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Implementation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures: The First Two Years

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Technological innovations together with policies that progressively reduced trade barriers have shrunk economic distances between nations in the post-World War II era. This deepening integration of world markets has blurred the lines of the formerly sharp distinctions drawn between "domestic" and "international" policies. In the past, the predominant view was that domestic policies should be determined by the preferences of the nation's citizens, with little regard to any effects they might have on other countries. More recently, the exponential growth in world-wide trade flows has inevitably led to closer international scrutiny of the differences that were formerly overlooked among domestic policies of nations.

Of the domestic polices now subject to international scrutiny, technical barriers--measures that sometimes restrict imports to prevent entry of products that fail to meet the health, quality, safety, compatibility, or environmental standards of importing countries--were among the first to attract attention. The consensus view that emerged was that the enforcement mechanism of these policies, which is to restrict unsatisfactory imports, made them in many instances indistinguishable from explicit trade policies that likewise limited entry of goods at the border. Consequently, the Contracting Parties to the General Agreement on Tariffs and Trade (GATT) agreed to negotiate disciplines on the preparation, adoption and application of these measures beginning with the 1973-1979 Tokyo Round of GATT negotiations. Multilateral disciplines on the use of technical barriers were subsequently expanded and strengthened in the 1986-1993 Uruguay Round Multilateral Trade

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Negotiations which culminated in the 1994 Agreement Establishing the World Trade Organization (hereinafter the WTO Agreement).

From the perspective of trade in primary and processed agricultural products, some of the most important new disciplines are found in the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. SPS measures are measures adopted by countries to protect human, animal or plant life and health from certain enumerated biological and chemical risks. In broad terms, the Agreement recognized the right of each Member to adopt SPS measures which provided the level health and environmental protection that it wished to provide its citizens, but required measures to be based on a scientific assessment of the risks, to be non-discriminatory, and to be applied only to the extent necessary to achieve its chosen level of protection. The SPS Agreement also recognized certain international standards (those promulgated by the *Codex Alimentarius*, the International Organization of Epizootics, or the International Plant Protection Convention) to be benchmark or "safe harbor" standards -- i.e., a Member that adopted a standard recommended by these organizations would be "rebuttably presumed" to be in compliance with the Agreement.

The challenge before the negotiators of the SPS Agreement was to create a set of rules which would strike the proper balance between allowing protection while disallowing regulatory protectionism. There are clearly public good arguments that make some SPS restrictions necessary to insure a safe food supply and protect the domestic environment from pests and diseases. In other cases, regulations rationalized on technical grounds seem to lack firm scientific foundations and, at least from the perspective of exporting countries, seem to be imposed primarily to thwart the commercial opportunities created by other trade liberalization policies. That regulatory processes can be “captured” by domestic producers with a vested interest in limiting competition is well recognized in the economic theory of regulation, and cases involving the promulgation of SPS measures are no exception [Roberts and Orden]. If the negotiators were successful, the SPS Agreement will be regarded as an important institutional innovation that counterbalances the influences of domestic interest groups that successfully lobby for SPS measures which lower net social welfare by restricting imports that pose negligible health or environmental risks.

The pivotal question is, did the negotiators achieve the proper balance? On one side, interested parties worry that the Agreement seriously threatens national sovereignty in the often emotionally and politically charged areas of food safety and environmental protection. Their claim is that under the Agreement, the standards for crafting SPS measures are too high. A central concern is that the Agreement limits the ability of governments to adopt measures in instances where the science may be immature -- that a government's evaluation of the likelihood or consequences of a risk associated with an imported product might not withstand international scrutiny. On the other side, some major agricultural exporting countries are troubled that the Agreement appears to allow wide latitude in adopting SPS measures -- that importing countries may impose measures that impede imports, no matter how unlikely or how inconsequential the risks.

This paper examines developments since the entry into force of the SPS Agreement in January, 1995, with a view to evaluating the evidence to date that supports the competing views of the SPS Agreement. The first section of the paper reviews the origins and principle provisions of the SPS Agreement itself. This review sets the stage for an assessment of the first WTO panel decision made under the SPS Agreement, the longstanding *Hormones* dispute, and the subsequent Appellate Body (AB) ruling. This evaluation assesses how the case might foreshadow other SPS disputes in the foreseeable future. The role that risk assessment played in the dispute is examined in the third section of the paper, as the perceived success or failure of the Agreement may hinge on whether these assessments will typically permit judgment about whether there is a "rational relationship" (to use the AB's words) between the SPS measure and the risks it mitigates (WTO, 1998). This paper argues that one of the principal challenges to effective enforcement of the new WTO disciplines in the near future may be the current state of risk assessment methodology and practice.

The fourth section of this paper turns from the landmark *Hormones* case to consider other U.S. experiences over the past two years with implementation of the Agreement -- the cases that command less attention than prominent disputes but are nonetheless important in gauging whether the new SPS disciplines have contributed to the effective functioning of the world trading system. Expanding beyond the U.S. perspective, evidence of the multilateral compliance with the transparency

provisions, which experts agree is key to effective implementation of the Agreement, is reviewed. The final section presents some tentative concluding remarks, based on the fragmentary evidence (relative to other trade barriers) available on SPS measures.

The SPS Agreement -- Origin and Principle Provisions

The 1994 WTO Agreement continued the historical progression of successive Rounds of multilateral trade negotiations and GATT case law which have steadily reinforced and periodically augmented rules disciplining the use of technical restrictions on imports [Roessler]. The principle legal instruments of the WTO Agreement are the GATT 1994[1] and 15 annexed Agreements. These Agreements establish rules for trade measures which affect a wide range of economic activity, from services to intellectual property, that are important to trade in primary and processed agricultural goods. However, three of these Agreements are most relevant for a comprehensive understanding of the multilateral legal environment for SPS measures in the post Uruguay Round era: the Agreement on Agriculture (Agriculture Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement) and the SPS Agreement.

The Agriculture Agreement itself contains no disciplines on the use of SPS measures, but rather provides a key motivation for adoption of the disciplines found in the SPS Agreement. Negotiators recognized that lowering the level of protection provided by tariffs and many non-tariff barriers (NTBs) would increase the relative and absolute importance of existing and potential technical barriers in international markets. This reduction in protection was especially important in agricultural markets, since the use of most agricultural NTBs had not been disciplined before the Uruguay Round. By reducing the ability of governments to protect domestic producers through various other border and domestic support measures, negotiators feared that the Agriculture Agreement would inadvertently create an incentive to replace former NTBs with new technical barriers, especially SPS

[1] GATT 1994 comprises the text of the original 1947 GATT Articles and subsequent amendments.

measures. The new SPS disciplines were viewed as critical to prevent governments from resorting to regulatory compensation to appease domestic interests.

The negotiation of the SPS Agreement during the Uruguay Round was also motivated by shortcomings in the two legal instruments that disciplined the use of SPS measures prior to the Round -- the original GATT Articles and the 1979 Tokyo Round Agreement on Technical Barriers to Trade (which was a plurilateral agreement known as the Standards Code). Although language in these documents stated that measures could not be "applied in manner which would constitute . . . a disguised restriction on international trade" or "create unnecessary obstacles to trade", the consensus view that emerged over the years that was that the GATT and the Standards Code had failed to stem disruptions of trade in international markets caused by proliferating technical restrictions.

