease.

The Panel and Appellate Body ruled against the Australian measure largely on three grounds. First, the Appellate Body determined that Australia's ban on imports of fresh and frozen Canadian salmon was not based on an assessment of risks. In doing so, the Appellate body established a three-pronged test for what would qualify as a risk assessment: (1) identification of the diseases and possible biological and economic consequences of their entry or spreading; (2) evaluation the likelihood of entry, establishment or spreading; and (3) evaluation of the impact of SPS measures on the likelihood of entry, establishment or spreading of the diseases.[49] Australia's "1996 Final Report," which established the ban on imports of fresh and frozen salmon, met the first requirement. But the Appellate Body said that Australia had failed the other two. This finding overturned the Panel, which had ruled that the 1996 Final Report did constitute a "risk assessment." The Panel had followed the cue of the earlier Appellate Body report on EC meat hormones, which had suggested that the requirement of the SPS Agreement be "based on an assessment" allowed WTO members to include many diverse factors. But the Panel had wrongly assumed that that permissive standard also meant a low threshold for what qualified as a "risk assessment." The Panel concluded that the 1996 Final Report "to some extent evaluates" the risks and risk reduction factors and thus qualifies as a risk assessment, but the Appellate Body established a stronger test for compliance.

Second, the Panel and Appellate Body found that the salmon import ban was a disguised restriction on trade. Both the Panel and the Appellate Body stressed that Australia was free to determine its own level of SPS protection; however, they found that Australia did not apply that high level of protection in other comparable situations. By allowing imports of bait and ornamental fish, Australia exposed itself to greater risk than if it had permitted salmon imports; not treating these comparable risks in comparable ways revealed that the salmon import ban was a disguised restriction on trade. To reach this decision the Panel applied the three-step test that the Appellate Body had developed in the EC meat hormones case: (1) it decided that the situation of disease risks from salmon imports was comparable with the disease risks from ornamental and bait fish because they involved similar diseases, media and modes propagation; (2) such different treatment for salmon and other disease risks was "arbitrary or unjustifiable;" and (3) the different

treatment for salmon resulted in a disguised restriction on international trade. Whereas the third element of the test failed in the EC meat hormones cases, the evidence was much stronger in the salmon case. The evidence included the fact that the draft of Australia's salmon rules would have permitted the importation of ocean-caught Pacific salmon under certain conditions; but the final rule—based on substantially the same risk assessment, but issued *after* stakeholders such as the Australian salmon industry had commented—barred imports. That factor, compounded by many other "warning signals," led the Panel and Appellate Body to decide that the import ban was, indeed, a disguised restriction on trade.[50]

Third, the Panel decided that the particular SPS measure required by Australia—heat treatment of salmon prior to export to Australia—was more trade-restrictive than necessary to achieve Australia's level of SPS protection. Heat treatment, in effect, barred Canadian salmon from a lucrative segment of the market because heat treatment, by definition, converted fresh or fresh-frozen fish intdess valuable heat -treated fish. (Moreover, some experts consulted by the Panel suggested that heat treatment might actually raise the disease risks because elevated temperatures were not high enough to kill all pathogens and could cause some to grow more rapidly.) An alternative sanitary measure—requiring the beheading and evisceration of fish—would yield a similar level of SPS protection for Australia with a much less deleterious impact on Canada's exports. The Appellate Body appeared to be inclined to agree with the Panel, but it overturned this aspect of the ruling. The AB argued that SPS measure at issue was not heat treatment but rather the import ban on fresh and frozen salmon from Canada. (Because of that ban, the only means available to Canada to supply salmon to the Australian market was heat treatment.) The Appellate Body overturned the Panel because it could not be determine Australia's "appropriate level of protection." The Appellate Body underscored that "determination of the appropriate level of protection…was a prerogative of the Member concerned [Australia]…."[51]

Having lost on the central aspects of the case, the Australian government changed it rules. In 1999 it allowed limited access to the Australian market for fresh, chilled and frozen salmon from Canada. Early in 2000 a WTO Panel ruled that this limited access still violated WTO rules; in May 2000, the Australian and Canadian governments reached a settlement that allowed much wider access to the Australian market, including for "consumer ready" fillets and steaks from fresh wild caught and farmed fish.[52] That final agreement resolved the case.

Japanese fruits and nuts

The final case concerns a Japanese regulation that had the effect of requiring exporters of various fruits and nuts to submit each new variety they intended to export to Japan to an extensive regime to verify that fumigation with methyl bromide would effectively kill the eggs and larvae of coddling moths.[53] The case focused on four species (apples, cherries, nectarines and walnuts) although potentially had application to others.[54] The United States challenged the requirement as not based on an assessment of risks; it also argued that the varietal testing requirement imposed excessive costs and delays and thus was more trade-restrictive than required. The US contested only the measures that Japan had applied; it explicitly did not

question Japan's right to determine its "appropriate level of SPS protection"—that is, for Japan to ensure that it's pristine islands remain free of coddling moth.[55]

The Panel found that the Japan's testing requirements were inconsistent with the SPS Agreement for three reasons. First, the varietal testing requirement was not based on a risk assessment. (The failure to employ risk assessment also violated the IPPC's requirement to base plant protection measures on risk assessments. However, in practice, the IPPC's requirements were redundant of the SPS Agreement's obligation to base measures on risk assessment; thus the IPPC played no significant role in this dispute.) In particular, the Panel concluded that "it has not been sufficiently demonstrated that there is a rational or objective relationship between the varietal testing requirement and the scientific evidence submitted to the Panel."[56] Japan claimed that its goal was to ensure that new varieties would impose no danger of coddling moth infestation that was greater than the infinitesimal risk of infestation from varieties that had already undergone extensive testing. Each variety must be tested individually, Japan argued, because there may be a chance (although extremely small) that differences between varieties of fruits and nuts could lead to ineffective treatments that would let a coddling moth slip through. However, the Panel found that "…so far not a single instance has occurred in Japan or any other country, where the treatment approved for one variety of a product has had to be modified to ensure an effective treatment for another variety of the same product."[57] Moreover, the United States as well as experts advising the Panel had shown that varietal differences did not influence the efficacy of quarantine methods, and Japan had not presented adequate evidence to the contrary.[58]

Japan argued that Article 5.7 allowed countries to adopt stringent measures when "relevant scientific evidence is insufficient." The Panel underscored that Article 5.7 is an exception to the general risk assessment obligations of the SPS Agreement (i.e., Articles 2.2 and 5.1) that applies only to *provisional* measures. The language of Article 5.7 itself suggests that such provisional measures must meet four cumulative requirements:

- the measure is imposed where "relevant scientific information is insufficient;"
- the measure is adopted "on the basis of available pertinent information;"
- the Member must "seek to obtain the additional information necessary for a more objective assessment of risk;" and
- the Member must "review the … phytosanitary measure accordingly within a reasonable period of time."[59]

The Panel concluded that Japan had failed on at least both the third and fourth requirements.[60]

Second, the Panel also found that the varietal testing requirement was more trade restrictive than necessary and thus violated Article 5.6 of the SPS Agreement. Because there is no significant difference in the efficacy of fumigation techniques across different varieties of the same product, alternative measures—such as setting fumigation requirements on the basis of the easily measured "sorption level" of new varieties, rather than a full re-testing of each variety—would be less restrictive of trade yet still achieve the level of SPS protection that Japan requires.[61] The Appellate Body overturned this ruling because it was based on evidence marshaled by the Panel itself and thus the Panel had over-stepped its authority;[62] the United States had not, first, presented a *prima facie* case that a measure based on determination of

sorption levels would have achieved the same level of protection that Japan demanded.[63] Since the U.S. had not made *prima facie* case, Japan could not be obliged to rebut it.

Finally, the Panel and Appellate Body found that Japan had violated the requirement to make its SPS measures transparent, especially the requirement in Article 7 that measures publish their SPS measures. The Japanese varietal testing requirement was based on numerous de facto rules that were not easily understood by outsiders, which made it difficult for exporters to understand and comply with the requirements of the Japanese market.

Having lost this case, the Japanese government changed its fumigation rules and notified the WTO in January 2000 that it was in formal compliance with the SPS agreement.

III. WHAT CAN WE LEARN?

It is difficult to draw strong conclusions about the effect of the WTO's SPS Agreement on the stringency and harmonization of national SPS protection policies. The Agreement has been in operation for only 5 years; many developing countries were not required to implement the agreement fully during that period; and only a handful of disputes have allowed some interpretation of the Agreement's critical provisions. Thus here I speculate on the lessons learned and focus on the same closely interlocking questions that I posed at the outset:

- What is the impact on national standards?
- Is the agreement leading to harmonization or diversity?
- Is there any trend toward tighter or looser standards ("trading up" or "trading down")?

