The Supervision of Health and Biosafety Regulation by World Trade Rules

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I. Introduction

The Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement or the SPS), which is part of the organic law of the World Trade Organization (WTO), can affect the ability of governments to provide health and achieve biosafety. Governments that are members of the WTO must follow SPS rules in enacting legislation and implementing regulations that come within the scope of the SPS Agreement. Consumer and environmental groups have widely criticized these rules for allegedly undermining public health.

This Article proceeds in the following way. The next part (Part II) reviews the operation of the SPS Agreement. Part III then briefly examines two important policy issues–the precautionary principle and product labeling. Part IV gives an overview of the new Cartagena Protocol on Biosafety. This Article concludes in Part V that, while there are legitimate concerns about whether the SPS interferes too much in health policy, a comprehensive evaluation of the SPS aimed at seeking major revisions is premature.

II. Operation of the SPS Agreement

Concerns about unjustified sanitary measures go back many decades. The League of Nations examined this problem with a view toward using science to determine the validity of trade bans. However, no multilateral discipline ensued until 1947, when the General Agreement on Tariffs and Trade (GATT) was established. Although GATT rules were intended to prohibit sanitation-based import bans that were disguised restrictions to trade, these rules were hardly ever tested. Instead, a GATT Standards Code was written in 1979, and when that proved inadequate, a new effort to draft a separate SPS agreement was begun in the late 1980s.

The SPS builds on the GATT in many ways. Perhaps the most important addition is the discipline on domestic measures. Under the GATT, a domestic health standard impeding an import was held only to the principle of "national treatment." So long as the import was treated no less favorably than the domestic product, it did not matter how flimsy the justification was for the domestic standard. As will be explained below, the SPS subjects non-discriminatory domestic measures to supervision whenever they affect trade. Because the SPS has more stringent disciplines than the GATT, the health exception in GATT Article XX(b) is not available to a government as a defense in an SPS lawsuit.

As of April 2000, WTO panels and the WTO Appellate Body (the Appellate Body) have handed down three SPS judgments. In all three cases, the defendant

government employing the health measure lost. Two of the disputes involved "sanitary" measures focusing on food safety and on fishery ecology. One dispute involved "phytosanitary" measures focusing on agricultural disease.

The first case was *EC–Measures Concerning Meat and Meat Products (Hormones*). The United States and Canada complained against a ban (begun in 1989) by the European Communities (EC) on the importation of meat produced from cattle that had been injected with or fed growth hormones. The EC had banned the use of six growth hormones in Europe to promote food safety and sought to keep out foreign meat produced with such hormones. The rationale for the ban was that the hormones might be carcinogenic. The Appellate Body ruled against the EC in January 1998; an arbitrator gave the European Commission (the Commission) fifteen months to bring its law into conformity with SPS rules. In mid-1999, the United States and Canada imposed trade retaliation against the European Union (EU) for failing to lift the ban against meat produced using growth hormones. EU officials refuse to lift the ban on the grounds that consumers do not want to eat meat produced with hormones because it may be unsafe.

The second case was *Australia–Measures Affecting the Importation of Salmon (Salmon*). Canada complained against an Australian ban (begun in 1975) on the importation of fresh, chilled, or frozen salmon (i.e., not heat-treated). Australia had enacted this ban to prevent the introduction of exotic pathogens not present in Australia. The Appellate Body ruled against Australia in October 1998; an arbitrator gave Australia eight months to bring its regulation into conformity with SPS rules. In February 2000, a WTO panel found that Australia failed to comply. Canada then sought authority from the WTO to retaliate against Australia. This pressure led to a settlement in May 2000, whereby Australia agreed to allow in Canadian salmon that meets sanitary processing standards.

The third case was *Japan–Measures Affecting Agricultural Products (Agricultural Products*). The United States complained about a Japanese phytosanitary measure (begun in 1950) that banned imports of apples, cherries, nectarines, and walnuts potentially infested with coddling moth. In 1987, Japan had provided for lifting this ban subject to certain quarantine and fumigation requirements which call for each variety of fruit to be individually tested. It was this separate testing requirement that provoked the WTO dispute. The Appellate Body ruled against Japan in February 1999. Thereafter, Japan agreed to bring its regulation into conformity with SPS rules by the end of 1999, and has apparently done so.

The victory by the plaintiffs in these three disputes will surely lead to more such cases in the future.

Disputes may be looming on issues such as antibiotics in animals and genetically modified (GM) organisms. Even when the substance being regulated is unquestionably harmful (e.g., dioxin), disputes can occur over whether the regulatory response is broader or longer lasting than necessary.

A. Overview of the SPS

The SPS is a trade agreement, not a health agreement. Although the preamble to the SPS takes note of a desire by governments to improve human and animal health, the SPS targets only the overuse of national health regulation. Thus, a government that abandoned all health regulations would not be in violation of the SPS. Governments do not violate the SPS by permitting exports unsafe for the foreign consumer.