In the view of some Members, the unresolved dispute between the United States and the European Communities (EC) over the EC's ban on imports of hormone-treated beef during the 1980s was one of the more visible failures of the pre-Uruguay Round legal disciplines [Stanton]. In March 1987, the United States raised the issue of the EC ban under the Standards Code. When bilateral consultations failed to resolve the dispute, the United States requested the establishment of a technical experts group to evaluate the scientific basis for the ban. This request was denied following the EC response that the use of growth promotants in beef production was a process and production method (PPM), and that parties to the Standards Code only had an obligation not to use PPMs to circumvent the Agreement. The matter remained unresolved. In 1989, the United States introduced retaliatory measures in the form of 100 percent duties on a list of products imported from the EC. The EC consequently asked for the establishment of a GATT dispute settlement panel to rule on the legality of these duties, but the United States denied the request [WTO, 1997].

Three flaws in the pre-Uruguay Round legal infrastructure blunted the effectiveness of disciplines on SPS measures and other technical barriers: 1) the lack of a single integrated rule system (sometimes referred to as "GATT à la carte"); 2) the GATT's consensus-based dispute settlement process; and

3) the arguable exemption of production and process standards from many of the disciplines of the Standards Code. Prior to the Uruguay Round, not all signatories of the previous GATT Agreement had signed the Standards Code, effectively precluding a number of standards-related disputes from being brought before a GATT panel for resolution. But even if two countries had signed the Standards Code, the consensus-based dispute settlement process effectively allowed either country to block a request to convene a panel or block adoption of a panel report. Another loophole was created by the Standard Code's definition of a measure which would be subject to the disciplines in the agreement -- "A specification contained in a document which lays down characteristics of a product such as levels of quality, performance, safety or dimensions" -- which omitted explicit reference to PPMs.[2]

Upon completion of the Uruguay Round negotiations, *all* Members became parties to the WTO's single integrated rules system, which includes, among many other things, both the SPS and TBT Agreements as well as GATT 1994. Moreover, under the new Understanding on Rules and Procedures Governing the Settlement of Disputes (known as the Dispute Settlement Understanding or DSU), it is no longer possible for a single country to block a dispute ruling or a request for a panel. The new TBT Agreement now stipulates legally binding rules for "related processes and production methods" and the SPS Agreement imposes several new substantive and procedural disciplines for a wide array of health and environmental measures.

Because the TBT Agreement contains language that refers to protection of human, animal, or plant life or health, as well as to the protection of the environment, questions arise over the applicable disciplines for a given measure. The TBT Agreement covers all technical regulations and conformity assessment procedures, *except* when these are sanitary and phytosanitary measures as defined by the SPS Agreement: those measures that mitigate certain specified risks within the territory of the

[2] The sole reference to PPMs in the Standards Code was found in Article 14, which stipulated that dispute settlement procedures could be invoked in cases where a Party considered that obligations under the Agreement were being circumvented by the drafting of requirements in terms of PPMs rather than in terms of characteristics of products.

Member (Figure 1). Knowing the objective of a measure is thus critical to the determination whether a measure is subject to the disciplines in the TBT or SPS Agreement. For example, a measure which proscribes use of an additive might be adopted to safeguard human health (an SPS measure) or to ensure the compositional integrity of a product (a TBT measure).

Figure 1: Definition of an SPS measure

Any measure applied to protect	**from**
human or animal life	risks arising from additives, contaminants, toxins or disease-causing organisms in their food;
human life	plant- or animal-carried diseases (zoonoses);
animal or plant life	pests, diseases, or disease-causing organisms;
a country	damage caused by the entry, establishment or spread of pests
Source: Secretariat of the WTO (1996). Understanding the Agreement on the Application of Sanitary and Phytosanitary Measures.	

Such distinctions matter to regulatory authorities because the SPS Agreement arguably holds governments to a higher standard than does the GATT 1994 or the TBT Agreement. For example, important disciplines which do not explicitly appear in the other two legal instruments are found in Article 5 (Assessment of Risk and Appropriate Level of SPS Protection) of the SPS Agreement (Figure 2). This Article requires, among other things, that any SPS measure be based on an assessment of risks posed by the import and provide a level of health protection that does not arbitrarily or unjustifiably vary from the level of health or environmental protection provided by other measures, *if* such distinctions result in discrimination or a disguised restriction on trade.

Other important disciplines found in the SPS Agreement can be found in Articles 2 (Basic Rights and Obligations) and 6 (Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas

Figure 2: Principle Provisions of the WTO SPS Agreement [3]

Article 2 (Basic Rights and Provisions): Members must ensure that SPS measures are applied only to the extent necessary to safeguard plant, animal and human health, are based on scientific principles, and are not maintained without sufficient scientific evidence. SPS measures must not discriminate between Members where identical or similar conditions prevail, including between their own territory and that of Members.

Article 3 (Harmonization): Members shall base their SPS measures on international standards, guidelines or recommendations (where they exist) (3.1), although they may adopt measures that result in a higher level of protection (3.3), as long as these measures are in accordance with the provisions of Article 5 (see below).

Article 4 (Equivalence): Members are obliged to recognize that measures adopted by other Members, although different, provide equivalent levels of protection for plant, animal and human health, if this is objectively demonstrated by the exporting country.

Article 5 (Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection): Members are obliged to base their measures on a risk assessment, taking into account, when possible and as appropriate, risk assessment methodologies developed under the auspices of relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention. Each Member is also obliged, in order to achieve the objective of consistency in the application of SPS measures, to avoid arbitrary or unjustifiable distinctions in the levels of protection it considers to be appropriate if the distinctions would result in a disguised restriction on international trade.

Article 6 (Adaption to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence): This provision recognizes that SPS risks do not necessarily correspond to political borders. In particular, the Agreement recognizes that pest- or disease-free areas are largely determined by geographic and other ecological conditions, and therefore may be part of one country, or all or parts of several countries. Therefore import protocols must be based on a risk assessment which evaluates the claims by countries [if made] that certain regions are disease- or pest- free.

Source: General Agreement on Tariffs and Trade (1994). THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS, Geneva.

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[3] Similar disciplines are found in the North American Free Trade Agreement (NAFTA), and are being negotiated as part of the Free Trade Area of the Americas (FTAA) and among Asia Pacific Economic Cooperation (APEC) participants.

and Areas of Low Pest or Disease Prevalence). Article 2 states that Members must ensure that their measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, which includes between their own territory and that of other Members. These disciplines are variants of GATT Article I (General Most-Favoured Nation Treatment or MFN) and GATT Article III (National Treatment on Internal Taxation and Regulation)[4], modified as suitable to the circumstances posed by the biological and chemical risks at issue. Article 6 of the SPS Agreement codifies the same modified MFN and National Treatment principles for sub-national units (i.e., regions) that are free from diseases/pests or where the prevalence of diseases and pests are low. Article 3 (Harmonization) stipulates that although Members can adopt a measure to provide a higher level of health or environmental protection than that provided by an existing international standard, scientific evidence must support that claim.

Distinguishing protection from protectionism relies on effective decentralized policing of the many SPS measures that are promulgated each year by WTO Members. Toward that end, the Agreement has created several mechanisms to improve the institutional setting for addressing SPS barriers. The Agreement establishes a Committee, made up of delegations representing each WTO Member country, which is charged with developing further SPS guidelines. Meetings of the Committee, which occur three or four times a year, likewise present an opportunity for discussion of selected SPS measures. The Agreement also permits the Committee to serve as an informal mediator or facilitator of disputes where the parties mutually agree to hold informal consultations.