It is clear that the Agreement is not leading to strict harmonization of SPS measures and levels. The Dispute Panel in the hormones case attempted to interpret the Agreement as requiring such strict harmonization, but the Appellate Body decisively rejected that interpretation. Indeed, the Appellate Body has interpreted the original Agreement as allowing even greater flexibility for nations to set their own SPS measures than a strict reading of the SPS Agreement would imply. For example, the Appellate Body has made an expansive interpretation of the term "risk assessment" and has created an elastic "rational relationship" test for assessing whether a nation's SPS measures are based on risk assessment.

Nor has the SPS Agreement resulted in much impact on national standards by transferring decision-making authority away from national governments and toward international standard-setting bodies such as the *Codex Alimentarius* Commission. Many critics had feared this outcome because these international bodies, they charged, were undemocratic and captured by industrial interests.[65] Understandably, public interest groups have been worried that their voices won't be heard when the *Codex* determines standards—with few exceptions, they have been poorly represented at *Codex* meetings.[66]

In each of the three WTO panel cases, international standards were referenced in the resolution of the disputes. But *none* of the outcomes from the disputes was affected by the existence of an international standard. The EC hormones case made most extensive use of international standards, but that was because the *Codex* system—in particular JECFA (which is

formally external to *Codex*)—had extensively reviewed the science related to hormones. Even so, the dispute panels did not rely exclusively on the JECFA reviews. Rather, the Panel (advised by experts it had retained) looked at the entire scientific literature, which included several non-JECFA reviews of hormone risks. The JECFA reviews were helpful and set a clear benchmark for quality scientific assessment, but the other scientific reviews came to the same conclusions. Moreover, by overturning the narrow interpretation of the SPS Agreement as requiring *conformity* with international standards, the Appellate Body underscored that international standards were at best a starting point for countries that wanted to deviate from them. Indeed, the existence of international standards was irrelevant for the main line of legal reasoning that decided the EC meat hormones case—the failure for the EC to have some "rational relationship" between risk assessment and the measures it imposed. The lack of any international standard for one of the six hormones (MGA) did not excuse the EC from the obligation to base even its ban of that hormone on a risk assessment. The AB's decision on MGA was the same as for the 5 hormones for which *Codex* standards existed.

The minimal influence of international standards is even more evident in the Australian salmon and the Japanese fruits and nuts cases. In those cases the OIE and IPPC, respectively, had few, if any, standards that were directly applicable to the issues in the disputes. Only a few of the fish diseases on the lists of diseases are in the OIE's *International Aquatic Animal Health Code*, and thus only for those did OIE specifically enable trade restrictions. For the other diseases, OIE was largely silent. Both OIE and the IPPC promulgated general standards for risk assessment that could be applicable in those cases where more specific international methods and standards did not exist, but those guidelines were so broad as to be essentially irrelevant to the resolution of these two cases. Since there is little evidence that international standards have had much impact on behavior—at least in these three disputes—it may also be true that these standards are not a conduit for a harmonization of SPS protection rules. In these three cases there is no evidence of harmonization "up" or "down." It is possible, as I suggested earlier, that the controversy over standard-setting has led to less useful standards and, in turn, to lower levels of SPS protection on emerging issues, especially in developing countries—but that remains a quite hypothetical argument (and deserves closer attention).

Perhaps the fact that SPS measures were struck down in all three cases is evidence that the WTO system is prone to find violations and is thus causing downward pressure on standards. However, the outcome—three cases and three defeats—is easy to explain: launching WTO disputes is extremely costly, and governments are unlikely to bring them unless they are confident of winning. Offending governments don't abandon the cases because SPS policies are politically extremely sensitive. And thus the WTO system is prone to yield winner cases that are shrouded in rhetoric claiming that the WTO system is leading to a decline in SPS protection. If the science is believable, however, in all three of these cases alternative SPS measures were available that would lead to the same *level* of SPS protection with less distortion of trade.

Are these cases are creating a dark precedent—a deterrent effect that is leading countries to adopt less stringent SPS measures in a host of other cases? This question is harder to answer because deterrence is hard to measure. One answer is found by observing the brewing trade dispute over genetically modified (GM) foods. The case appears to parallel closely the basic facts of the hormones dispute. The science about safety of GM foods is incomplete but, so far,

remarkably consistent in upholding the safety of those products that are on markets already. Consumers are increasingly concerned about the safety of GM foods; their rising concern reflects the contagion of public concern more than the appearance of new scientific evidence. In addition, European farmers could lose if they are forced to compete with more efficient overseas producers. Some countries (e.g., Austria) have vehemently opposed allowing imports of GM foods while others are more tolerant, but the single European market requires a single European regulatory approach. Mired in controversy, the European Commission has adopted a *de facto* moratorium on approval of new genetically modified foods—which hurts exports from firms in the U.S. and elsewhere that produce and grow GM crops—and is under pressure to ban all imports of GM products. Does the hormone case demonstrate that Europe will be forced to open its doors more widely to GM foods? Mindful that it lost the hormones case, is Europe's reluctance to impose an outright ban on these foods—which most consumer groups in Europe are demanding—evidence of the chilly deterrent that is exposing European consumers to risks that they don't want?

Indeed, the GM case shows that the SPS Agreement is having an effect—on *procedures* for setting trade-related SPS measures, but not on the *level* of food safety. Mindful of the SPS Agreement, governments are "playing the SPS game" differently. For new uncertain risks, such as GM foods, the game is to adopt provisional measures and then to establish a (never-ending?) process to complete the scientific assessment of risks. That approach, within some (still unclear) limits, is permissible under Article 5.7 of the SPS Agreement. This is the first serious application of the "precautionary principle" in a trade agreement, and it is mirrored in the Biosafety Protocol adopted in early 2000. Furthermore, to the extent that European regulators are worried about the risks to consumers from GM foods they will likely require labeling of GM products. The validity of such labels is an issue for the Technical Barriers to Trade (TBT) Agreement of the WTO and is outside the scope of this paper, but as a matter of food safety they allow individuals to make their own choices. If some choose to consume these products then trade will increase; food safety for those that avoid products is not harmed.

Thus the SPS Agreement has not required weakening of SPS measures that countries apply to protect humans, animals and plants. But it may have a different, much larger effect on how countries manage risks. In all three of the disputes one of the critical complaints has been that import bans were arbitrary—challengers argued that the importers had used less restrictive measures in other comparable situations. Although not all of those complaints were successful, the intense focus on ensuring comparable treatment has put all members of the world trading system on notice that they must be able to justify SPS regulations that were previously regarded as purely internal policy matters.

If countries are under constant pressure to justify that they adopt comparable SPS measures in comparable situations then they are likely to give much greater attention to internal alignment of risk assessment and management policies—in other words, they are more likely to ensure that comparable levels required in comparable situations. They are also more likely to ensure that the particular measures they impose are based on risk assessment. The consequences of these external pressures will include much greater application of risk assessment and more transparent national SPS rules. That could be a boon for those who advocate the making of public policy according to sober assessment of risks. It will be difficult to discern how much of

this shift towards risk management is the consequence of the SPS Agreement rather than simply the consequence of the spreading norm that favors rational risk management as one pillar of good government. The recent decision by the European Commission to create an independent group of expert advisors on food safety matters illustrates the problem in assessing cause and effect. That expert group should allow more rational management of risks, which should reduce the tendency for EC rules to run afoul of the SPS Agreement. However, the decision to create that group was mainly the consequence of declining public confidence in food safety regulation after the poor handling of the BSE ("mad cow disease") crisis, rather than the result of international pressure related to the SPS Agreement.

The net effect of much greater transparency and internal alignment of risk management should result in more *trade*, but the effect could be very small. Greater transparency should facilitate trade by making it easier for importers to identify and comply with applicable rules; the Japanese fruits and nuts case makes is clear that transparency requirements in the SPS Agreement will be enforced strictly. Greater transparency may also make it easier for exporters to declare that they have imposed SPS measures that are "equivalent" to the SPS protection required by importing countries. In democratic societies, more transparency may also make governments less likely to adopt rules that would be embarrassing and vulnerable to attack. The requirement that SPS measures not be more trade restrictive than necessary should also facilitate trade. The requirement that governments align risks at "comparable levels" will eliminate grossly protective SPS measures—as in the three cases reviewed here—which should open trade.[67]

However, greater use of risk management and the requirement to align risks at "comparable levels" may have little net effect on SPS protection levels. Some measures may not be adopted because of fears that they will violate the SPS Agreement, but we have already seen that countries enjoy extensive freedom to devise ways to avoid conflicts with the Agreement. In some cases, more attention to risk alignment may lead to tighter SPS protection. One of Australia's main responses to the argument that allowing imports of potentially disease-carrying live ornamental fish was incompatible with their ban on imports of fresh and frozen salmon was to point out that it was reviewing the rules that govern imports of ornamental fish (and other potential disease carriers).[68] Similarly, the European Community's response to the inconsistency between allowing the use of known carcinogens (carbadox and olaquindox) while prohibiting hormones used for growth promotion was to underscore that the carcinogens were under review and might be regulated more tightly.[69]

More generally, increased attention to evaluating risks is likely to result in a greater number and diversity of SPS measures. As societies have become more aware of risks and better able to afford risk management they have demanded more stringent social regulation. Within this context, international rules that force countries to look more closely at their SPS policies are likely to yield more SPS measures by accelerating the tendency for countries to impose SPS measures. And, the SPS measures that countries do adopt are more likely to be tuned to local conditions and interests if they are explicitly based on risk assessment. It is thus plausible—perhaps even likely—that the result of greater attention to SPS measures will be *greater diversity* in SPS levels and measures, not harmonization.