Consider food safety, for example. Even though world food trade is very important economically and nutritionally, the SPS contains no minimum standard for food safety or for applying science to the food production process. In other words, although a government can violate the SPS by using poor science to

impose food safety regulation, a government cannot violate the SPS by neglecting science in failing to impose adequate food safety regulation.

SPS rules apply only to sanitary and phytosanitary measures as defined in the Agreement. In broad terms, the SPS pertains to laws that protect against exposure to pests (e.g., insects and weeds), disease-carrying organisms, disease-causing organisms, disease-carrying animals or plants, and to laws restricting additives, contaminants, and toxins in food and feedstuffs. For example, protection against pesticide residues in fruit is covered by the SPS because such residues are contaminants. Protection against the entry of exotic species is covered if the species cause disease or are pests. On the other hand, many health or environmental risks are not covered; a law regulating the entry of drugs or cigarettes will usually not come within the terms of the SPS. Protection against (real or imagined) human health risks from bioengineered processed products is apparently not covered by the SPS because genetic modification is not listed in the above categories. But the risk that bioengineered seeds might spread insect pests is covered by the SPS because the "spread of pests" is a listed SPS risk.

Whether a product is covered by the SPS has caused considerable confusion. If the SPS applies to a particular risk, then governments must not undertake health regulation prohibited by SPS rules. If the SPS does not cover a particular risk, then governments have no SPS obligations for that product or process. Governments are not necessarily prevented from regulating that risk; rather, the WTO will review such regulation under less onerous rules in the Agreement on Technical Barriers to Trade (the TBT Agreement or the TBT) or the GATT. The TBT Agreement does not supervise any measure covered by the SPS Agreement.

The SPS Agreement only pertains to health standards applied to imports. Thus, a country imposing an unscientific domestic ban (e.g., on a pesticide residue) that

did not apply to imports would not violate the SPS Agreement. Of course, this retained autonomy is unlikely to prevent trade conflict. Governments do not typically impose a health standard on domestic production while legally permitting imports that do not meet that standard.

Before turning to the SPS rules, a brief discussion of the burden of proof and the standard of review may be helpful. As is typical in lawsuits, the initial burden lies with the plaintiff government lodging the complaint, which must establish a clear (i.e., prima facie) case of inconsistency with SPS rules. Once that occurs, the defendant government employing the health measure has the burden to bring forward evidence and arguments to refute the allegation that it is violating a WTO rule. The standard of review dictates whether the panel should be deferential to the regulatory or judicial authorities of the defendant country imposing the health measure. As can be seen in *Hormones*, the Appellate Body rejected the Commission's arguments for deference. The Appellate Body stated that the role of the panel is to make an "objective assessment of the facts" relying on the evidence as presented by governments and outside experts.

B. SPS Disciplines

The complex SPS rules can be abridged into eight disciplines and one exemption. This section will briefly discuss these rules drawing from the language of the SPS and, when available, WTO case law.

The first SPS discipline is the science requirement. SPS Article 2.2 states that governments "shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles, and is not maintained without sufficient scientific evidence." In *Agricultural Products*, the Appellate Body interpreted this provision to require "a rational or objective relationship between the SPS measure and the scientific evidence." The panel and Appellate Body concluded that Article 2.2 was

being violated because Japan could not show that the quarantine and fumigation used for one variety of fruit or nut would be inadequate for other varieties.

Although many commentators suggest that "sound science" is a requirement of the SPS Agreement, that term does not appear anywhere in the Agreement itself. In omitting this term, the Agreement remains unclear as to what extent panels may discount questionable scientific findings presented by a government. So far, no panel has been faced with such a decision. Eventually, a dispute will arise where a government presents a scientific study for a SPS measure that is then challenged by other scientists as being a poorly conducted study. Future WTO panels will likely seek to weigh competing studies in the manner that many national courts do.

A second SPS discipline is the requirement for a risk assessment. Analysts looking for coherence within the WTO might view this discipline as part of a new pro-competitive regulatory thrust of world trade rules. At a sufficient level of abstraction, there is a common thread between the WTO requirements to protect intellectual property, to administer regulations on trade in services "in a reasonable, objective and impartial manner," and to utilize a risk assessment. The common thread is the articulation of appropriate government regulatory practices.

SPS Article 5.1 requires governments to ensure that their sanitary and phytosanitary measures are "based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health." This requirement has proven to be of central importance in enforcing the SPS Agreement; it was litigated in all three WTO disputes and consequently, there is now a small body of case law in which each defendant government was found to be in violation of Article 5.1.