The general WTO dispute settlement procedures are available to Members in instances where bilateral and multilateral technical exchanges have reached an impasse. If initial consultations do not result in a mutually agreeable solution between the parties to a dispute, a Member can request a WTO dispute panel to rule whether the SPS measure is in compliance with the disciplines set forth in the

[4] The MFN principle found in Article I stipulates that concessions offered to one trading partner must be offered to all. The National Treatment principle codified in Article III holds that imported products be "accorded treatment no less favorable than that accorded to like products of national origin" under the importing nation's laws and regulations.

Agreement. A losing party is obliged to implement the panel's recommendations and to report on how it has complied, unless one of the parties appeals the decision[5]. Appeals are limited to issues of law and legal interpretation by the panel.

The *Hormones* Dispute[6]

Critics of the WTO Agreement in "high level" countries -- countries that have rigorous laws rigorously enforced -- have voiced concern about the new disciplines in the SPS Agreement [Farber and Hudec]. These critics argue that the new rules place too great a burden on regulatory authorities to justify SPS measures, in particular those measures that safeguard human health or the natural environment. The perspective of environmental and consumer advocates in these "high-level" countries is that the language in the Agreement which encourages governments to use international standards will inevitably lead to "downward harmonization," as strict measures which they have fought long and hard to achieve are successfully challenged by an exporting country before a WTO dispute panel. One prominent claim is that the Agreement, with its injunction that an SPS measure must be "based on scientific principles and not (be) maintained without sufficient scientific evidence" fails to make adequate allowance for regulating risks which are imperfectly understood but which could potentially cause irreversible harm, often referred to as the "precautionary principle."

Farber and Hudec note that the *Hormones* complaint brought by the United States and Canada against the EC is often cited by environmental and consumer groups as a prime example of the type of downward pressure that strict food safety and environmental regulations will face in the post-

[5] Or unless all WTO Member countries (including the complaining Member) convening as the Dispute Settlement Body (DSB) decide by consensus not to adopt the panel's report.

[6] The information in this section is drawn from the Report of the Panel (WT/DS26/R/USA), EC Measures Concerning Meat and Meat Products (Hormones): Complaint by the United States and the Report of the Appellate Body (WT/DS48/AB/R) [WTO, 1997 and WTO, 1998].

Uruguay Round era. As noted in the previous section, in the 1980s,[7] the EC banned the use of hormones for growth promotion purposes in domestic cattle herds, and likewise banned imports of cattle and bovine products that were treated with growth hormones. The United States and other beef exporters objected to the ban on imports, arguing that it was a trade barrier thinly disguised as a health measure. Pointing to its own record of stringent food safety standards (which allow use of growth-promoting hormones in cattle), the United States claimed that the EC measure was unscientific. The hormone prohibition did not hinge on the presence or absence of residues, the United States noted, but rather on the *use* vs. *non-use*, with a certain *intent*, of the banned substances. Upon completion of the Uruguay Round, the United States resurrected its complaint against the EC's measure. As anticipated, formal WTO consultations in 1996 between the United States and the EC (and subsequently Canada and the EC) failed to produce a mutually acceptable solution to the parties, and the long-standing *Hormones* dispute became the bellwether test of the new disciplines in the SPS Agreement.

The United States and Canada argued that the EC ban violated disciplines found in Article 2 (Basic Rights and Obligations), Article 3 (Harmonization) and Article 5 (Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection) of the SPS Agreement. On August 18, 1997 the WTO Panel that heard the dispute found that the EC ban was inconsistent with four provisions in the SPS Agreement, and recommended that the EC to bring its measure into conformity with its obligations under the Agreement.

Opponents of the SPS Agreement were quick to register their dissatisfaction with the Panel's report. Greenpeace, for example, noted that the ruling "impose(d) lowest common denominator health and environmental standards" and "neglect(ed) fundamental principles underlying present environment

[7] The EC Council of Ministers adopted this measure in December, 1985, but it was challenged in the European Court of Justice, which annulled it on procedural grounds. The proposal was re-introduced by the Commission and re-adopted by the Council (Directive 88/146) on March 16, 1988.

and health policies and regulations such as the precautionary principle". Such statements seem to overlook important features of the actual case.

The case was undeniably complex -- the 365 page ruling includes 204 pages of evidence provided by six experts (five scientists and the representative from the Codex secretariat) that the Panel consulted during the proceedings under the terms of Article 13 of the DSU. Specifically, the United States and Canada objected to the EC ban on imports of meat and meat products from animals which had been administered any one of six hormones, alone or in combination, to promote growth. Three of the six hormones at issue, oestradiol-17β, progesterone, and testosterone, are natural hormones endogenously produced by humans and animals. The other three hormones involved in the dispute, trenbolone, zeranol, and melengestrol acetate (MGA), are synthetic hormones that mimic the action of the three natural hormones. MGA is a feed additive, while the remaining five hormones are formulated as pellets designed to be implanted in the ear of the animal (which is discarded at slaughter). The hormones are variously used to increase the rate of animal growth (growth promotion purposes); to synchronize of the estrus cycles of dairy cattle to lower production costs (zootechnical purposes); or to correct certain endocrine dysfunctions (therapeutic purposes).

The *prima facie* scientific case against the EC ban was established by reference to the findings of a number of studies of the hormones at issue, together with the existence of international standards for their use (except for MGA). The United States and Canada pointed out that assessments by experts over the past four decades, including those by EC's own experts[8], the U.S. Food and Drug Administration (FDA), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA)[9],

[8] Including the Lamming Committee which was appointed by the EC Commission to determine whether the five hormones at issue (all but MGA) could be used in livestock production without hazard to the public health as well as the 1995 EC Scientific Conference on Growth Promotion in Meat Production.

[9] The JECFA is composed of independent scientists who serve in their individual capacities as experts, not as representatives of their governments or organizations. The goal of a JECFA evaluation of veterinary drugs is to determine safe levels of intake and to recommend maximum residue limits based on these intake levels.

indicated that there is no evidence that six specific hormones pose risks to human health when used according to good animal husbandry practices. And in 1995, the *Codex Alimentarius* Commission adopted standards for five of the six hormones upon the recommendation of JECFA.[10] Specifically, the Commission established maximum residue levels (MRLs) for zeranol and trenbolone.[11] It adopted no MRLs for the three natural hormones as JECFA had considered them "unnecessary".[12] Because there was no international standard for MGA, the U.S. and Canadian case against the EC ban on beef produced with MGA rested on the argument that the EC had not based its measure on a risk

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[10] No Codex Member has requested the Codex Commission to establish an international standard for MGA.

[11] The 32nd and 34th (1989) JECFA Reports state that the toxic effects of the two synthetic hormones, zeranol and trenbolone, are related to their hormonal effect, and therefore recommended that an Acceptable Daily Intake (and hence an MRL) could be established on the basis of a no-hormonal-effect level. The reports noted that the residues that would likely remain in the meat and organs of cattle treated with the synthetic hormones would fall substantially short of the levels regarded by the experts as safe. For example, under the assumption that a 70 kilogram person would consume 500 grams of meat daily over an entire lifetime, the maximum permissible level of zeranol residues in meat would be 70 µg/kg of edible tissue. The 32nd Report notes that when properly administered, maximum mean zeranol residues did not exceed .2 µg/kg in muscle and 10 µg/kg in liver, which had the highest amount of any tissue examined in the studies consulted by JECFA.