IV. CONCLUDING THOUGHTS

This paper has reviewed the provisions of the 1994 SPS Agreement and all three WTO Disputes that have related to the application of the SPS Agreement. It has argued that large areas of interpretation remain open. However, the cases to date have underscored that nations have wide latitude in setting their SPS protection levels and measures. Thus far from imposing a strict harmonization between national and international standards—which was the main fear of the Agreement's detractors—the Agreement actually allows diversity to flourish. Harmonization of SPS *levels* and *measures* is not under way. Nor is there evidence of any significant change—towards stringency or laxity—in SPS protection levels.

However, the agreement is having two procedural effects. One is harmonization of national SPS *procedures*, such as the requirement for risk assessment. The other, not evident from these three cases but likely as governments ponder the lessons from these cases, is to favor increased use of the "precautionary principle" (Article 5.7) when governments try to defend SPS policies that are based on dubious or incomplete risk assessments.

To close, I note that procedural harmonization without the strict requirement for harmonization of levels and measures may help to mute the backlash against globalization that, in part, is animated by the fear that national sovereignty is being lost to undemocratic international standard-setting bodies. Such harmonization could be an attractive model for other areas of national policy—such as environmental regulations—that both serve legitimate purposes as well as pose potential trade barriers. The SPS Agreement shows how such a system could be designed, but it also underscores that there are no easy remedies for the backlash against globalization. In the hormones case, even the wide latitude afforded to European regulators did not avert the backlash caused by strong consumer support for the hormone ban. Nor is there an easy way to promote free trade by taming nontariff trade barriers. The clearest conclusion from this study is not that the SPS Agreement is trampling national freedom of action but, rather, how little influence it has exerted.

Notes

1. For a comprehensive treatment of the cases that were handled, see: Hudec, R.E. 1993, *Enforcing International Trade Law: The Evolution of the Modern GATT Legal System* (Salem: Butterworth Legal Publishers).
2. A. Tutwiler, 1991, "Food Safety, the Environment and Agriculture Trade: The Links," International Policy Council on Agricultural Trade, Discussion Ppaers, series no. 7, June, p.2, cited in: David Vogel, 1995, *Trading Up: Consumer and Environmental Regulation in a Global Economy* (Cambridge: Harvard University Press). For a current overview of all technical barriers to trade in U.S. agriculture exports see: Donna Roberts and Kate DeRemer, 1997, "Overview of Foreign Technical Barriers to U.S. Agricultural Exports," *ERS Staff Paper*, No. 8705, Economic Research Service, Commercial Agriculture Division, U.S. Department of Agriculture.
3. In addition, the WTO agreement included four "plurilateral" agreements (on aircraft, government procurement, dairy products, and bovine meat) that were adopted in 1994 along with the Core WTO agreements. Unlike the "multilateral" obligations that all WTO members must implement, plurilateral agreements are optional. They are not

necessarily useless because an agreement—even if voluntary—helps to signal proper conduct and facilitate cooperation. Moreover, often voluntary agreements lay the groundwork for later agreements that are binding and backed by an enforcement mechanism. For example, the conclusion of the 7th round in 1979 included a plurilateral code on technical barriers to trade; the failure of that code to have much effect led to the creation of similar, but binding, multilateral TBT and SPS agreements that were adopted in 1994 along with the other WTO agreements.

4. The Agreement's preamble underscores the goal: "*Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations…." The Agreement declares that "Members shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations…. (Article 3.1)." When a member imposes SPS measures that conform with international standards, guidelines or recommendations, those measures will automatically be "presumed to be consistent with the relevant provisions of this Agreement… (Article 3.2)." However, countries may introduce measures that are stricter than international standards "if there is a scientific justification, or as a consequence of the level of [SPS] protection a Member determines to be appropriate in accordance with the relevant provisions…of Article 5 (Article 3.3, emphasis added)." The SPS agreement also includes a footnote at this point: "For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection." Although the obligations and reasoning are a bit convoluted, this footnote has been interpreted as meaning that measures that deviate from international standards are acceptable if based on a risk assessment—that is, if they meet the requirements of Article 5, which includes the requirement of a risk assessment (Article 5.1). In plain language: Article 3 promotes harmonization with international standards. And Article 5 allows countries to escape the straitjacket of international standards, provided that an assessment of risks is the first step in setting such stricter SPS measures.
5. For simplicity, hereafter I use the term "international standards" to denote "international standards, guidelines, or recommendations." While the full term is important for legal purposes because it is broader, the simpler plain English term is most appropriate for this paper. One of the remaining gray zones in applying the Agreement concerns just how broadly to apply this definition. For example, as I review below, the *Codex Alimentarius* Commission adopts not only specific standards (e.g., on food additives) but also more general standards for commodities and advisory guidelines. Does the WTO Agreement apply to all three, even though *Codex* guidelines were never designed nor intended to have binding application?
6. For simplicity I will use the terms "country" and "WTO Member" interchangeably. For purposes of discussing legal obligations I will also treat countries as single units. However, some SPS measures (e.g., quarantines) apply only to certain parts of countries and thus have trade effects only for imports (from outside as well as inside the country) into that part of the country. Examples include quarantines for many exports to Hawaii,

which are stricter than exports to the rest of the United States. Moreover, although the obligations of the WTO agreements are imposed on "Members," it is not necessary that *governments* perform all of the required tasks. Often risk assessments and trade controls are implemented by NGOs (especially private firms, industrial associations and scientific laboratories), with government acting only a supervisor. (See SPS Agreement, Article 13.)

7. The SPS Agreement also includes a specific application of the "equivalent" requirement, which is especially important for SPS measures: pest- and disease-free areas. Countries that can demonstrate that all or some of their country is free from a hazard are allowed to circumvent SPS measures that are intended to block diseases on products from that country. (See Article 6.)
8. For example, see Silverglade, Bruce A., 1998, "The Impact of International Trade Agreements on U.S. Food Safety and Labeling Standards," *Food and Drug Law Journal*, vol. 53, pp. 537-541; "Consumer Groups, Officials Demand Strong U.S. Action at Codex Commission Session," *World Food Chemical News*, vol. 4, No. 5, p.3; Jacobson, Michael F., 1997, "Comments of the Center for Science in the Public Interest," Consideration of Codex Alimentarius Standards, Advance Notice of Proposed Rulemaking, U.S. Department of Health and Human Services, Food and Drug Administration, Docket 97N-0218. There have been numerous letters to the President of the United States, responses to proposed rulemaking, and other political actions based on similar arguments.
9. The legal reasoning is a bit convoluted because the SPS Agreement is also convoluted and layered on this point. For the link between Article 3.3 and Article 5 see Article 3.3 itself, which specifically cites Article 5 as a justification for deviation from international standards. (However, the citation is odd because it suggests that a Member may employ a "scientific justification" *or* Article 5 when, in fact, they have been interpreted as the same.) Moreover, see the footnote to Article 3.3 cited above (ref. 4). For a statement on the need to examine Article 5 in order to interpret the basic rights and obligations enumerated in Article 2 see: Appellate Body, "EC Measures Concerning Meat and Meat Products (Hormones)," WT/DS26/AB/R & WT/DS48/AB/R (16 January 1998), AB-1997-4, which argues that: "Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1. (para 180)." In addition, the same report (para. 212) notes that Article 2.3 must be read together with Article 5.5—the former declares a general obligation, and the latter elaborates "a particular route" for determining whether the general obligation has been met.
10. The WTO disputes related to risk assessment have focused on Articles 5.1 and 5.2; Article 5.3 is also relevant because it outlines the type of information that should be included in a risk assessment. Article 5.7 concerns provisional measures taken when information is insufficient and is an extension of the basic risk assessment requirements in Articles 5.1, 5.2 and 5.3. In the EC Meat Hormones case the WTO's Appellate Body noted that Article 5.7 is a reflection of the precautionary principle—in particular, strict measures may be put into place on a temporary basis if information is insufficient (similar statements are found in the sixth paragraph of the preamble and in Article 3.3). However, the precautionary principle and Article 5.7 do not override the requirement to base measures on a risk assessment as denoted in Articles 5.1 and 5.2. See WT/DS26/AB/R & WT/DS48/AB/R, paras 120-125. For more on the tests that must be

met to qualify under Article 5.7 see the discussion of the Japanese fruits and nuts case, below.