What is a risk assessment? The SPS Agreement explains that a risk assessment can be either "the evaluation of the likelihood of entry, establishment or spread of

a pest or disease . . . or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs." In interpreting this provision, the Appellate Body explains that, while an adequate assessment must evaluate the probability of risk, it does not have to make a monolithic finding. Thus, a risk assessment that presented both a "mainstream" and a "divergent" scientific view could be an adequate assessment. Moreover, a risk assessment is not required to be expressed as a quantitative conclusion.

According to the Appellate Body, a risk assessment must find evidence of an "ascertainable" risk. The Appellate Body has stated that it will not be sufficient for governments to impose regulations simply on the basis of the "theoretical" risk that underlies all scientific uncertainty. In *Salmon*, for example, the Appellate Body agreed with the panel that the analysis conducted by the Australian Government was not a proper risk assessment because it lent too much weight to "unknown and uncertain elements." On the other hand, there is no minimally sufficient magnitude of risk that regulators must ascertain. Adding this up, the Appellate Body appears to be stating that a risk assessment can still be acceptable even if it points to an extremely small risk.

Hormones made clear the central importance of a risk assessment. In that dispute, there was considerable evidence that the use of hormones as a growth promoter was safe. Yet most of this evidence assumed that the hormones would be used in accordance with "good veterinary practice." Thus, if hormones were misused in fattening animals, the available evidence did not demonstrate the safety of eating such meat.

This lacunae did not prevent the EC from losing the case, however. Even while admitting that hormone abuse could constitute a health risk, the Appellate Body faulted the Commission for not having a risk assessment of such potential abuse. Although it is often said that the SPS only prohibits import bans on products that

have been proven safe, this episode shows that SPS disciplines can disallow a health regulation aimed at a potentially unsafe practice when no risk assessment exists.

Once the existence of an adequate risk assessment is shown, the panel must then consider whether the health measure is "based on" this assessment. The Appellate Body reads "based on" as a "substantive requirement." In the first SPS case, *Hormones*, the panel sought to impose a procedural requirement that the defendant government actually rely upon the risk assessment. The panel then undertook an administrative law analysis of the Commission's decision-making process. This approach had the effect of excluding new scientific evidence that arose during the course of WTO review. In an important ruling, the Appellate Body rejected this attempt to incorporate rulemaking-type obligations into the SPS.

The Appellate Body has been a bit unclear on how this "based on" test operates. Within the same decision, it said that the risk assessment must "sufficiently warrant," "sufficiently support," "reasonably warrant," "reasonably support," or "rationally support" using the health measure, and that there must be an "objective relationship" or a "rational relationship" between the risk and the measure. This test was first implemented in the *Hormones* case, where the panel and Appellate Body found that the thin EC risk assessment did not rationally support banning the importation of meat produced with growth hormones.

The Appellate Body noted that Dr. George Lucier of the U.S. National Institute of Environmental Health Sciences, an expert consulted by the WTO panel, had testified that one out of every million women would get breast cancer from eating meat produced with growth hormones. But the Appellate Body viewed Lucier's testimony, noting that his opinion was not based on studies that he had conducted and that his views were "divergent" from the other views received by the panel. It is unclear whether the Appellate Body dismissed Lucier's opinion as

scientifically unsound, or adjudged a one-in-a-million risk to women to be unimportant.

The SPS Agreement does not direct WTO panels to apply a benefit-cost analysis. Thus, so long as a governmental measure is based on an adequate risk assessment, the fact that the measure's cost exceeds its benefit would not constitute a violation of the SPS. Looking ahead, one can foresee attempts by litigant governments to impose an economic test on defendant governments via Article 2.2 or Article 5.3, which requires governments to "take into account as relevant economic factors" several factors including "the relative cost-effectiveness of alternative approaches to limiting risks." Even in its first SPS decision, the Appellate Body noted that promoting international trade and protecting human health were "sometimes competing" interests. This may lead to efforts by panels to weigh these competing interests.

The third core SPS discipline is the requirement for national regulatory consistency. Article 5.5 states that "[w]ith the objective of achieving consistency" in levels of protection against health risks, a government "shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade." This is the most controversial SPS rule because it supervises a government's choice of a "level" of health protection to be sought.

The Appellate Body has confirmed that there are three elements to an Article 5.5 violation. First, the defendant government must be seeking different levels of health protection in "comparable" situations. In *Salmon*, the Appellate Body explained that situations are "comparable" when there is "in common a risk of entry . . . or spread of one disease of concern." For example, health regulations on salmon (for consumption) may be compared to regulations on herring (for bait) because both salmon and herring can cause the same health risk. The second element is that the differences in the government's intended level of

protection must be "arbitrary or unjustifiable." This can be found if the risks are commensurate but the level of protection is different. The third element is that the health measure embodying these differences results in discrimination or a disguised restriction on international trade. In the disputes so far, the first two elements have been more easily shown. Therefore, it is the third element on which many cases will hinge.