[12] The 32nd (1988) JECFA Report states that the potential carcinogenic effect of residues of the three natural hormones is likewise directly related to their hormonal effect. Since the additional residue levels in treated animals have no hormonal effect, according to JECFA, these residue levels are not capable of exerting any toxic effect. The residues from exogenously administered natural hormones, when properly used, would insignificantly increase hormone exposure beyond background levels in even the most sensitive populations, according to JECFA. For example, the 11.4 nanograms of oestrogens found in 500 grams of steer meat implanted with oestradiol-17β are negligible when compared with the daily production of oestrogens by young boys (41,000 nanograms), an adult man (136,000 nanograms), or a pregnant woman (20,000,000 nanograms). On the basis of this safety assessment, and in view of the difficulty of determining the levels of residues attributable to the exogenous administration of these hormones for growth promoting purposes in cattle (because the total residue levels in treated animals fall well within the normal range of levels found in untreated animals of different types and ages), JECFA concluded that it was unnecessary to establish MRLs for the three natural hormones.

assessment. The complainants pointed out that MGA had been studied extensively during the regulatory approval process in the United States and Canada, and these studies were in the public domain. The EC was entitled to base its measure on these assessments or entitled to prepare its own assessment based on proprietary data that could be provided by the manufacturer, but it had failed to do either, the complainants argued.

The EC maintained that the ban afforded a higher level of protection than that provided by the international standards, a right protected by the SPS Agreement. The higher level of protection chosen by the EC for its consumers was "no residues of added hormones for growth promotion." Canada and the U.S. countered that this statement constituted a restatement of the EC measure, not a stated level of protection, and that the EC had not provided scientific evidence to support the claim that the import ban actually provided a higher level of health protection. Much of the scientific evidence that was presented by the EC, the complainants argued, was related to the carcinogenic potential of entire categories of hormones, or of the hormones at issue in general, but did not constitute the kind of risk assessment that could inform public health choices related to the use of hormones as growth promotants in cattle. For example, Canada and the United States contended that the scientific evidence presented by the EC on the toxicity of hormones at elevated levels -- amounts that were equivalent to the amount of hormones that would be found in 11.5 million 500 gram servings of hormone-treated beef -- could not be considered as an actual evaluation of risks from consuming beef treated with hormones.

The United States and Canada also produced evidence to support their allegation that the EC ban resulted in arbitrary and unjustifiable distinctions in levels of health protection that resulted in trade discrimination or a disguised barrier to trade. Both parties provided information to facilitate comparison of the effects of the use of the three natural and three synthetic hormones to promote growth in beef cattle with 1) the endogenous levels of natural hormones in other foods, including untreated beef; 2) the use of natural hormones for therapeutic and zootechnical purposes; and 3) the use of carbadox in the EC to promote growth in pigs.

Endogenous level of natural hormones in other foods. The United States and Canada argued that the infinitesimal residues that remained in meat treated with growth hormones was far below the

Table 1: Comparative oestrogen intakes from food sources

Food	Weight of portion (g)	Oestrogen intake (ng)
Unimplanted steer meat[1]	500	6.1
Oestradiol-Implanted steer meat[1]	500	11.4
Zeranol-Implanted steer meat[3]	500	7*
Cow meat[1,2]	500	75 (7.2-540)*
Hen's egg	50-60	1,750*
Cabbage	100	2,400*
Peas	100	400*
Wheat germ	10	200*
Soybean oil	10 ml	20,000*
Milk	500 ml	75*

*Oestradiol equivalents. Ng = nanograms.
Assuming 25 per cent fat, 75 per cent muscle; [2]Oestrogen only; [3]Muscle tissue only.

levels found naturally in other foods (Table 1). Evidence submitted by the complainants indicated, for example, that the oestrogen content of one egg was equivalent to 76.5 kg of implanted steer beef. If the EC were genuinely concerned with the health effects of these hormonal substances, the complainants argued, the EC Commission should be regulating eggs and cabbage as well as beef produced with these hormones.

Use of natural hormones for therapeutic/zootechnical purposes. Although the EC's regulatory action is frequently cast as "a ban on hormones", the EC does allow use of the three natural hormones for therapeutic and zootechnical purposes. The EC argued that these uses would result in lower residues than those that would remain after using hormones for growth promoting purposes. The scientists that the Panel consulted during the proceedings testified that there was no qualitative difference between the residues in beef treated with hormones for growth promotion purposes and residues in beef treated with hormones for therapeutic or zootechnical purposes. The scientists also agreed that the quantity of residues would vary with the amount administered, either for growth

promotion or for therapeutic/zootechnical purposes, and noted that no matter how small the doses, or how long the withdrawal period before slaughter, some molecules would remain in the animal (normally at undetectable levels). The biological persistence of these compounds complicated any claims that might have been made that the EC ban was aimed at protecting consumers from any exposure to hormones in their food over and above the levels which occur in nature. Presumably this was why the EC argued that its level of protection for its consumers was "no residues of added hormones for growth promotion."

The use of carbadox. The fact that the EC allows the use of carbadox, a feed additive, to promote growth in swine provided additional evidence that EC food safety measures resulted in unjustifiable and arbitrary distinctions in levels of health protection, according to U.S.-Canadian arguments. The complainants pointed out that, according to the 36th JECFA report, carbadox is a known genotoxic (cancer inducing) carcinogen, unlike the six hormones at issue (which may, at elevated levels, promote but not induce cancer), and for that reason the Codex Commission had declined to establish an MRL for this compound. The United States argued that the EC's decision to allow the sale and consumption of meat from animals to which carbadox had been administered was but one example of a food safety standard that was less stringent than the one adopted for the six hormones at issue. The United States contended that the reason for this difference was that the EC swine industry was more efficient than the beef sector. It was no coincidence, the United States argued, that EC officials were willing to allow the use of productivity-enhancing inputs in the internationally competitive pork sector, but substantially more conservative about allowing the use of such inputs in a sector which relied on costly domestic price support measures, import protection, and export subsidies to maintain producer profitability.

Throughout the proceedings, the United States and Canada had drawn attention to the possible economic motives behind the ban. The complainants noted that in April, 1984, the EC had introduced milk quotas to reduce the oversupply of milk, which resulted in an increase in cattle slaughter. EC intervention stocks of beef, which were slightly less than 400,000 tons in November 1983 increased to over 800,000 tons by the end of 1985, the year the EC Commission drafted Directive 85/640 which

banned the use of hormones for growth promoting purposes. A ban on the sale of domestic or imported bovine products that were treated with growth promoting hormones provided EC officials with a seductive solution, the complainants argued. A ban justified on food safety grounds would simultaneously reduce productivity in the domestic beef sector and reduce imports from some of the world's most competitive beef exporters. The United States and Canada testified that the value of their annual export sales of bovine products to Europe had fallen by more than several hundred million dollars when the ban went into effect.

The Panel ultimately concurred with most of the arguments made by the complainants. The Panel found that the EC ban on imported beef treated with hormones for growth-promotion purposes was inconsistent with its obligations under the SPS Agreement, specifically that: 1) it was not based on a risk assessment (Article 5.1); 2) it was not based on existing international standards (Article 3.1); 3) the EC had not presented evidence that constituted a scientific justification for the ban which the EC claimed resulted in a higher level of protection than that provided by the international standard (Article 3.3); and 4) the EC ban on beef produced with hormones for growth-promoting purposes provided a level of protection that arbitrarily or unjustifiably varied from the level of protection provided by other EC measures, and this distinction had resulted in a disguised restriction on trade (Article 5.5).

At the conclusion of their report, the Panelists suggested that a voluntary labeling regime might constitute an acceptable compromise in this dispute, but none of the parties to the dispute have publicly endorsed the labeling option to date. The argument in favor of voluntary labeling is that consent criteria and minority rights imply that public policy should permit a minority to avoid the consumption of foods that are questionable in their opinion. The opposing view is that labels can inadvertently stigmatize a product, and good public policy should not implicitly suggest that there is some health risk associated with consumption of a food if scientific evidence does not support that view [Thompson].