11. The other related provisions are, in particular, Articles 2 and 3 and the definitions in Annex A.
12. There is a small qualifier to this statement. Article 3.3 also says that Members may impose SPS measures "…which result in a higher level of [SPS] protection…" *if* one of two conditions is met: the measures are based on a "scientific justification" or the measures are in conformity with Article 5. The concept of "scientific justification" is defined in a footnote (see ref. 4) such that, in practice, "scientific justification" means based on a risk assessment. The provisions for risk assessment are outlined in Article 5 and in Annex A ("definitions") of the SPS Agreement. Thus the discipline on the *level* of SPS protection that a country may establish funnels through Article 5, and the only part of Article 5 that explicitly addresses the *level* of SPS protection is Article 5.5.
13. This is especially evident in the EC's meat hormones ban and Australia's ban on imports of fresh and frozen salmon, which are the only two cases where a country's *level* of SPS protection has been challenged directly. In both cases, the level of protection that the importing country sought was zero risk because the country had imposed a ban on imports. Thus testing whether the bans were consistent with the requirement to base SPS measures on risk assessment was, de facto, a test of whether the goal of zero risk was based on risk assessment.
14. Two statements in the preamble make this point: "*Recognizing* the important contribution that international standards, guidelines and recommendations can make in this regard…" and "*Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards…." In contrast, the preamble does not mention risk assessment or rules to govern deviations from international standards as principal objectives.
15. This section is based mainly on Victor, David G., 1998, "The Operation and Effectiveness of the Codex Alimentarius Commission," in: *Effective Multilateral Regulation of Industrial Activity: Institutions for Policing and Adjusting Binding and Nonbinding Legal Commitments*, Ph.D. Thesis, Department of Political Science, Massachusetts Institute of Technology. For the early history of Codex see: Leive, D.M., 1976, *International Regulatory Regimes: Case Studies in Health, Meteorology and Food*, 2 volumes, (Lexington: Lexington Books for the American Society of International Law); Kay, D.A., 1976, *The International Regulation of Pesticide Residues in Food* (Washington: American Society of International Law). And for a study with particular attention on pesticide (residue) standards see: Boardman, R., 1986, *Pesticides in World Agriculture: The Politics of International Regulation* (New York: St. Martin's Press), chapter 4.
16. See Victor (1998), *op cit.* ref. 15 and also Victor, David G., 2000, "Risk Management and the World Trading System: Regulating International Trade Distortions Caused by National Sanitary and Phytosanitary Policies," in: *Incorporating Science, Economics and Sociology in Developing Sanitary and Phytosanitary Standards in International Trade: Proceedings of a Conference* (Washington: National Academy Press), ch. 6, online at: http://www.nap.edu/catalog/9868.html; and see Victor, David G., 2000, "The Sanitary and Phytosanitary Agreement of the World Trade Organization: An assessment after five

years," *New York University Journal of International Law and Politics*, vol. 32, No. 4 (summer), pp. 865-937.

17. The process also ensures that the MRLs adopted are consistent with testing equipment and practices for food safety inspection so that the standards are relatively easy to implement.
18. See statements by the experts in "Annex: Transcript of the Joint Meeting with Experts, held on 17-18 February 1997," WT/DS26/R/USA, for example paras, 743, 819, 824, and 826.
19. See ref. 5.
20. Most of the full acceptances by advanced industrial (OECD) nations were notified by the least developed of the OECD members, such as Portugal.
21. Office International Des Epizooties, *International Animal Health Code* (Seventh Edition, 1998).
22. Office International Des Epizooties, *International Aquatic Animal Health Code* (Second Edition, 1997).
23. The statements here apply strictly to the 1952 IPPC (with revisions that came into force in 1991). A New Revised IPPC was adopted by the FAO Conference in 1997, but it has not entered into legal force. The new treaty explicitly aligns the requirements of the IPPC with the SPS Agreement, but in practice that has required few significant deviations from the 1952/1991 IPPC Agreement. One significant revision is that the new treaty will create a Commission on Phytosanitary Measures that can provide a standing body to address issues that arise; that body could be important for fine-tuning plant-related SPS issues since such matters will probably be more technical than would be appropriate for handling within the SPS Committee (created by the SPS Agreement). Although the new IPPC is not in effect, guidelines for Pest Risk Analysis—adopted in 1995 in parallel with development of the new treaty—probably do apply, regardless of their legal status, because the SPS Agreement has an expansive requirement to base SPS measures on "international standards, guidelines, and recommendations developed by the relevant international organizations.…"
24. * This is actually two cases—one originating from a US complaint and one from a Canadian complaint. But both were heard by the same panel, employed the same experts, were conducted on parallel decisionmaking tracks, and had the same outcome. See World Trade Organization, "EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States," Report of the Panel, WT/DS26/R/USA (18 August 1997); World Trade Organization, "EC Measures Concerning Meat and Meat Products (Hormones), Complaint by Canada," Report of the Panel, WT/DS48/R/CAN (18 August 1997). Both of these cases were appealed, and the WTO Appellate body issued a single report on the two measures: World Trade Organization, "EC Measures Concerning Meat and Meat Products (Hormones)," Report of the Appellate Body (AB-1997-4), WT/DS26/AB/R, WT/DS48/AB/R (16 January 1998). Finally, the question of what constituted a "reasonable period of time" during which the EC must bring its measure into line was submitted to binding arbitration, which determined that the EC must comply no later than 13 May 1999 (15 months after 13 February 1998, the date of the adoption of the Appellate Body and Panel Reports by the WTO's Dispute Settlement Body). For the outcome of the arbitration see: World Trade Organization, "EC Measures Concerning Meat and Meat Products (Hormones)," Arbitration under Article 21.3(c) of

the Understanding on Rules and Procedures Governing the Settlement of Disputes, WT/DS26/15, WT/DS48/13 (29 May 1998).

25. World Trade Organization, "Australia—Measures Affecting Importation of Salmon," Report of the Panel, WT/DS18/R (12 June 1998). The case was appealed: World Trade Organization, "Australia—Measures Affecting Importation of Salmon," Report of the Appellate Body (AB-1998-5), WT/DS18/AB/R (20 October 1998). Citations to the Appellate Body Report are in the form of page numbers because paragraph numbering is not accurate in the available (online) version of that Report.
26. World Trade Organization, "Japan—Measures Affecting Agriculture Products," Report of the Panel, WT/DS76/R (27 October 1998); World Trade Organization, "Japan—Measures Affecting Agriculture Products," Report of the Appellate Body WT/DS76/AB/R (22 February 1999).
27. See "Understanding On Rules And Procedures Governing The Settlement Of Disputes," Annex 2 of "Agreement Establishing the World Trade Organization." On the matter of a "reasonable period of time"—which is intended to be typically no longer than 15 months—see the Arbitrator's report in the EC meat hormones case at ref. 24.
28. Roberts, Donna, 1998, "Preliminary Assessment of the Effects of the WTO Agreement on Sanitary and Phytosanitary Trade Regulations," *Journal of International Economic Law*, pp. 377-405, esp. pages 396-398.
29. The discussion of the cases is purposely simplified. The goal here is not to identify the twists and turns in the legal and technical arguments. Rather, it is to identify the main arguments that proved to be most important in resolving the case and thus are likely to have the strongest value as precedents for future cases. The excerpts are based on analysis of the full Panel and Appellate Body reports (cited at refs. 24, 25, and 26).
30. For more on the origins of this dispute see David Vogel, 1995, *op. cit.*ref. 2, chapter 5; for more on the WTO aspects of the dispute see Steve Charnovitz, 1997, "The World Trade Organization, Meat Hormones, and Food Safety," *International Trade Reporter*, vol 14, No. 41 (15 October), pp. 1781-1787; Donna Roberts, 1998, *op. cit*, ref. 28.
31. *32nd JECFA Report*, published in 1988 ("1988 JECFA Report"); *34th JECFA Report*, published 1989 ("1989 JECFA Report"); Report of the Scientific Group on Anabolic Agents, Interim Report, 22 September 1982 ("Lamming Report"); EC Scientific Conference on Growth Promotion in Meat Production, 29 November to 1 December 1995 ("1995 EC Scientific Conference"). For a conclusion from the 1995 EC Scientific Conference that starkly states that growth hormones are safe see Maddox, J., 1995, "Contention Over Growth Promoters," *Nature*, vol. 378, p. 553.
32. The EC did cite some risk assessments that pointed to a risk of cancer due, broadly, to hormone exposure. However, those assessments did not examine the risks associated with particular hormones and were not treated as relevant evidence by the Panel, especially as numerous other more focused assessments showed no particular risk.
33. For the arguments, including quotes from European Parliament reports favoring a ban, see WT/DS26/R/USA, paras 2.26-2.33.
34. In particular, the Panel decided that "based on" meant that the SPS measure should afford the same level of SPS protection as the international standard. See WT/DS26/R/USA, para 8.72.
35. See WT/DS26/AB/R & WT/DS48/R, paras 160-177.