In *Salmon*, the Appellate Body made five arguments for concluding that the Australian health measure constituted discrimination or a disguised restriction on trade. It will be useful to examine the Appellate Body's analytical approach because the five arguments do not prove much. The first two arguments were mere bootstrapping; the Appellate Body pointed to the lack of a risk assessment (discussed above with Article 5.1) and to the different levels of health protection being sought for salmon and herring. The third argument was that there was a "substantial" difference in the levels of health protection pursued. The fourth argument was that an Australian Government draft report in 1995, which would have been tolerant of salmon imports, was revised in the final report of 1996. The fifth argument is that Australia lacks strict internal controls on salmon equivalent to what it imposes at the border.

This judicial approach is confounding in its analytical weakness and in its potential for mischief. Accusing a government of trade discrimination or a disguised trade restriction is a serious charge that should not be hurled lightly. As the Australian representative explained to the Appellate Body, it should not be a violation of the WTO for a government to change a recommendation between a draft and a final report. Similarly, it should not be a WTO violation for an island country to lack internal health controls on commerce equivalent to external border controls. Yet, according to the Appellate Body, such possibly innocent acts can aggregate into a SPS violation. The mistake the Appellate Body made was to assume that the incoherence of Australia's policy implied a protectionist motivation. This puts the WTO in the indefensible position of refusing to tolerate

irrational government policy in matters of public health while continuing to tolerate irrational government trade policies such as tariffs and quotas.

A government convicted of violating Article 5.5 has two choices if it wants to comply. It can upwardly harmonize its chosen level of health protection or it can downwardly harmonize. Thus, although it would not be correct to say that Article 5.5 promotes downward harmonization, there is that potential and therefore the implementation of SPS decisions should be closely monitored.

The fourth core SPS discipline is the least trade restrictiveness requirement. Article 5.6 states that governments shall ensure that their sanitary and phytosanitary measures "are not more trade-restrictive than required to achieve their appropriate level" of protection. To prove a violation, an alternative measure, that is significantly less restrictive to trade, must be reasonably available.

In two cases, the panels held that Article 5.6 was being violated, but both decisions were reversed on appeal. These Appellate Body rulings contain some important interpretations of Article 5.6. The first is that governments are obligated to determine and reveal their chosen level of protection to WTO panels so that SPS rules can be applied. Another is that in analyzing an alternative measure, panels will consider whether it matches the intended level of protection, not the actual level of protection achieved by the SPS measure that is the target of the WTO lawsuit. Third is that the complaining country must show that the alternative measure exists. In other words, a panel may not posit the alternative based on the advice of experts.

In the most recent SPS Article 5.6 decision, the Australia Salmon Panel held that the new measures instituted by Australia violated Article 5.6. The panel’s decision was particularly noteworthy in failing to identify any particular alternative measure that would have fulfilled Australia’s own chosen level of protection; instead, the panel pointed to a menu of options from which it asserted that

Australia could have fashioned an alternative policy. If future panels follow this approach, it will become much easier to prosecute an Article 5.6 claim.

The fifth SPS discipline, Article 2.3, forbids measures that "arbitrarily or unjustifiably discriminate" between countries "where identical or similar conditions prevail." It also states that SPS measures "shall not be applied in a manner which would constitute a disguised restriction on international trade." This provision has not yet been independently invoked in finding a SPS violation.

The sixth SPS discipline is the requirement to use international standards. Article 3.1 states that governments "shall base" their SPS measures on international standards, where they exist, except as otherwise provided. As this provision links with others in a very confusing skein of obligations and exceptions, this Article will seek only to give a summary of this part of the SPS Agreement. International standards are the standards drafted by organizations such as the Codex Alimentarius Commission for food safety, the International Office of Epizootics for animal health, and the International Plant Protection Convention for plant health. When such standards do not exist, Article 3.1 has no effect.

When international standards do exist, a government has three choices: (1) use a higher standard in order to pursue a higher level of health protection, (2) use a lower standard, or (3) conform its SPS measure to the international standard. By conforming to the international standard, a government would gain a presumption in the WTO that its measure complies with SPS rules. This presumption would be rebuttable, however. Some analysts have suggested that governments would have a greater incentive to use international standards if they were truly a "safe harbor" from being challenged as SPS violations. Other analysts have criticized benchmarking to standards drafted in closed processes. For example, in February 2000, the Transatlantic Consumer Dialogue declared that "[g]overnments should only recognize or be involved in harmonization activities

negotiated in open, accountable democratic fora, with clear avenues for public input and transparent methods of rulemaking and recordkeeping."