It is significant to note that the EC invoked the precautionary principle at several points in its defense of the ban. Specifically it argued that a Member was entitled under the SPS Agreement to adopt bans or similar conservative risk management protocols even if the weight or the preponderance of scientific evidence indicated that a substance posed negligible risks. The EC argued that in adopting its precautionary approach, it was putting the interests of consumers ahead of the commercial interests of farmers and pharmaceutical companies. However, throughout the proceedings, the EC failed to defend its measure under Article 5.7, a codification of the precautionary principle in the SPS Agreement. This Article states that "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information . . ."

The SPS Agreement thus clearly permits the precautionary taking of measures when a government considers that sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process. It also permits immediate measures to be taken in an emergency situation, as many countries did in 1996 when scientists in the United Kingdom announced that they could not rule out that bovine spongiform encephalopathy (BSE) could be transmissible to humans. However, the EC considered its ban final, not provisional, and was therefore unwilling to formally defend it under the terms of Article 5.7. The Panel concurred with the complainants that the EC measure must therefore be consistent with the obligations specified in the other Articles of the Agreement.

The EC notified its intention to appeal this panel report on September 24, 1997, on a wide range of procedural and substantive issues. The United States and Canada cross-appealed the finding, arguing that the Panel should have also found that the EC ban was inconsistent with Article 2.2 (the measure was maintained without sufficient scientific evidence) and Article 5.6 (that measures should not be more trade restrictive than necessary to achieve the level of protection chosen by a Member).

The AB released its report in January, 1998, ruling on fourteen issues that had been raised by the three appellants. The AB concurred with the Panel that the EC measure was not in conformity with

all of the SPS Agreement disciplines and recommended that the DSB request the EC to bring its measure into conformity with the treaty. Specifically, it upheld the Panel's findings that the EC's measure was not based on a risk assessment, and that while the EC was entitled to adopt a measure which provided a higher level of protection than the Codex standards, it had not produced scientific evidence to support the claim that the ban actually did so. Significantly, the AB did overturn two findings by the Panel, ruling that the EC's ban had not been shown to violate the obligation to base measures on international standards (where they exist), or that the ban had provided a level of protection that arbitrarily and unjustifiably varied from other EC food safety measures such that the variation resulted in a disguised restriction on trade.[13]

In the first deviation from the original Panel, the AB held that the statement in the SPS Agreement that a measure shall be *based on* an international standard where one exists (except as otherwise provided for in the agreement) does not imply that measures need to *conform to* international standards. If this were so, contended the AB, the SPS Agreement would vest international standards (which are recommendations under the terms of the Codex Commission) with *obligatory* force and effect. To sustain such an assumption, the AB argued, language far more specific and compelling than that found in Article 3 of the SPS Agreement would be necessary.

The AB also disagreed with the Panel's finding that the EC ban provided a level of protection that arbitrarily and unjustifiably differed from levels provided by other measures, when such differences result in a disguised restriction on trade. The AB noted that while the EC does not regulate hormones in cabbage or eggs while regulating hormone-treated beef, this difference was not arbitrary or unjustifiable. In the view of the AB, there is a fundamental distinction between *added* hormones (natural or synthetic) and *naturally occurring* hormones. To regulate the latter would entail a comprehensive and massive governmental intervention in nature, reducing the comparison itself to an "absurdity" in the view of the AB. The judges also concurred with the EC that the distinction

[13] It also concluded that the Panel had exercised appropriate judicial economy in not making a determination whether the EC's measure was in conformity with Articles 2.2 and 5.6 of the SPS Agreement, thereby turning down the request made in the U.S. and Canadian appeals.

drawn between using natural hormones for therapeutic/zootechnical purposes and for growth promoting purposes was not arbitrary. The AB reasoned that although it is empirically impossible to monitor the quantity of exogenously administered natural hormones for growth promotion purposes because of endogenously produced background levels, consumers would be exposed to greater amounts of hormones if allowed for use as growth promotants. Growth-promoting hormones were administered continuously (by means of an ear implant) and over long periods of time (most of the lifespan of the animals involved), the AB argued, while hormones would be administered but once a year for zootechnical purposes.

The AB agreed with the Panel that the evident distinction between the regulation of carbadox and the regulation of hormone treated beef in the EC was indeed arbitrary and unjustifiable. However, the judges disagreed that this distinction constituted a disguised restriction on trade. The AB argued that the import prohibition could not have been designed simply to protect beef producers in the EC *vis-à-vis* beef producers in the United States and Canada, because the ban on the use of hormones applied to EC producers as well. Likewise, the AB took note of the legislative history of the measure, which documented the depth and extent of EC consumer concerns over 1) the results of general scientific studies on the carcinogenicity of hormones, and 2) the dangers of veterinary drug misuse which were brought to the attention of the public because of scandals related to the black market in these drugs in Europe. The AB concluded that a measure which would allay the fears of EC consumers would have the effect of increasing the consumption of beef within the Communities, which would be in the interest of farmers who produced hormone-free beef in exporting countries as well as EC farmers.

The EC has notified the WTO DSB that it intends to implement the findings of the Panel and AB reports. However, this long-standing dispute has yet to draw to a close. Press releases from the parties to the dispute indicate that the principles are still some distance apart in their interpretation of what constitutes "implementation" or a reasonable period of time for implementation. For example, the EC has indicated that it first intends to carry out a lengthy risk assessment before it decides on whether to lift the ban. The United States and Canada have countered that conducting

yet another risk assessment does not constitute implementation of the WTO decisions. At the moment, these matters are still under discussion.

What can be said of the legacy of this landmark dispute? First, that it provides supporting evidence for the observation by legal scholars that the hardest cases for WTO dispute panels will involve facially neutral measures --- measures that appear to apply equally to domestic and foreign producers. Adjudicating disputes over regulatory measures also presents a "delicate challenge" for tribunals because their decisions can be viewed as an implicit finding that the stated justification of the measure at issue was not its actual purpose [Farber and Hudec]. And in SPS cases, a decision can be interpreted as a judgment about the competency of a Member's official scientific establishment, as well as its motives.

Controversy over panel decisions can be compounded in cases such as the *Hormones* dispute, where the measure at issue could be viewed as a hybrid of protection (a crisis management decision) and protectionism (an economically expedient decision). However convenient the ban on hormone-treated beef may have eventually been for EC authorities seeking to reduce expenditures on disposal of intervention stocks of beef, it must be acknowledged that the original ban was proposed to allay public anxieties that emerged in the early 1980's following widely publicized reports of the "estrogen scandal" in Italy when residues of the illegal growth promotant DES were found in manufactured baby food.

Studies indicate that the occurrence of a low probability, high consequence event can cause the public's estimate of the probability of the re-occurrence of the event to be biased upward, thereby fomenting demand for stricter regulations [Camerer and Kunreuther]. Although experts, focused on the statistical measurement of risk likelihood, may not concur with public opinion about the need for revision of technical measures in such circumstances, regulators have sometimes decided to design policies that reflect public risk perceptions, defending their choices by pointing to the democratic foundations of their actions.