36. Other reports were also presented by the EC and other members as "risk assessments" but they were discounted. Some were cursory examinations of the issues. In particular, the EC's strongest evidence that hormones caused risks were in reports (the "IARC Monographs") that examined only categories of hormones or the hormones at issue in general. Those studies were discounted as not adequately focused. See WT/DS26/AB/R & WT/DS48/R, paras 195-202.
37. WT/DS26/AB/R & WT/DS48/R, paras 207-208.
38. WT/DS26/AB/R & WT/DS48/R, para 193 (emphasis added).
39. WT/DS26/AB/R & WT/DS48/R, para 201. Due to the lack of evidence, the EC might have maintained the ban on MGA as a "provisional" measure under Article 5.7 of the SPS Agreement. However, the WTO Dispute Panel dismissed that argument because the EC did not claim the measure was "provisional" and concluded that the ban on MGA still would need to comply with the other provisions of the SPS Agreement (e.g., the requirement to conduct a risk assessment). See WT/DS26/R/USA, para 8.248 to 8.249 and paras 8.250 to 8.271. The EC might have overturned at least part of that ruling on appeal which could have, perhaps, allowed the MGA ban to stand under Article 5.7's allowance for strict measures in the face of uncertainty (in essence, the "precautionary principle"). However, this was not a central issue in the appeal and the AB did not rule on that particular argument (i.e., Article 5.7) directly; and generally the AB did not view the "precautionary principle" as giving countries wide latitude (see ref. 10).
40. The Appellate Body derived this three part test in part from Article 5.5, which requires that "each Member shall avoid arbitrary or unjustifiable distinctions in the levels [of SPS protection] it considers to be appropriate in different situations." The interpretation of that requirement requires, in part, looking to Article 2.3 of the SPS Agreement which is part of the Agreement's basic rights and obligations: "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, *including between their own territory*… (emphasis added.)" For the three-part test see WT/DS26/AB/R & WT/DS48/AB/R, paras 210-246.
41. In addition to allowing the use of carbadox and olaquindox while banning growth hormones in beef, the WTO Panel had also suggested that there were many other examples where the EC had not applied comparable levels of protection in comparable situations. The Panel drew particular attention to the fact that the natural residues of these hormones were higher in some foods—such as eggs and broccoli—than would occur if applied as growth promoters. The Appellate Body rejected these comparisons because the addition of hormones for growth promotion was different from the natural presence of hormones in food—the former concerns an intervention by humans in the food production process, whereas the latter is a fact of nature that humans can't alter without a "comprehensive and massive governmental intervention in nature." See WT/DS26/AB/R & WT/DS48/AB/R, para 221.
42. For the third part of the test see WT/DS26/AB/R & WT/DS48/AB/R, paras 236-246.
43. Of course the dispute also touched on many other issues—here I have raised only the most important ones that related directly to the interpretation of the SPS Agreement and the effect of the SPS Agreement on nations' SPS policies. Among the other issues is the burden of proof. The Panel argued that the importing (defending) country had the obligation to prove the consistency of its SPS levels. The Appellate Body argued that the

complainant must first establish a *prima facie* case that the defending country violated the SPS Agreement; only then must the defender disprove the claim. The Appellate Body also addressed proceduralissues related to the handling of matters related to the WTO's dispute settlement procedures and whether a dispute could be prosecuted for measures, including the EC hormone ban, that were imposed before 1 January 1995 (the date when the WTO Agreements came into force).

44. Office International Des Epizooties, *International Aquatic Animal Health Code* (Second Edition, 1997), Section 1.1.
45. The Guidelines are codified in the *International Aquatic Animal Health Code*. See: Office International Des Epizooties, *International Aquatic Animal Health Code* (Second Edition, 1997), Sections 1.4.2.1 through 1.4.2.3.
46. The *International Aquatic Animal Health Code* does include a more general requirement that countries conduct "import risk analysis to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of aquatic animals, aquatic animal products, aquatic animal genetic material, feedstuffs, biological products and pathological material." (Section 1.4.1.1). A liberal interpretation of the *Code* would suggest that that requirement applies generally to imports and not only to listed diseases. However, the *Code* explicitly allows countries to determine their own methodology for conducting such analysis; countries can use procedures outlined in OIE reference documents for conducting such analysis, but they are not required to do so (Section 1.4.1.3). Moreover, the broad requirement to conduct import risk analysis also exists in the SPS Agreement. Finally, the definition of "disease" in the*International Aquatic Animal Health Code* strictly applies only to diseases that are included on one of the *Codes* two lists.
47. An example of the chain of events required: a disease-ridden fish carcass would be disposed in thesewers, sewage would leak into waterways, and waterways would then carry the disease (perhaps via an intermediate host) into the Australian fisheries. Canada argued that the probability of each step was low and, in total, the probability of the full chain of events was extremely low. The case focused on pacific wild salmon, which were the most important potential Canadian export and had been the subject of a special effort by Canada and the United States to perform a risk assessment and obtain export permission from Australia. Later that same risk assessment process would be extended to other species. Such risk assessment must differentiate between populations and species because the incidence of disease and risk of transmission probably vary.
48. The three-pronged test is based on Article 5.1 and Annex A (paragraph 4) of the SPS Agreement. For the test see WT/DS18/AB/R, page 73.
49. The Panel's ruling on all the major issues in this case was developed by focusing on ocean-caught Pacific salmon because those were the first that Canada sought to export. However, similar issues arose for other salmon since the import ban applied to all Canadian fresh and frozen salmon, and where possible the Appellate Body extended its ruling to cover other salmon as well. (Salmon stocks must be considered separately because some of the disease risks vary with the ecosystem in which the salmon are caught.) For the three part test applied to ocean-caught Pacific salmon see WT/DS18/AB/R, pages 80-93. For the test applied to other salmon see WT/DS18/AB/R, pages 108-111.

50. The ambiguity reflects that Australia's measure (the import ban) was not based on a risk assessment—in particular, it failed to assess the risk reduction that might be caused by alternative SPS measures. Australia maintained that its level of protection was "very conservative" (Panel report, para 8.107); but its prohibition on imports suggested that the actual level of SPS protection that Australia sought was zero-risk. On ocean-caught Pacific salmon see WT/DS18/AB/R, pages 93-104; for other salmon see WT/DS18/AB/R, page 112. For the quotation here see page 99.
51. "News Release: Canada and Australia Reach Agreement on Salmon," Office of the Minister for International Trade, Government of Canada, Ottawa (16 May 2000).
52. The case also included attention to non-fumigation techniques (cold treatment). The treatment varies not only with the characteristics of the fruit/nut but also the season of harvest because coddling moths exist in different forms (e.g., eggs, larvae, adults) in different seasons. Different varieties have different harvest times, and thus Japan argued that test results for one variety were not applicable to another.
53. The United States challenged the Japanese varietal testing requirement for all "US products on which Japan claims that coddling moth may occur," which included apricots, pears, plums and quince. But the US had not provided a *prima facie* case that the Japanese testing requirement was maintained "without sufficient scientific evidence." The US met that standard for apples, cherries, nectarines and walnuts but not for the other four fruits. See WT/DS76/AB/R, paras 132-138.
54. Ensuring that Japan would remain "free" of coddling moth is, of course, impossible to guarantee. Japan's requirement is that all 30,000 insects at the most resistant stage in their development die in large-scale fumigation tests. Japan considers that efficacy as equivalent to at least a 99.9968% ("probit 9") treatment efficacy. See WT/DS76/R, paras 2.15 and 2.23. In addition to this large-scale mortality test there are preliminary ("basic") small-scale tests and on-site confirmatory tests. The Japanese varietal testing requirement obliged exporters to perform the basic test and on-site confirmatory tests for each variety, but the large-scale mortality test need not be repeated for each variety. See WT/DS76/R, paras 2.23 and 2.24.
55. WT/DS76/R, para 8.27.
56. ibid.
57. ibid. Data did exist to show that the measurements which are typically used to determine quarantine efficiency varied across tests on different varieties. However, the United States argued (and experts advising the Panel confirmed) that the differences were easily due to differences in testing conditions and did not indicate substantive differences in the efficacy of the varietal testing requirement. The Appellate Body endorsed the conclusion that the Japanese testing requirement was not based on a risk assessment; echoing Article 2.2. of the SPS Agreement, the Appellate Body found that the testing requirement was maintained "without sufficient scientific evidence." However, as in the hormones and salmon cases, the Appellate Body also avoided creating any standard for "sufficient" or "rational relationship;" instead, they found, "[w]hether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence." WT/DS76/AB/R, paras 76 and 84.
58. SPS Agreement, Article 5.7.