If a government chooses to pursue a level of health protection higher than the international standard, then it must meet all the SPS requirements including the disciplines discussed above. The existence of the international standard does not put a government in a worse position for not having followed it. Thus, a government does not have to justify a deviation from the international standard. This point was litigated in the *Hormones* case where the WTO panel, surprisingly, sought to shift the burden of proof to a government that chose not to use an international standard. The Appellate Body quickly reversed this ruling.

If a government chooses to pursue a level of health protection lower than the international standard, then it must meet other SPS requirements. It would not have to justify the deviation from international standards, even for its exports. The government need only assert that the lower standard results from its chosen level of protection. It should also be noted that a government of a country exporting food that fails to meet international health standards has no obligation to notify importing countries.

The seventh SPS discipline involves the recognition of equivalence. Article 4.1 requires the government of an importing country to accept a SPS regulation by an exporting country as equivalent to its own, if the exporting country's government can objectively demonstrate that its health regulation achieves the level of protection chosen by the importing country's government. This provides a valuable opportunity for exporting countries that often face impenetrable regulatory systems in importing countries.

The eighth SPS discipline regards approval and inspection procedures. SPS Article 8 and Annex C require such procedures to be undertaken and completed "without undue delay." This provision has not yet been the subject of dispute settlement.

In addition to these eight SPS disciplines, there is one other core SPS provision: Article 5.7, regarding provisional measures. This provision states that, "[i]n cases where relevant scientific evidence is insufficient," a government may "provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information." In such circumstances, the government is required to obtain additional information necessary for a more objective assessment of risk and to review the SPS measure within a reasonable period of time. This provision provides a qualified exemption from SPS Article 2.2.

The first country to invoke Article 5.7 was Japan in the *Agricultural Products* case, wherein Japan argued that "varietal testing could be considered a provisional measure." In an important decision, the WTO panel suggested that it was up to the United States, the plaintiff, to establish that Japan had not complied with Article 5.7. On the facts before it, however, the panel rejected Japan's argument and was upheld by the Appellate Body. The Appellate Body stated that Japan had not obtained information for an objective assessment as to whether different fruit varieties manifest dissimilar quarantine effects.[150a] Japan had also failed to review its measure within a reasonable period of time.

A discussion of Article 5.7 provides a good window for introducing the so-called "precautionary principle," which is relevant to this provision and also relevant to the SPS as a whole. The Rio Declaration on Environment and Development (the Rio Declaration), Principle 15, states that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." In the *Hormones* dispute, the EC chose not to invoke Article 5.7 as a defense; instead, it sought to justify its failure to follow Article 5.1 by calling attention to the precautionary principle, which it characterized as a rule of customary international law. The presiding WTO panel responded that even if it was part of customary international law, the precautionary principle would not override Article

5.1, particularly since the precautionary principle had been incorporated into Article 5.7.

The Appellate Body agreed with this conclusion and offered some additional observations about the precautionary principle. First, it expressed uncertainty as to whether the precautionary principle had crystallized into a general principle of customary international environmental law. Second, it found that outside of environmental law–in other words, health law–the status of the precautionary principle awaits more authoritative formulation. Third, it stated that the precautionary principle had not been written into the SPS Agreement as a ground for justifying a measure that otherwise violates the SPS. Fourth, it said that the precautionary principle "finds reflection" in SPS Article 5.7, but that this provision does not exhaust the relevance of the precautionary principle for the SPS. Fifth, the Appellate Body counsels those panels considering whether "sufficient scientific evidence" exists to bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks are irreversible. The Appellate Body counterbalances this point, however, by stating that the precautionary principle does not by itself relieve a panel from applying principles of treaty interpretation. What all these dicta add up to must await clarification in future cases.

As noted above, Article 5.7 states that when relevant scientific evidence is insufficient, governments may provisionally adopt SPS measures on the basis of available pertinent information. Future adjudications will determine how insufficient evidence can be and still justify a SPS measure. It is also unclear whether Article 5.7 provides an exemption to other SPS disciplines beyond Article 2.2.

C. Appraisal of SPS Dispute Settlement

SPS dispute settlement is providing good results for producers in exporting countries. Three complaints have been brought to the WTO and have been

adjudicated in favor of the exporter. As of June 2000, two of these decisions have forced changes in national health regulations. Champions of SPS claim that no health interests have been sacrificed because the overruled import bans were unjustified, but until new imports enter, and time ensues, no one can know for sure.

Resolving the legal dispute is not equivalent to resolving the health dispute. Suppose that Australia complies with the WTO ruling, allows in Canadian salmon, and then suffers a huge loss from foreign salmon disease. Who would bear the cost of the WTO panel being wrong about the danger of alien pathogens? Surely not the panel. Not the Canadian exporter, nor the WTO. No, it would be Australians that would suffer that liability. Right now, defendant countries like Australia have nothing to gain from SPS litigation and plaintiff countries like Canada have nothing to lose.