Successful challenges of measures whose most visible advocates are consumer or environmental groups rather than domestic producers, such as the measures at issue in both *Hormones* and *Tuna/Dolphin I* and *II*, can quickly undermine popular support of trade liberalization efforts [Hoekman and Leidy]. The general public (and their public representatives) can regard broad claims by environmental and consumer activists that the WTO Agreement lowers food safety or threatens marine mammals as credible because they are not perceived as personally gaining from the import restriction at issue. The technical complexity of these cases can make refutation of these claims difficult for free trade advocates.

A review of the disputes that will be heard in the near future suggests that a case with the emotional dimensions of the *Hormones* dispute will not likely emerge in 1998. Both of the next two cases to be heard, the Australian-Canadian *Salmon* dispute and the Japan-U.S. *Varietal Testing* dispute involve facially discriminatory measures that are justified on the basis of protecting, respectively, animals and plants from quarantine[14] pests and diseases (Table 2).

Table 2: Overview of complaints under the SPS Agreement[1]

Measure	**Complaining Party (Third Parties)**	**Status**
EC Measures Concerning Meat and Meat Products (Hormones)	United States and Canada	Appellate Body Report Adopted
Australian Measures Affecting the Importation of Salmon	Canada (United States & EC)	Active Panel
Japanese Varietal Testing Requirements	United States (EC, Hungary, Brazil)	Active Panel
Korean Measures Concerning Inspection of Agricultural Products	United States	Pending Consultations

[14] Quarantine pests and diseases are defined by the international standard setting organizations as those which are not present in the importing country, or are present, but under official control programs.

U.S. Measures Affecting Poultry Imports from the EC	EC	Pending Consultations
Korean Shelf-life Measures	United States	Settled Case
Korean Measures Concerning Bottled Water	Canada	Settled Case

[1] Distinct issues.

Also diminishing the contentiousness of these disputes is that while they could be broadly seen as "environmental" issues, the disputed measures do not involve controversial protection of favored species.[15] In fact, the *Varietal Testing* dispute involves Japanese conformity assessment procedures for judging the efficacy of methyl bromide treatments on fruit, a cause that the environmental community will probably not rush to embrace. The only other complaint involving a facially neutral food safety measure at the present time is the EC complaint again U.S. poultry process standards enacted in 1997. As the EC exported little more than $1 million in poultry products to the United States before current measures were adopted, it is unlikely that this case will be perceived as a significant threat to U.S. public health.

The Role of Risk Assessment in the SPS Agreement

The debate over whether the Panel and AB's decisions in the *Hormones* dispute could be interpreted as evidence in support of the view that the multilateral disciplines on SPS measures are either too stringent or too lax will likely overlook the one of the principle lessons of the case -- the fact that risk assessments may not only serve as the normative basis for SPS decisions in the post-Uruguay Round era, but will also constitute key evidence in SPS disputes. The *Hormones* dispute highlighted the fact

[15] A study of the use of trade measures against foreign environmental practices points out that the more controversial measures adopted or proposed by the EC and the United States have involved essentially moral objections to killing or mistreatment of animals, such as dolphins and the use of leghold traps. The author notes that the justification for these controversial measures is some distance from the conventional justification (threat of serious, immediate and irreversible harm to the global ecosystem) for the use of environmental trade measures [Hudec].

that risk assessment as typically performed by regulatory bodies may make judgement about a measure's conformity with the SPS disciplines difficult.

Risk assessment is a vehicle for interpreting and characterizing scientific evidence, and involves hazard identification, an estimate of the likelihood of a hazard, and an evaluation of the consequences of the hazard should it occur[16]. Assessments are usually oriented toward the evaluation of a single target exposure that can be regarded as providing an acceptably small risk -- which involves a mixture of scientific analysis, scientific opinion, and value judgments -- rather than evaluating a number of risk management alternatives that provide an array of different benefits and costs for national authorities to consider [Kopp, Krupnick, and Toman].

Whether by default or design, most assessments of hazards are either binary (safe or not safe) or qualitative (negligible risks, no appreciable risk) rather than quantitative. This complicates evaluation of claims that measures provide a higher level of protection -- can a measure that is apparently more stringent than an international standard be safer than safe? The two questions that such assessments raise is what is the definition of "safe"? and what are the assumptions that underpin the determination of "safe"? With respect to the first question, it has been observed that risk assessments often provide end points which mean little to policymakers or the general public, but which are more easily measurable from a biological standpoint. How should one weigh an infinitesimal increment in the number of cells that could potentially promote cancer, given that thousands or millions of these cells are produced by the body itself on a daily basis or occur naturally in beef and other foods? It is notable that the one estimate of a "statistical death" that could be associated with consumption of hormone-treated beef that emerged from the *Hormones* dispute was not provided by any of the parties to the dispute, but by one of the experts consulted by the Panel, who made the following statement during the proceedings:

[16] A definition of risk assessment, in addition to factors that should be considered in a risk assessment are found in Articles 5.1 through 5.3 of the SPS Agreement.

> ". . .the accompanying risk that would be associated by consuming meat containing residues would be extraordinarily small. It would be very hard on scientific grounds to say that the risk was zero. But it is likely to be very, very small. It could be zero. It could be as high by estimates [*sic*] as one cancer in a million people exposed to them over their lifetime. So the risk, to sum up those comments, is somewhere between zero and somewhere around one in a million.[17] And that one in a million is a very difficult number to pin down. A lot of assumptions go into it."

Without such recognizable end points, panelists will find it difficult to determine whether an SPS measures is, in the words of the AB, "sufficiently supported or reasonably warranted" by the risk assessment.

The assumptions that underpin determinations of "safe" will also likely be regarded as important information by panelists, if only because defending Members can be expected to argue that any violation of these assumptions therefore renders a measure "unsafe". The standard practice in risk assessment methodology is to employ conservative risk assessment assumptions to compensate for gaps in field data that may unavailable on *ex ante* basis. For example, the Codex ADI and MRLs for the hormones at issue in the *Hormones* dispute are based on an exposure assumption that the consumer will consume 500 grams of hormone-treated beef over an entire lifetime so as to provide a safety factor that would sufficiently mitigate risks associated with intentional or unintentional misuse. And notwithstanding the testimony of one the scientific experts in the *Hormones* dispute, who stated that the 32nd JECFA report indicated that a concentrated intravenous injection of 100 times the recommended dose of the hormones under study resulted in residues that reached only 15 - 16 percent of ADIs, the EC repeatedly raised questions about the safety of hormones when they were not used according to "good agricultural practice." The AB noted that the risk that is to be evaluated

[17] The same expert put this estimate into context, noting that about 110,000 of every million women will develop breast cancer. It is estimated that several thousand of the 110,000 breast cancer cases would be related to the total intake of exogenous oestrogens from every source, including foods such as eggs and meat, as well as from pharmaceuticals, such as the use of oestrogens for family planning purposes or hormonal replacement.

in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also, " the actual potential for adverse effects on human health in the real world where people live and work and die." Shortcomings in the previous risk assessments, the EC argues, provide sufficient justification for completing a new assessment, rather than basing any potential revisions of their current measure on existing evaluations.

It is widely recognized that although the bounds of uncertainty for risks assessment of chemical stressors (such as hormones and other additives) may span multiple orders of magnitude, the principles, methods, data, and conventions for chemical risk assessment are far more developed than for biological risk assessment [Powell]. Powell notes that there may be "large, irreducible uncertainties in predicting the effects of biological stressors" because they 1) grow, reproduce, and may multiply; 2) actively and passively disperse; 3) interact with ecosystems in unpredictable ways; and 4) randomly evolve. This observation is important in view of recent data collected by the U.S. Department of Agriculture on foreign technical barriers.

