CATTLE, DOLPHINS, AND THE WTO:
The Potential Impact of the World Trade Organization Agreements on United States Food Regulation

Submitted to Mr. Peter Barton Hutt for the Seminar on Food and Drug Law in Satisfaction of the Written Work Requirement

Robyn E. Ridler

May 5, 1998
Table of Contents

Introduction 1
I. Overview of the US Food Regulatory System 2
II. Internationalizing Food Trade and the Role of the WTO 5
   A. The World Trade Organization 7
   B. Member Obligations under the Treaties 9
   C. Trade Disputes Between WTO Members 11
III. The WTO Treaties and Domestic Food Regulation 17
   A. Case Study: BGH and Scientific Uncertainty 17
      3. Other Applications of the SPS Agreement 33
   B. Scientific Uncertainty and Food Policy Within the US 39
      1. Tunal(1991) 48
      2. Subsequent Events and Tuna 11(1994) 51
IV. Concluding Remarks: The Potential Impact of the WTO Treaties on Domestic Food Regulation 61
   A. Issues for Consideration 61
   B. Recommendations 71
Adequate food safety concerns all nations and affects everyone’s lives. In that sense, food safety is an international issue. However, the regulation of food products to achieve a desired level of safety has traditionally been a purely national matter with governments determining what minimum standards will apply to the food products sold and consumed within their own borders. However, this picture is changing with the increasing internationalization of the food supply and the signature of multilateral trade agreements between nations.

This paper focuses specifically on the relationship between World Trade Organization (WTO) agreements and American regulation of food products and additives. Section I provides background information on how the United States regulates domestic and imported food products. Section II explains the nature of the WTO agreements and the WTO dispute settlement process; discusses the WTO dispute between the EU, Canada, and the US over administration of growth hormones to increase beef production (Meat Hormones); reveals parallel domestic issues in the US regarding scientific uncertainty and the effect of federalism on state sovereignty; and considers the relationship between food regulation and environmental ethics in the context of three WTO panel reports (Tuna I, Tuna 11, and Shrimp). Finally, Section III considers the domestic policy implications of the WTO agreements as interpreted by the WTO dispute settlement body and applied in the context of food; and makes recommendations as to

While other multilateral agreements, such as the North American Free Trade Agreement (NAFTA) and the US-Canada Free Trade Agreement (UCFTA), could impact domestic food regulation as well, this paper focuses on the WTO agreements as perhaps the most comprehensive and inclusive set of international agreements to date. NAFTA and UCFTA both contain rules pertaining to sanitary and phytosanitary measures like those at issue in the Meat Hormones dispute. For a critique of NAFTA’s potential threat to American food safety laws, see generally Public Citizen Global Trade Watch, NAFTA’s Broken Promises: Fast Track to Unsafe Food, September 1997.

The European Union (EU) subsumed the European Communities (EC). For consistency, I refer throughout
how concerned parties should continue to act, at both the national and international levels, to address the difficult issues raised in the Meat Hormones, Tuna, and Shrimp disputes.

I. Overview of the US Food Regulatory System

Before exploring the relationship between international treaties and domestic regulation, it is necessary to understand the United States’ basic system for regulating food products, including imports. Essentially, three governmental entities can create food law in the US: the US Congress, US administrative agencies, and the states. First, the US Congress can directly pass laws relating to food and food safety. For instance, the Tuna and Shrimp disputes discussed below both arose from federal laws passed by Congress. More typically though, Congress leaves food policy decisions to administrative agencies, occasionally amending their implementing statutes to reflect Congressional policy changes. Most agencies can create their own rules, effectively federal laws, through formal or informal procedures, so long as they are aimed at furthering Congressional objectives within the limits of the Constitution. Agencies have some discretion, for instance enforcement discretion, when applying these laws and rules, which they utilize to handle micro-policy issues that arise in daily practice. Finally, state governments may pass laws applicable to their own jurisdictions so long as they are not preempted by federal law. As for the relationship between all these laws, rules, and discretionary judgments, each is generally preempted by a decision at a higher level. Until relatively recently, therefore, the voice of Congress was the final source of authority on domestic food regulation in the US and subject only to the limits of other federal laws and the to the EU.
Constitution. Today, however, Congress must also consider the United States’ obligations under the WTO agreements and other multilateral treaties.

Two US government agencies share primary responsibility for ensuring the safety of the domestic food supply: the Department of Agriculture (USDA) and the Food and Drug Administration (FDA). USDA regulates meat and poultry products under the auspices of its Food Safety and Inspection Service (FSIS) and its Animal and Plant Health Inspection Service (APHIS). FDA regulates all other domestic and imported food articles under the auspices of its Center for Food Safety and Applied Nutrition (CFSAN) and its Center for Veterinary Medicine (CVM). In practice, FDA and USDA inspectors must make practical decisions every day about the safety and wholesomeness of food imports to which they usually do not have access during the manufacturing process. These day-to-day decisions may be complicated by lack of information about food safety policy and enforcement in importing countries, as well as by formal or informal recognition of potential food safety crises in importing countries, for example trichinosis or mad cow disease. To improve the validity of the process and to maximize food safety, both FDA and USDA work with their international counterparts to facilitate cooperation and standard-setting. Indeed, given the impossibility of conclusively determining the safety and wholesomeness of every single imported food article, countries must necessarily rely to varying degrees on the interests of other nations in maintaining a safe food supply through enforcement of high standards.