It should also be noted that the SPS Agreement–which was largely initiated by the U.S. government–favors those countries that have a surfeit of administrative procedures. Governments that can produce a voluminous risk assessment, show that it was considered by regulators, and document each step of the regulatory process will probably do better as SPS defendants than countries with thinner regulatory structures. This may be one reason why no case has been lodged against the United States even though there are numerous U.S. regulations that keep out foreign agricultural products. On the other hand, the United States could be disadvantaged by its activist judiciary. If a federal agency undertakes a risk assessment and decides to allow in an import, and then the agency's action is overturned by a court for having exceeded the agency's authority, the exporting country would have a strong SPS case against the United States.

Although most SPS disciplines need extended observation before one can draw any conclusion, it is not too soon to begin drawing conclusions about Article 5.5, the requirement for regulatory consistency in levels of health protection being

sought. In conducting an examination of national policymaking, a SPS panel is bound to provoke public concern about the loss in regulatory autonomy. The stringency of SPS Article 5.5 can be seen by comparing it to U.S. Commerce Clause and European Community internal market jurisprudence. While an odd exception may exist, facially neutral regulations are not struck down either in Europe or the United States for being more stringent than regulations applied in comparable situations. Thus, Article 5.5 is too extreme an should be repealed.

III. Precautionary Principle and Labeling

Part III of this Article reviews two of the most controversial topics in SPS law. The first section of this Part discusses the ambiguities of the precautionary principle and how they relate to the SPS. In the second section, the topic of labeling, particularly as it relates to GM products, is discussed.

A. Precautionary Principle

As noted above, the Appellate Body held that the precautionary principle finds reflection in SPS Article 5.7, which states that where scientific evidence is insufficient, governments "may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information." Article 5.7 provides leeway to an interventionist-minded government worried about unknown risk. At this early stage of SPS adjudication, there is no reason to conclude that the existing language in Article 5.7 is inadequate to address the problem of uncertain science.

Nevertheless, Article 5.7 is viewed as insufficient from two sides. Consumer groups and the Commission say that the precautionary principle should be written into the Article, or, more broadly, into the WTO Agreement. The word "provisionally" is also objected to because it suggests that precautionary measures should be time limited. On the other side, some business groups and

developing country governments view Article 5.7 as a potential loophole that allows trade restrictions lacking a scientific basis.

One problem with incorporating the precautionary principle into the SPS is that there is no single authoritative statement of the principle. The various intergovernmental renditions of the principle differ on key elements. For example, the 1982 World Charter for Nature states that "[a]ctivities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed." This seems to be directed at individual economic activity and mandates a cost-benefit analysis. In 1990, the Bergen Conference Ministerial Declaration on Sustainable Development (the Bergen Declaration) employed the term "precautionary principle" and states that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation." The Bergen Declaration seems to be directed at governmental measures and proposes that they go forward in the absence of full scientific certainty. Measures to prevent environmental degradation could be inhibitory (e.g., government regulations) or promotional (e.g., government subsidies).

The most well-known formulation came in the Rio Declaration of 1992. Denoted as the "precautionary approach," it states that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." This provision seems to be directed at governmental measures and suggests that cost-effective action not be postponed while awaiting more scientific information. Similar to all versions of the precautionary principle, it provides guidance in situations of scientific uncertainty. According to James Cameron, a leading legal expert on the principle, when scientific certainty is present, measures to forestall harm are "preventative," not precautionary.

It is unclear what "cost-effective" means in this context. In 1998, the Commission formulated guidelines for the application of the precautionary principle which state that "[m]easures based on the precautionary principle must include a cost/benefit assessment . . . ." This accords with the views of one prominent environmental analyst who explains that "[i]t is critical to recognize that the precautionary principle is meaningless without a robust analysis of the economic aspects of its application in particular cases."

Incorporating the Rio Declaration precautionary approach into the SPS would constitute a major change because, as presently interpreted, the SPS does not mandate reliance on benefit-cost analysis. The SPS permits governments to impose very costly controls so long as some minimal risk is being avoided. Although the precautionary principle might loosen the SPS in allowing regulation without "full scientific certainty," such loosening would be countered by a new requirement for a cost-effectiveness finding. Thus, contrary to the assumptions of some consumer advocates, adding the precautionary principle to the SPS would not necessarily make it easier for governments to justify bans on hormones or GM products.

There is no one official rendition of the precautionary principle. Some commentators exclude the cost-benefit test; for instance, the WTO Secretariat states that the precautionary principle calls for caution "to ensure safety margins against possibly irreversible damage." Another interpretive issue involves the allocation of the burden of proof in a regulatory process. For example, the 1998 Wingspread Statement on the Precautionary Principle says that "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof." The advocacy group Public Citizen states the principle as "potentially dangerous substances must be proven safe before they are put on the market." Both the Wingspread and Public Citizen

formulations seek to put the onus on the producer rather than the regulator. The World Charter for Nature seems to do so as well.