In 1996, USDA asked field personnel in its Foreign Agriculture Service (FAS) and producer groups that participate in the FAS Cooperator Program[18] to identify questionable foreign technical measures that threatened, constrained or blocked U.S. exports of primary and processed agricultural, forestry and fishery products. This information was subsequently vetted by scientists and analysts in USDA's regulatory agencies[19] who recommended deletion of identified barriers in the data set that were judged to be in conformity with international legal commitments, such as the WTO Agreement.[20]

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[18] The Cooperator Program at FAS includes approximately 40 groups representing specific U.S. commodity sectors such as horticultural products, feed grains, wheat, soybeans, and rice. These groups are funded by their members, primarily agricultural producers and processors. FAS and the cooperators share in the cost of overseas market development activities.

[19] These agencies include the Animal and Plant Health Inspection Service (APHIS), the Food Safety and Inspection Service (FSIS), the Agricultural Marketing Service (AMS), and the Grain Inspection, Packers and Stockyards Administration (GIPSA).

[20] The USDA survey results provide the most comprehensive view to date of regulatory regimes facing an important agricultural exporting nation. Questionable technical barriers were

The measures identified in the survey were dominated by SPS barriers (Table 3), particularly those addressing commercial plant and animal heath issues (210 barriers affecting trade of $3.02 billion) and food safety (76 barriers affecting $ 2.36 billion[21]). All of the measures justified on the basis of protecting production agriculture and most (47) of the measures in the food safety category mitigate risks associated with biological hazards.

Table 3: Foreign SPS barriers to U.S. agricultural exports by regulatory goal of measure and by importer income status

(Number of restrictions)

Regulatory Goal of Measure/ Importer Income Status[1, 2]	Protection of commercial production (crops and herds)	Protection of human health	Protection of the natural environment
Low Income	27	5	--
Lower Middle Income	41	15	1
Upper Middle Income	59	22	--
High Income	83	34	5
Total	210	76	6

[1]As defined by the World Bank

[2] Eight of the countries in this sample, most notably China and Russia, are not yet WTO Members.

reported for 62 countries. Over 300 market restrictions were identified that threatened, constrained or blocked $4.97 billion of U.S. agricultural exports, 7.1 percent of the $69.7 billion 1996 export value of the covered products. A detailed description of the survey design in addition to summary descriptive statistics of foreign technical barriers to U.S. agricultural exports can be found in Roberts and DeRemer (1997). Summaries of the aggregated survey results are also provided in Thornsbury, Roberts, DeRemer and Orden (forthcoming).

[21] The dollar totals sum to more than $4.97 billion because some restrictions span regulatory goals, and are therefore counted twice.

It is not known how robust the profile of regulatory regimes that emerges from the USDA survey results is across countries. Another major net agricultural exporter may face a substantially different distribution of questionable regulatory regimes if the commodity composition of its exports varies from that of the United States. The destination of exports is also likely to be a relevant factor -- a country that exports primarily to developing countries may face different regimes than one that ships to markets in North America, Japan, and Europe. But even in view of these uncertainties, it does not seem unreasonable to predict that many SPS disputes in coming years will center on different assessments of risks posed by biological stressors such as noxious weeds, yield-reducing arthropods, or food-borne microbial pathogens. The current state of biological risk analysis methodology could therefore represent one of the principle challenges facing the SPS Agreement in the coming years.

The SPS Agreement as a Catalyst for Regulatory Reform

Legal scholars have noted that while it is potentially constructive to have the SPS Agreement and the new WTO dispute settlement procedures in place, their formal existence does not guarantee that greater discipline will be imposed on disingenuous use of SPS barriers [Abbott]. Nonetheless, one hope of the Agreement has been that the enunciation of the principles for SPS regulations and the mere existence of binding adjudicatory mechanisms will prompt unilateral reconsideration of some SPS measures or contribute to negotiated resolution of some disagreements without recourse to lengthy, and sometimes fractious, dispute settlement proceedings.

As anticipated, evidence is accumulating that suggests that, at least in the G-8 countries that led the SPS negotiations[22], regulatory authorities in several instances are either unilaterally modifying regulations to comply with the Agreement or voluntarily modifying regulations after technical bilateral exchanges. For example, the United States' recent adoption of its "regionalization regulation" is

[22] The Group of Eight (or "G-8") Members that most actively participated in the negotiation of the SPS Agreement were: Argentina, Australia, Canada, the EC, Japan, New Zealand, Thailand, and the United States.

a significant departure from its long-standing practice of only recognizing entire countries as "free" or "not free" of a particular disease [Ahl and Acree]. This regulatory action has allowed imports of uncooked beef from regions in Argentina that have been recognized as aftosa-free into the United States for the first time in 80 years. And after three years of bilateral technical exchanges and joint research, the United States recently replaced its controversial 83-year ban on imports of Mexican avocados with a process standard which will allow avocados from a specified region in Mexico to be exported to the northeastern United States during the winter months. Similar examples of an accelerated schedule for "upgrading" SPS measures in the G-8 countries, including Japan's acceptance of U.S. tomatoes and Australia's acceptance of cooked poultry meat, can likewise be found. Although in all of these cases, a finding by regulatory scientists that an import protocol could be designed to reduce risks to negligible levels was a necessary condition, it was no doubt easier to enact these changes within the new framework of multilateral SPS disciplines which provided policymakers with the assurance that the measures of trading partners would likewise be obliged to conform to the same principles.

Members have also used the forum provided by the SPS Committee to air grievances over SPS measures when bilateral technical exchanges have reached an impasse. The opportunity to elucidate the details of a regulations and its enforcement before other Members has sometimes led to the correction of erroneous accounts of trade barriers reported by industry sources. In other cases, these discussions have served to pinpoint the source of disagreement between trading partners. On occasion, when Committee exchanges have failed to produce results that are satisfactory to both parties, Members have requested formal WTO consultations. These consultations have, in some instances, obviated the need for referring the matter to a WTO panel.

South Korea's change in policy regarding government mandated shelf-life standards provides one example where formal consultations led to a negotiated settlement (Table 2). The U.S. government questioned the scientific basis for uniform shelf-life requirements during WTO consultations with South Korea in May, 1995. Three months later, the two governments notified the WTO that they had reached a mutually acceptable solution to the dispute: South Korea agreed to allow

manufacturers of frozen foods and vacuum-packed meat to set their own use-by dates. Formal consultations may also successfully resolve the 1996 complaint by the United States against some of Korea's inspection measures that result in port delays that greatly exceed the norm in Asia. To date, Korea has modified some, but not all, of the measures at issue. The United States is currently monitoring the progress that Korea is making on implementation of the pledged reforms.

However, it is the transparency provisions of the SPS Agreement that offer the greatest promise of effective implementation of the new disciplines. Transparency provisions for regulatory measures are particularly important in view of the fact that exporters often report that complying with an undocumented *de facto* measure is a significant impediment to gaining access to a market. Annex B of the SPS Agreement details the new transparency obligations of WTO members which include: 1) notification of an *enquiry point* which is responsible for provision of answers to all reasonable inquiries from interested Members as well as for the provision of relevant documents (usually a copy of the actual regulation or a summary of it in one of the three official languages of the WTO); 2) notification of the *notification authority*, the single central government authority responsible for notifying SPS measures to the WTO Secretariat; and 3) notification of proposed modifications to existing SPS regulations or new SPS measures that could affect international trade so as to allow comment by Members before they are adopted.