59. WT/DS76/R, paras 8.49-8.60.
60. WT/DS76/R, paras 8.70 to 8.104. The Appellate Body agreed: see WT/DS76/AB/R, paras 86-94.
61. The idea for a "determination of sorption level" approach derived from suggestions from the experts advising the Panel (see Panel report, para 8.74).
62. WT/DS76/AB/R, paras 123-131.
63. See ref. 8.
64. See Victor, 1998, *op. cit.*, ref. 15.
65. Of course a nation could align risks so as to support a grossly protective measure. But I discount that possibility for two reasons. One is that it would require massive distortion of trade, perhaps across many sectors, which would become apparent and vulnerable to challenge both in internal political processes as well as through the WTO. The other is that even if SPS risks are aligned internally they must be based on a risk assessment (SPS Agreement, Article 5).
66. World Trade Organization, "Australia—Measures Affecting Importation of Salmon, Report of the Panel," WT/DS18/R (12 June 1998), para 4.190.
67. WT/DS26/AB/R & WT/DS48/AB/R, para 234.

[1] For a comprehensive treatment of the cases that were handled, see: Hudec, R.E. 1993, *Enforcing International Trade Law: The Evolution of the Modern GATT Legal System* (Salem: Butterworth Legal Publishers).

[2] A. Tutwiler, 1991, "Food Safety, the Environment and Agriculture Trade: The Links," International Policy Council on Agricultural Trade, Discussion Papers, series no. 7, June, p.2, cited in: David Vogel, 1995, *Trading Up: Consumer and Environmental Regulation in a Global Economy* (Cambridge: Harvard University Press). For a current overview of all technical barriers to trade in U.S. agriculture exports see: Donna Roberts and Kate DeRemer, 1997, "Overview of Foreign Technical Barriers to U.S. Agricultural Exports," *ERS Staff Paper*, No. 8705, Economic Research Service, Commercial Agriculture Division, U.S. Department of Agriculture.

[3] In addition, the WTO agreement included four "plurilateral" agreements (on aircraft, government procurement, dairy products, and bovine meat) that were adopted in 1994 along with the Core WTO agreements. Unlike the "multilateral" obligations that all WTO members must implement, plurilateral agreements are optional. They are not necessarily useless because an agreement—even if voluntary—helps to signal proper conduct and facilitate cooperation. Moreover, voluntary agreements often lay the groundwork for later agreements that are binding and backed by an enforcement mechanism. For example, the conclusion of the 7th round in 1979 included a plurilateral code on technical barriers to trade; the failure of that code to have much effect led to the creation of similar, but binding, multilateral TBT and SPS agreements that were adopted in 1994 along with the other WTO agreements.

[4] The Agreement's preamble underscores the goal: "*Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations…." The Agreement declares, "Members shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations…. (Article 3.1)." When a member

imposes SPS measures that conform to international standards, guidelines or recommendations, those measures will automatically be "presumed to be consistent with the relevant provisions of this Agreement… (Article 3.2)." However, countries may introduce measures that are stricter than international standards "if there is a scientific justification, or as a consequence of the level of [SPS] protection a Member determines to be appropriate in accordance with the relevant provisions…of Article 5 (Article 3.3, emphasis added)." The SPS agreement also includes a footnote at this point: "For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection." Although the obligations and reasoning are a bit convoluted, this footnote has been interpreted as meaning that measures that deviate from international standards are acceptable if based on a risk assessment—that is, if they meet the requirements of Article 5, which includes the requirement of a risk assessment (Article 5.1). In plain language: Article 3 promotes harmonization with international standards. And Article 5 allows countries to escape the straitjacket of international standards, provided that an assessment of risks is the first step in setting such stricter SPS measures.

[5] For simplicity, hereafter I use the term "international standards" to denote "international standards, guidelines, or recommendations." While the full term is important for legal purposes because it is broader, the simpler plain English term is most appropriate for this paper. One of the remaining gray zones in applying the Agreement concerns just how broadly to apply this definition. For example, as I review below, the *Codex Alimentarius* Commission adopts not only specific standards (e.g., on food additives) but also more general standards for commodities and advisory guidelines. Does the WTO Agreement apply to all three, even though *Codex* guidelines were never designed nor intended to have binding application?

[6] For simplicity I will use the terms "country" and "WTO Member" interchangeably. For purposes of discussing legal obligations I will also treat countries as single units. However, some SPS measures (e.g., quarantines) apply only to certain parts of countries and thus have trade effects only for imports (from outside as well as inside the country) into that part of the country. Examples include quarantines for many exports to Hawaii, which are stricter than exports to the rest of the United States. Moreover, although the obligations of the WTO agreements are imposed on "Members," it is not necessary that *governments* perform all of the required tasks. Often risk assessments and trade controls are implemented by NGOs (especially private firms, industrial associations and scientific laboratories), with government acting only a supervisor. (See SPS Agreement, Article 13.)

[7] The SPS Agreement also includes a specific application of the "equivalent" requirement, which is especially important for SPS measures: pest- and disease-free areas. Countries that can demonstrate that all or some of their country is free from a hazard are allowed to circumvent SPS measures that are intended to block diseases on products from that country. (See Article 6.)

[8] For example, see Silverglade, Bruce A., 1998, "The Impact of International Trade Agreements on U.S. Food Safety and Labeling Standards," *Food and Drug Law Journal*, vol. 53, pp. 537-541; "Consumer Groups, Officials Demand Strong U.S. Action at Codex Commission Session," *World Food Chemical News*, vol. 4, No. 5, p.3; Jacobson, Michael F., 1997, "Comments of the Center for Science in the Public Interest," Consideration of Codex Alimentarius Standards, Advance Notice of Proposed Rulemaking, U.S. Department of Health and Human Services, Food

and Drug Administration, Docket 97N-0218. There have been numerous letters to the President of the United States, responses to proposed rulemaking, and other political actions based on similar arguments.

[9] The legal reasoning is a bit convoluted because the SPS Agreement is also convoluted and layered on this point. For the link between Article 3.3 and Article 5 see Article 3.3 itself, which specifically cites Article 5 as a justification for deviation from international standards. (However, the citation is odd because it suggests that a Member may employ a "scientific justification" *or* Article 5 when, in fact, they have been interpreted as the same.) Moreover, see the footnote to Article 3.3 cited above (ref. 4). For a statement on the need to examine Article 5 in order to interpret the basic rights and obligations enumerated in Article 2 see: Appellate Body, "EC Measures Concerning Meat and Meat Products (Hormones)," WT/DS26/AB/R & WT/DS48/AB/R (16 January 1998), AB-1997-4, which argues that: "Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1. (para 180)." In addition, the same report (para. 212) notes that Article 2.3 must be read together with Article 5.5—the former declares a general obligation, and the latter elaborates "a particular route" for determining whether the general obligation has been met.

[10] The WTO disputes related to risk assessment have focused on Articles 5.1 and 5.2; Article 5.3 is also relevant because it outlines the type of information that should be included in a risk assessment. Article 5.7 concerns provisional measures taken when information is insufficient and is an extension of the basic risk assessment requirements in Articles 5.1, 5.2 and 5.3. In the EC Meat Hormones case the WTO's Appellate Body noted that Article 5.7 is a reflection of the precautionary principle—in particular, strict measures may be put into place on a temporary basis if information is insufficient (similar statements are found in the sixth paragraph of the preamble and in Article 3.3). However, the precautionary principle and Article 5.7 do not override the requirement to base measures on a risk assessment as denoted in Articles 5.1 and 5.2. See WT/DS26/AB/R & WT/DS48/AB/R, paras 120-125. For more on the tests that must be met to qualify under Article 5.7 see the discussion of the Japanese fruits and nuts case, below.

[11] The other related provisions are, in particular, Articles 2 and 3 and the definitions in Annex A.

[12] There is a small qualifier to this statement. Article 3.3 also says that Members may impose SPS measures "…which result in a higher level of [SPS] protection…" *if* one of two conditions is met: the measures are based on a "scientific justification" or the measures are in conformity with Article 5. The concept of "scientific justification" is defined in a footnote (see ref. 4) such that, in practice, "scientific justification" means based on a risk assessment. The provisions for risk assessment are outlined in Article 5 and in Annex A ("definitions") of the SPS Agreement. Thus the discipline on the *level* of SPS protection that a country may establish funnels through Article 5, and the only part of Article 5 that explicitly addresses the *level* of SPS protection is Article 5.5.