Given these variations, the existence of a coherent precautionary principle seems doubtful. Proponents of the principle need to explain what its value-added would be to a rational decision-maker using analytical techniques for the estimation and management of risks. It is not clear that the principle of "precaution" (or simply caution) would improve the quality of decisions.

A little-noted characteristic of SPS rules is that they apply in the same way to national regimes where:

> (A) private activities are prohibited unless the proponent shows them to be safe, and
>
> (B) private activities are permitted unless a regulator shows them to be unsafe and hence prohibits them.

While there are probably no governments that are pure Type A or B, governments differ widely in their regulatory approach to risk. Yet the SPS is procrustean in requiring evidence of risk before a product can be regulated (other than provisionally). Even regulatory inaction–refusing to approve a new product–is a governmental measure if there is an underlying law which prohibits activities unless they are permitted.

SPS rules are not neutral between Type A and B countries. Consider the following example: Suppose a regulator wants to be very cautious about the bioengineering practice of blending fish genes into fruit and decides to wait twenty years (i.e., one human generation) of innocuous use elsewhere before granting approval for such GM products. Assuming that GM products come within the scope of the SPS, its rules would seem to disallow such extreme risk aversion, if twenty years is too long to be "provisional." This example shows that

Type A countries may have a harder time complying with the SPS than Type B countries.

This situation has led many environmentalists to call for a change in the burden of proof in WTO/SPS proceedings. In the *Hormones* dispute, for example, the United States was able to prevail by showing that the Commission's hormone ban was not based on a risk assessment. The SPS rules could be changed to require the United States to prove that the banned hormones are safe.

The tightness of SPS rules is only one aspect of the broader debate about the precautionary principle. Proponents have a much broader goal than taking the WTO's thumb off national regulators: They want to fortify national regulation of technological change. It would be interesting to run a simulation of a "strong" precautionary principle and apply it to the major innovations of the Twentieth Century, such as nuclear fission, lasers, jet engines, contact lenses, antibiotics, etc. Would the precautionary principle have slowed these down?

B. Product Labeling

SPS rules are unclear regarding mandatory product labeling. In its definition of SPS measures, the Agreement includes "packaging and labeling requirements directly related to food safety." The implication is that other labeling requirements are not supervised by the SPS. For example, labeling for general consumer information would seem to be supervised, if at all, by other WTO agreements such as the TBT and the GATT. But no panel has yet clarified this point. Some legal analysts have suggested that a labeling requirement for meat produced with added hormones would violate WTO rules. Many developing country governments argue that ecological labeling (eco-labeling) requirements are inconsistent with WTO rules.

Within civil society, there is strong support for labeling. Recently, Consumers International stated that "[m]easures to support informed choice should not be

undermined by the WTO; for example, the labeling of genetically modified foods should not be threatened by WTO rules." Recognizing the adage that "you are what you eat," many consumers seek information not only about the salubriousness of food, but also the corporate ethics of its producers.

The biggest labeling conflict involves genetic modification. Many governments are already implementing labeling requirements (e.g., the EU and Japan) or are moving toward them (e.g., Australia). Indeed, in 1999, a United Nations Development Programme study urged that every country should demand transparency and labeling of transgenic products. But some governments, such as the United States and Canada, have resisted the labeling movement. According to the U.S. Trade Representative: "In the United States, companies are not required to label products simply because they are produced through biotechnology. The United States believes that such labeling is unnecessary, in the absence of an identified and documented risk to safety and health."

In general, factual product labels are a market friendly measure. Providing consumers additional information empowers them to make choices according to their own self-interest. Although a labeling requirement is coercive when the manufacturer would prefer not to disclose the information, labeling is a lot less coercive than banning a product. In the long run, labeling could prove beneficial to the GM industry by enabling a gradual buildup of consumer confidence regarding the safety of genetic modification.

It may be true that gratifying consumer inquisitiveness with unnecessary information will turn counterproductive if consumers make irrational choices with that information. But even so, it is hard to see how the WTO can call factual food labeling unnecessary when the WTO permits governments to require labels disclosing the country of origin. The WTO would put itself in peril by attempting to restrict factual labeling.

IV. Cartagena Protocol on Biosafety

In January 2000, an intergovernmental conference approved the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Biosafety Protocol or the Protocol). A similar effort a year earlier had ended in deadlock, and it appears that the new willingness of governments to compromise resulted from a more conciliatory stance by industry and a desire by politicians to avoid another failure like the WTO Seattle Ministerial Conference. The Biosafety Protocol has many important facets beyond the scope of this Article and the discussion here will focus only on implications for the SPS agreement, the precautionary principle, and labeling.