The requirement to notify trading partners of changes in SPS measures -- together with the requirement to base SPS decisions on a risk assessment -- underpin the monitoring system established by the Agreement to facilitate decentralized policing of the many SPS measures that are promulgated each year by WTO Members. On the notification form, Members are asked to provide a justification of the measure, explicitly identify the products to which it applies, and note whether it conforms to an international standard (if one exists).

Two years after the entry into force of the Agreement, complete transparency still remains a goal. More than half of the Members have not yet notified a single SPS measure, although all the transparency disciplines have been obligatory for all Members since the entry into force for the

Agreement (Table 4).[23] Most of these Members, as could have been anticipated, are low or lower-middle income countries. It is encouraging to note that the major agricultural importing and exporting Members are conscientiously observing the transparency obligations. Together these 52 Members have notified a total of 724 measures during the first two years that the Agreement has been in force. Many of those Members in the upper middle and high income categories that have not yet notified an SPS measure are Member States of the EC[24] or small economies whose actions are unlikely to perturb international markets.

Table 4: WTO Member SPS Notifications by Income Class, 1995-1997

WTO Members/ Income Status[1]	Non-Notifying Members	Notifying Members	Number of Measures
Low Income	34	6	15
Lower Middle Income	21	17	87
Upper Middle Income	10	10	218
High Income	15	19	404
Total	80	52	724

[1] As defined by the World Bank

Source: WTO (G/SPS/W/50, G/SPS/GN/11, AND G/SPS/GEN/48) and author's calculations.

It is too early to judge if the transparency provisions of the SPS Agreement will significantly curb regulatory protectionism, but in the short run, its contribution to promoting symmetry of information among Members, many of whom are developing countries that are highly dependent upon the import and export of raw and semiprocessed agricultural products, should be recognized. For example, the EC's recent notification of a proposed regulation to lower maximum residue levels for aflatoxin in a wide range of foodstuffs (together with new testing regimes to detect these lower levels) prompted

[23] Other provisions of the Agreement are not obligatory for least-developing countries until 2000.

[24] The Commission of the EC notifies EC-wide SPS regulations, but individual Member States notify measures that fall outside of the competence of the Commission.

comment from a large number of Members, including Senegal, The Gambia, India, Brazil, and The Philippines. Under other circumstances, these Members may have had difficulty in learning about the details of the regulation at the proposal stage, either to raise questions about the measure or to prepare for its eventual adoption.

Concluding Remarks

The outcome of the highly visible *Hormones* dispute is likely to dominate any judgment in the near term about whether the SPS Agreement (and jurisprudence which interprets that Agreement) has struck the proper balance in disciplining the use of SPS measures. If one understands "proper balance" as a dispute settlement outcome that both consumer/environmental advocates and free-trade advocates could alternately support and criticize, then the Agreement has achieved its objective. Those who voiced concerns that the SPS Agreement would promote "downward harmonization" of national standards are likely pleased that the AB ruled that international standards are not obligatory under the terms of the Agreement. And although the Agreement's recognition of the "precautionary principle" is not likely broad enough to please some, the case also highlighted the fact that the SPS negotiators made provision for the adoption of conservative SPS measures to mitigate unfamiliar risks on a temporary basis. On the other hand, the Panel and AB findings put Members on notice that although measures may apply equally to domestic and foreign producers -- and are therefore in compliance with the National Treatment principle -- there still must be a "rational relationship" between the measure and the risks it supposedly mitigates, which some will consider to be an unacceptable affront to national sovereignty.

Those who saw the EC hormone ban as a vexing example of a nontransparent trade barrier that escaped discipline before the Uruguay Round are likely satisfied with the effectiveness of the new SPS disciplines in view of the Panel and AB rulings. However, confidence in the effectiveness of the Agreement could be seriously eroded if compliance with a ruling that a measure is "not based on a risk assessment" can be interpreted as a requirement to *perform* a risk assessment without changing the measure at issue. At this time, any judgment about the SPS Agreement that rests on the outcome of the *Hormones* dispute is complicated by the fact that it is not yet known how the EC will fulfill its obligation to bring its measure into conformity with the Agreement.

As legal scholars have repeatedly observed (and the *Hormones* dispute outcome illustrates), the effectiveness of the new WTO/GATT "hard law" (specific rules, quasi-judicial) system still depends

fundamentally on the political will of WTO Members to comply with legal discipline over their policies. In the case of the SPS Agreement, that will has been revealed in a number of politically costly unilateral and negotiated regulatory decisions made by authorities in both net agricultural exporting and importing countries over the past two years. But if political will is the necessary condition, it was evidently not a sufficient condition prior to the Uruguay Round. The principles and the institutional mechanisms established by the Agreement are therefore credited with being an important contributing factor in prompting or prodding Members to revise some restrictive SPS policies which have eased strains in bilateral trade relations, notably between the United States and East Asia, and the United States and Latin America.

Compliance with the transparency provisions of the Agreement may weigh heavily in future evaluations of whether the Agreement has made a significant contribution to the liberal international trading system. Changes in regulatory regimes, which track changes in production, processing, and detection/eradication technologies, are the norm, not the exception, and these changes will likely continue to spawn disagreements between importers and exporters. In this context, the continuing injunction to base measures on a risk assessment and to notify one's trading partners of proposed SPS measures, requirements which "increase the costs of self-serving or scientifically dubious decision making and thus discourage it" [Sykes] could make a sizable (albeit, difficult to measure) contribution to the multilateral trading system. Gauging this contribution will entail weighing whether an ounce of prevention has produced a pound of cure.

Further study of individual SPS measures will provide evidence about the degree to which the SPS disciplines contribute to good economic policy. True, Members have revised some conservative risk management protocols over the past two years, but in many instances these changes have been modest. While the Agreement requires a measure to be based on "scientific principles" and on "sufficient scientific evidence", nothing in the Agreement requires countries to enact only those measures whose "benefits" outweigh the "costs". The new SPS disciplines emphasize the use of pest- or disease-related costs associated with imports as a normative basis for regulatory decisions. The Agreement thus appears to be firmly rooted in a risk assessment paradigm, which embeds value

judgments about "acceptable" risks into regulatory policies, rather than an economic paradigm in which normative rules for designing SPS measures rests on cost-benefit analysis to *infer* appropriate levels of protection from individual preferences. In many cases sound science is compatible with sound economics, but in others, SPS regulations may have net economic costs even if they have solid scientific justification. Two recent studies of quarantine policies -- the U.S. geographic/seasonal ban on Mexican avocados and the Australian ban on bananas -- underscore the point that restrictive phytosanitary measures can produce consumer welfare losses that exceed the domestic costs of possible pest infestations [Orden and Romano; James and Anderson]. These cases are not unusual. James and Anderson observe that "SPS policy assessment currently is about where environmental policy assessment was two or three decades ago."

A larger question is whether the SPS Agreement could actually hinder efforts to base SPS measures on economic efficiency criteria if policymakers chose to do so. This issue is addressed in one recent paper which examines whether the legal obligations found in SPS Agreement are wholly congruent with welfare analysis guidelines that have been promulgated in various regulatory reform initiatives in the United States and other developed countries over the past few years [Roberts]. This study notes that the Agreement is ambiguous about the standing that [trade] benefits should have in SPS regulatory decisionmaking, creating uncertainty about the WTO-legality of measures based on cost-benefit analysis in some circumstances. However, any divergence between what economists would recommend and what the Agreement might proscribe may eventually be seen to be more apparent than real. Over time, one can anticipate that further research, drawing on evidence provided by unilateral policy choices and future dispute panel decisions, will permit more substantive judgement about how well the legal principles of the WTO/GATT system function to address SPS measures, and how might they be improved.

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