[13] This is especially evident in the EC's meat hormones ban and Australia's ban on imports of fresh and frozen salmon, which are the only two cases where a country's *level* of SPS protection has been challenged directly. In both cases, the level of protection that the importing country sought was zero risk because the country had imposed a ban on imports. Thus testing whether the bans were consistent with the requirement to base SPS measures on risk assessment was, de facto, a test of whether the goal of zero risk was based on risk assessment.

[14] Two statements in the preamble make this point: "*Recognizing* the important contribution that international standards, guidelines and recommendations can make in this regard…" and "*Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards…." In contrast, the preamble does not mention risk assessment or rules to govern deviations from international standards as principal objectives.
[15] This section is based mainly on Victor, David G., 1998, "The Operation and Effectiveness of the Codex Alimentarius Commission," in: *Effective Multilateral Regulation of Industrial Activity: Institutions for Policing and Adjusting Binding and Nonbinding Legal Commitments*, Ph.D. Thesis, Department of Political Science, Massachusetts Institute of Technology. For the early history of Codex see: Leive, D.M., 1976, *International Regulatory Regimes: Case Studies in Health, Meteorology and Food*, 2 volumes, (Lexington: Lexington Books for the American Society of International Law); Kay, D.A., 1976, *The International Regulation of Pesticide Residues in Food* (Washington: American Society of International Law). And for a study with particular attention on pesticide (residue) standards see: Boardman, R., 1986, *Pesticides in World Agriculture: The Politics of International Regulation* (New York: St. Martin's Press), chapter 4.
[16] See Victor (1998), *op cit. ref. 15 and also Victor, David G., 2000, [add cite to chapter forthcoming in NRC report]*.
[17] The process also ensures that the MRLs adopted are consistent with testing equipment and practices for food safety inspection so that the standards are relatively easy to implement.
[18] See statements by the experts in "Annex: Transcript of the Joint Meeting with Experts, held on 17-18 February 1997," WT/DS26/R/USA, for example paras, 743, 819, 824, and 826.
[19] See ref. 5.
[20] Most of the full acceptances by advanced industrial (OECD) nations were notified by the least developed of the OECD members, such as Portugal.
[21] [add examples.]
[22] Office International Des Epizooties, *International Animal Health Code* (Seventh Edition, 1998).
[23] Office International Des Epizooties, *International Aquatic Animal Health Code* (Second Edition, 1997).
[24] The statements here apply strictly to the 1952 IPPC (with revisions that came into force in 1991). The FAO Conference adopted a New Revised IPPC in 1997, but it has not entered into legal force. The new treaty explicitly aligns the requirements of the IPPC with the SPS Agreement, but in practice that has required few significant deviations from the 1952/1991 IPPC Agreement. One significant revision is that the new treaty will create a Commission on Phytosanitary Measures that can provide a standing body to address issues that arise; that body could be important for fine-tuning plant-related SPS issues since such matters will probably be more technical than would be appropriate for handling within the SPS Committee (created by the SPS Agreement). Although the new IPPC is not in effect, guidelines for Pest Risk Analysis—adopted in 1995 in parallel with development of the new treaty—probably do apply, regardless of their legal status, because the SPS Agreement has an expansive requirement to base SPS measures on "international standards, guidelines, and recommendations developed by the relevant international organizations.…"
[25] This is actually two cases—one originating from a US complaint and one from a Canadian complaint. But both were heard by the same panel, employed the same experts, were conducted on parallel decision-making tracks, and had the same outcome. See World Trade Organization,

"EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States," Report of the Panel, WT/DS26/R/USA (18 August 1997); World Trade Organization, "EC Measures Concerning Meat and Meat Products (Hormones), Complaint by Canada," Report of the Panel, WT/DS48/R/CAN (18 August 1997). Both of these cases were appealed, and the WTO Appellate body issued a single report on the two measures: World Trade Organization, "EC Measures Concerning Meat and Meat Products (Hormones)," Report of the Appellate Body (AB-1997-4), WT/DS26/AB/R, WT/DS48/AB/R (16 January 1998). Finally, the question of what constituted a "reasonable period of time" during which the EC must bring its measure into line was submitted to binding arbitration, which determined that the EC must comply no later than 13 May 1999 (15 months after 13 February 1998, the date of the adoption of the Appellate Body and Panel Reports by the WTO's Dispute Settlement Body). For the outcome of the arbitration see: World Trade Organization, "EC Measures Concerning Meat and Meat Products (Hormones)," Arbitration under Article 21.3(c) of the Understanding on Rules and Procedures Governing the Settlement of Disputes, WT/DS26/15, WT/DS48/13 (29 May 1998).

[26] World Trade Organization, "Australia—Measures Affecting Importation of Salmon," Report of the Panel, WT/DS18/R (12 June 1998). The case was appealed: World Trade Organization, "Australia—Measures Affecting Importation of Salmon," Report of the Appellate Body (AB-1998-5), WT/DS18/AB/R (20 October 1998). Citations to the Appellate Body Report are in the form of page numbers because paragraph numbering is not accurate in the available (online) version of that Report.

[27] World Trade Organization, "Japan—Measures Affecting Agriculture Products," Report of the Panel, WT/DS76/R (27 October 1998); World Trade Organization, "Japan—Measures Affecting Agriculture Products," Report of the Appellate Body WT/DS76/AB/R (22 February 1999).

[28] See "Understanding On Rules And Procedures Governing The Settlement Of Disputes," Annex 2 of "Agreement Establishing the World Trade Organization." On the matter of a "reasonable period of time"—which is intended to be typically no longer than 15 months—see the Arbitrator's report in the EC meat hormones case at ref. 25.

[29] Roberts, Donna, 1998, "Preliminary Assessment of the Effects of the WTO Agreement on Sanitary and Phytosanitary Trade Regulations," *Journal of International Economic Law*, pp. 377-405, esp. pages 396-398.

[30] The discussion of the cases is purposely simplified. The goal here is not to identify the twists and turns in the legal and technical arguments. Rather, it is to identify the main arguments that proved to be most important in resolving the case and thus are likely to have the strongest value as precedents for future cases. The excerpts are based on analysis of the full Panel and Appellate Body reports (cited at refs. 25, 26 and 27).

[31] For more on the origins of this dispute see David Vogel, 1995, *op. cit.*ref. 2, chapter 5; for more on the WTO aspects of the dispute see Steve Charnovitz, 1997, "The World Trade Organization, Meat Hormones, and Food Safety," *International Trade Reporter*, vol 14, No. 41 (15 October), pp. 1781-1787; Donna Roberts, 1998, *op. cit*, ref. 29.

[32] *32nd JECFA Report*, published in 1988 ("1988 JECFA Report"); *34th JECFA Report*, published 1989 ("1989 JECFA Report"); Report of the Scientific Group on Anabolic Agents, Interim Report, 22 September 1982 ("Lamming Report"); EC Scientific Conference on Growth Promotion in Meat Production, 29 November to 1 December 1995 ("1995 EC Scientific Conference"). For a conclusion from the 1995 EC Scientific Conference that starkly states that

growth hormones are safe see Maddox, J., 1995, "Contention Over Growth Promoters," *Nature*, vol. 378, p. 553.

[33] The EC did cite some risk assessments that pointed to a risk of cancer due, broadly, to hormone exposure. However, those assessments did not examine the risks associated with particular hormones and were not treated as relevant evidence by the Panel, especially as numerous other more focused assessments showed no particular risk.

[34] For the arguments, including quotes from European Parliament reports favoring a ban, see WT/DS26/R/USA, paras 2.26-2.33.

[35] In particular, the Panel decided that "based on" meant that the SPS measure should afford the same level of SPS protection as the international standard. See WT/DS26/R/USA, para 8.72.

[36] See WT/DS26/AB/R & WT/DS48/R, paras 160-177.

[37] The EC and other members as "risk assessments" also presented other reports but they were discounted. Some were cursory examinations of the issues. In particular, the EC's strongest evidence that hormones caused risks was in reports (the "IARC Monographs") that examined only categories of hormones or the hormones at issue in general. Those studies were discounted as not adequately focused. See WT/DS26/AB/R & WT/DS48/R, paras 195-202.

[38] WT/DS26/AB/R & WT/DS48/R, paras 207-208.

[39] WT/DS26/AB/R & WT/DS48/R, para 193 (emphasis added).

[40] WT/DS26/AB/R & WT/DS48/R, para 201. Due to the lack of evidence, the EC might have maintained the ban on MGA as a "provisional" measure under Article 5.7 of the SPS Agreement. However, the WTO Dispute Panel dismissed that argument because the EC did not claim the measure was "provisional" and concluded that the ban on MGA still would need to comply with the other provisions of the SPS Agreement (e.g., the requirement to conduct a risk assessment). See WT/DS26/R/USA, para 8.248 to 8.249 and paras 8.250 to 8.271. The EC might have overturned at least part of that ruling on appeal, which could have, perhaps, allowed the MGA ban to stand under Article 5.7's allowance for strict measures in the face of uncertainty (in essence, the "precautionary principle"). However, this was not a central issue in the appeal and the AB did not rule on that particular argument (i.e., Article 5.7) directly; and generally the AB did not view the "precautionary principle" as giving countries wide latitude (see ref. 10).