The Biosafety Protocol is an environmental treaty with the stated objective of "ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology." Living organisms are defined as "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids." Living modified organisms (LMOs) are defined as living organisms that "possess a novel combination of genetic material obtained through the use of modern biotechnology." Thus, for example, raw grain shipped to a food producer is an LMO, while the content of canned goods made by the producer is not an LMO. Pharmaceuticals for humans are excluded from the Protocol.

The Protocol sets up a system to regulate international trade of LMOs. For LMOs intended to be introduced into the environment (e.g., planted), the Protocol requires the government of the exporting country to give advance notice to the government of the intended importing country and declares that the importing country may prohibit such imports following a risk assessment. The Protocol further provides that "[l]ack of scientific certainty . . . shall not prevent that Party from taking a decision, *as appropriate* . . . in order to avoid or minimize such potential adverse effects." For LMOs intended for direct use as food, feed, or processing, the Protocol declares that a Party may take a decision on imports under a domestic regulatory framework, or if it is a developing or transition

country, may regulate imports following a risk assessment. Such import decisions are subject to the same guidance regarding a lack of scientific certainty. The importing country would need to be proactive as there is no advance notice procedure for LMOs used for food, feed, or processing. The Protocol also directs that "[m]easures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects" of LMOs on biodiversity. This is a positive requirement for action.

The Protocol includes provisions regarding the minimum documentation needed for the transboundary movement of LMOs. When intended to be introduced into the environment or held in contained use, LMOs are to be clearly identified. When intended for use as food, feed, or processing, the requirements are less strict; the container need only say that it "may contain" LMOs. Detailed requirements for this are to be developed by the Conference of the Parties.

The drafters sought to make the Biosafety Protocol compatible with the SPS, and it appears that they conceded. To the extent that the Protocol requires a trade measure–most notably in declaring that measures based on a risk assessment shall be imposed to the extent necessary to prevent adverse effects–this would seem to be potentially consistent with SPS Articles 2.2 and 5.1. In permitting national discretion in using trade measures in the absence of scientific certainty, the Protocol would seem to be potentially consistent with SPS Article 5.7. Furthermore, action taken pursuant to the Protocol may become an international standard privileged under SPS Article 3.2, which would give an import ban or a label a presumption of consistency with SPS disciplines.

Disputes about a national measure taken pursuant to the Biosafety Protocol could, of course, be brought to the WTO. But there is no reason to think that a WTO panel would rule against an import ban or label that meets the terms of the Protocol. As we look ahead, a key issue may be whether the dispute procedure of the Convention on Biological Diversity (CBD) will be utilized to make these

judgments in an environmental context rather than relegating them to be made in the WTO trade context. Unlike the WTO dispute procedures which have compulsory jurisdiction, the CBD procedures depend upon prior consent of the parties before going to arbitration or submitting the dispute to the International Court of Justice. But if the CBD arbitration or adjudication takes place, it seems likely that the WTO would grant deference to it.

The Biosafety Protocol employs a fairly strong version of the precautionary principle with no mention of cost-effectiveness. Yet it does state that importation decisions will be taken "as appropriate." It is unclear whether this is meant to incorporate a proportionality test.

V. Conclusion

In its first five years, the SPS Agreement has been used by governments to challenge foreign trade barriers that may not be necessary. With the exception of a few rough spots, the process has worked reasonably well. Nevertheless, there are grounds for worry that the SPS endangers public support for the trade regime. As European Trade Commissioner Pascal Lamy admitted recently, the SPS Agreement "was not primarily conceived with consumers in mind."

In adjudicating SPS complaints, the WTO may gain a reputation as a naysayer to health and biosafety regulation. Every time it declares an SPS measure to be WTO-illegal, there will be consumers who lament a perceived loss in health security. Already there are many non-governmental organizations around the world who oppose the WTO because they believe that it privileges trade over a healthy environment. The WTO rules on food safety were one of the chief targets for protestors at the WTO Ministerial Conference in Seattle.

The WTO demands science to justify sanitary measures that impede trade, but it seeks no science to justify commercial measures that impede trade, such as

antidumping duties. This selective application of science undermines the WTO's claim that it is operating in the public interest.

The debate over the precautionary principle has helped to clarify the difficulty of imposing science-based rules on national risk management processes that routinely balance science against social values. The drafters of the SPS thought it would be flexible enough to accommodate all legitimate health concerns, and perhaps it is. But the drafters did not foresee that the process of international supervision would become so controversial among consumers.

The Biosafety Protocol is significant because it establishes new environmental rules that cut through some of the uncertainty in the SPS. By achieving a treaty that appears to balance trade and environmental concerns, the governments have taken an important step to head off GM related disputes that could undermine the WTO. A similar approach could be used for other health and environmental concerns in the years ahead.