[41] The Appellate Body derived this three-part test in part from Article 5.5, which requires that "each Member shall avoid arbitrary or unjustifiable distinctions in the levels [of SPS protection] it considers to be appropriate in different situations." The interpretation of that requirement requires, in part, looking to Article 2.3 of the SPS Agreement which is part of the Agreement's basic rights and obligations: "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, *including between their own territory.*. (emphasis added.)" For the three-part test see WT/DS26/AB/R & WT/DS48/AB/R, paras 210-246.

[42] In addition to allowing the use of carbadox and olaquindox while banning growth hormones in beef, the WTO Panel had also suggested that there were many other examples where the EC had not applied comparable levels of protection in comparable situations. The Panel drew particular attention to the fact that the natural residues of these hormones were higher in some foods—such as eggs and broccoli—than would occur if applied as growth promoters. The Appellate Body rejected these comparisons because the addition of hormones for growth promotion was different from the natural presence of hormones in food—the former concerns an intervention by humans in the food production process, whereas the latter is a fact of nature that humans can't alter

without a "comprehensive and massive governmental intervention in nature." See WT/DS26/AB/R & WT/DS48/AB/R, para 221.

[43] For the third part of the test see WT/DS26/AB/R & WT/DS48/AB/R, paras 236-246.

[44] Of course the dispute also touched on many other issues—here I have raised only the most important ones that related directly to the interpretation of the SPS Agreement and the effect of the SPS Agreement on nations' SPS policies. Among the other issues is the burden of proof. The Panel argued that the importing (defending) country had the obligation to prove the consistency of its SPS levels. The Appellate Body argued that the complainant must first establish a *prima facie* case that the defending country violated the SPS Agreement; only then must the defender disprove the claim. The Appellate Body also addressed procedural issues related to the handling of matters related to the WTO's dispute settlement procedures and whether a dispute could be prosecuted for measures, including the EC hormone ban, that were imposed before 1 January 1995 (the date when the WTO Agreements came into force).

[45] Office International Des Epizooties, *International Aquatic Animal Health Code* (Second Edition, 1997), Section 1.1.

[46] The Guidelines are codified in the *International Aquatic Animal Health Code*. See: Office International Des Epizooties, *International Aquatic Animal Health Code* (Second Edition, 1997), Sections 1.4.2.1 through 1.4.2.3.

[47] The *International Aquatic Animal Health Code* does include a more general requirement that countries conduct "import risk analysis to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of aquatic animals, aquatic animal products, aquatic animal genetic material, feedstuffs, biological products and pathological material." (Section 1.4.1.1). A liberal interpretation of the *Code* would suggest that that requirement applies generally to imports and not only to listed diseases. However, the *Code* explicitly allows countries to determine their own methodology for conducting such analysis; countries can use procedures outlined in OIE reference documents for conducting such analysis, but they are not required to do so (Section 1.4.1.3). Moreover, the broad requirement to conduct import risk analysis also exists in the SPS Agreement. Finally, the definition of "disease" in the *International Aquatic Animal Health Code* strictly applies only to diseases that are included on one of the *Codes* two lists.

[48] An example of the chain of events required: a disease-ridden fish carcass would be disposed in the sewers, sewage would leak into waterways, and waterways would then carry the disease (perhaps via an intermediate host) into the Australian fisheries. Canada argued that the probability of each step was low and, in total, the probability of the full chain of events was extremely low. The case focused on pacific wild salmon, which were the most important potential Canadian export and had been the subject of a special effort by Canada and the United States to perform a risk assessment and obtain export permission from Australia. Later that same risk assessment process would be extended to other species. Such risk assessment must differentiate between populations and species because the incidence of disease and risk of transmission probably vary.

[49] The three-pronged test is based on Article 5.1 and Annex A (paragraph 4) of the SPS Agreement. For the test see WT/DS18/AB/R, page 73.

[50] The Panel's ruling on all the major issues in this case was developed by focusing on ocean-caught Pacific salmon because those were the first that Canada sought to export. However, similar issues arose for other salmon since the import ban applied to all Canadian fresh and

frozen salmon, and where possible the Appellate Body extended its ruling to cover other salmon as well. (Salmon stocks must be considered separately because some of the disease risks vary with the ecosystem in which the salmon are caught.) For the three part test applied to ocean-caught Pacific salmon see WT/DS18/AB/R, pages 80-93. For the test applied to other salmon see WT/DS18/AB/R, pages 108-111.

[51]The ambiguity reflects that Australia's measure (the import ban) was not based on a risk assessment—in particular, it failed to assess the risk reduction that might be caused by alternative SPS measures. Australia maintained that its level of protection was "very conservative" (Panel report, para 8.107); but its prohibition on imports suggested that the actual level of SPS protection that Australia sought was zero-risk. On ocean-caught Pacific salmon see WT/DS18/AB/R, pages 93-104; for other salmon see WT/DS18/AB/R, page 112. For the quotation here see page 99.

[52] "News Release: Canada and Australia Reach Agreement on Salmon," Office of the Minister for International Trade, Government of Canada, Ottawa (16 May 2000).

[53] The case also included attention to non-fumigation techniques (cold treatment). The treatment varies not only with the characteristics of the fruit/nut but also the season of harvest because coddling moths exist in different forms (e.g., eggs, larvae, adults) in different seasons. Different varieties have different harvest times, and thus Japan argued that test results for one variety were not applicable to another.

[54] The United States challenged the Japanese varietal testing requirement for all "US products on which Japan claims that coddling moth may occur," which included apricots, pears, plums and quince. But the US had not provided a *prima facie* case that the Japanese testing requirement was maintained "without sufficient scientific evidence." The US met that standard for apples, cherries, nectarines and walnuts but not for the other four fruits. See WT/DS76/AB/R, paras 132-138.

[55] Ensuring that Japan would remain "free" of coddling moth is, of course, impossible to guarantee. Japan's requirement is that all 30,000 insects at the most resistant stage in their development die in large-scale fumigation tests. Japan considers that efficacy as equivalent to at least a 99.9968% ("probit 9") treatment efficacy. See WT/DS76/R, paras 2.15 and 2.23. In addition to this large-scale mortality test there are preliminary ("basic") small-scale tests and on-site confirmatory tests. The Japanese varietal testing requirement obliged exporters to perform the basic test and on-site confirmatory tests for each variety, but the large-scale mortality test need not be repeated for each variety. See WT/DS76/R, paras 2.23 and 2.24.

[56] WT/DS76/R, para 8.27.

[57] ibid.

[58] ibid. Data did exist to show that the measurements which are typically used to determine quarantine efficiency varied across tests on different varieties. However, the United States argued (and experts advising the Panel confirmed) that the differences were easily due to differences in testing conditions and did not indicate substantive differences in the efficacy of the varietal testing requirement. The Appellate Body endorsed the conclusion that the Japanese testing requirement was not based on a risk assessment; echoing Article 2.2. of the SPS Agreement, the Appellate Body found that the testing requirement was maintained "without sufficient scientific evidence." However, as in the hormones and salmon cases, the Appellate Body also avoided creating any standard for "sufficient" or "rational relationship;" instead, they found, "[w]hether there is a rational relationship between an SPS measure and the scientific

evidence is to be determined on a case-by case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence." WT/DS76/AB/R, paras 76 and 84.
[59] SPS Agreement, Article 5.7.
[60] WT/DS76/R, paras 8.49-8.60.
[61] WT/DS76/R, paras 8.70 to 8.104. The Appellate Body agreed: see WT/DS76/AB/R, paras 86-94.
[62] The idea for a "determination of sorption level" approach derived from suggestions from the experts advising the Panel (see Panel report, para 8.74).
[63] WT/DS76/AB/R, paras 123-131.
[64] Add citation to the notification (in proof).
[65] See ref. 8.
[66] See Victor, 1998, *op. cit.*, ref. 15.
[67] Of course a nation could align risks so as to support a grossly protective measure. But I discount that possibility for two reasons. One is that it would require massive distortion of trade, perhaps across many sectors, which would become apparent and vulnerable to challenge both in internal political processes as well as through the WTO. The other is that even if SPS risks are aligned internally they must be based on a risk assessment (SPS Agreement, Article 5).
[68] World Trade Organization, "Australia—Measures Affecting Importation of Salmon, Report of the Panel," WT/DS18/R (12 June 1998), para 4.190.
[69] WT/DS26/AB/R & WT/DS48/AB/R, para 234.