US food safety and quality standards apply equally to imported and domestic foodstuffs. USDA requires meat and poultry imports to be produced under standards
equivalent to those of the US for safety, wholesomeness, and labeling accuracy. Regarding processed meats, FSIS evaluates individual countries’ processing and inspection systems and approves those that are equal to or stronger than that of the US; approved countries may then certify local processors for US importing purposes. FSIS inspectors examine certified plants two to three times annually to evaluate actual compliance, and work with their foreign counterparts to achieve compliance where it is lacking and to decertify as necessary. Live animals are tested and quarantined both abroad and in the US. USDA maintains inspectors in foreign countries to ensure enforcement of the testing and quarantine requirements.

While USDA handles meat, FDA verifies that all other domestic and imported food articles are safe, unadulterated, and properly branded within the meaning of the Federal Food Drug and Cosmetic Act. Section 381 of the FFDCA permits FDA to place a hold at the border on imported food articles suspected, due to examination or otherwise, to violate the good manufacturing process, adulteration, or misbranding sections of the


4 See USDA, Importing Meat and Poultry to the United States, USDA Food Safety and Inspection Service website (16 January 1998) <http://www.usda.gov/fsis/imports.htm>. Some American public interest groups have raised concerns about reduced efficacy in the inspection process as a result of multilateral trade agreements. See Public Citizen, International Harmonization of Social, Economic and Environmental Standards, 16 (noting increased importation of contaminated meat under the US-Canada Free Trade Agreement) & 22 (questioning compliance of Mexican poultry with US food safety standards following NAFRA). One major issue in this regard is what constitutes equivalent standards for purposes of more lax enforcement through physical inspection. A related issue is what must be equivalent given the WTO agreements’ disallowance of process distinctions. As indicated in the Statement of Administrative Action pertaining to the WTQ and the Uruguay Round Agreements Act [hereinafter Statement of Administrative Action], 8431(1), the US amended the Federal Meat Inspection Act 820(e) to reflect US obligations under the WTO. Congress replaced the language that required foreign producers to meet standards equivalent to or better than those in the US with language that required foreign producers to comply with requirements that achieve an equivalent or better level of sanitary protection than the US.

∼ Conversation with Dr. Ronald Caffey, USDA APHIS, 30 January 1998. In the case of BSE, or mad cow disease, for example, 31 countries currently cannot import fresh meat unless it has been processed in a specific way, i.e. deboned, etc., and certified by the UK counterpart of APHIS as not having been fed ruminant protein in feed. Id.
Act. FDA also regularly issues import alerts. These alerts may be based upon past history or other information that suggests particular imports contain violations. FDA inspectors may automatically detain goods that come from a particular manufacturer, from a particular food source, or belong to a particular food class. This administrative action can even extend to automatic detention of products from an entire country or national region when there appear to be geographically widespread instances of the violation. The authority to hold imports on suspicion alone must reflect Congress’s concern about FDA’s inability to inspect imports during manufacture as it does domestic goods. When a product is detained at the border, the burden shifts to the importer to prove that the article meets applicable FDA standards. If the importer fails and the articles are rejected, the importer may re-export them in certain circumstances as an alternative to their destruction.

II. Internationalizing Food Trade and the Role of the WTO

Food technology has grown amazingly complex in the last century. The complicated world of preservatives, additives, and food biotechnology has placed new demands on science to establish food safety, while simultaneously raising ethical questions related to the relationship between food and technology and between food.

See US FDA, Overview of Import Program, FDA Office of Regulatory Affairs website (November 1997) <http:llwww.fda.gov/ora/importlorajmpoitsystem.txt>

~ FDA rarely pursues this extreme option, and only after exhausting other options. Id.

~ The FFDCA 6334(d) explains the circumstances under which re-exportation within 90 days of refusal is permitted, including: (1) the adulteration, misbranding or violation occurred prior to shipment to the US, (2) the importer had no cause to know of such violation, and (3) re-exportation to a country other than that of origin does not violate 6381(e) regarding exports. Section 334(d) specifies that articles condemned under certain regulations, e.g., because potentially injurious to human health, may not be re-exported. See, e.g., United States v. 76,552 Pounds of Frog Legs, 423 F.Supp. 329 (S.D.Tex. 1976). Note that 6418 of the FDA Modernization Act of 1997 affects condemned imported goods but does not apply to refused imports during the 90 day re-export window (Covington & Burling, Short Summary of the FDA Modernization Act, at 37 (12 January 1997)).
production/harvesting methods and the environment. In the face of scientific uncertainty and philosophical debate, the inherently subjective component of food regulation becomes most obvious. There is simply no one right way to answer these questions, and, as mentioned above, nation states have historically acted alone in making these balancing decisions and establishing what each considers appropriate minimum standards.

While international treaties like the WTO agreements certainly do not dictate one right way, they do put some limits on sovereignty by their nature. Just as the American federal government sometimes preempts state governments in the interest of facilitating trade among states and creating more uniform standards, nations that trade significantly with other nations have found global harmonization of standards to be an increasingly attractive goal. Today, most international trade agreements cite harmonization as a significant component of any plan to level the playing field for trading nations. International institutions like the Codex Alimentarius, discussed infra, create international standards which countries are encouraged to utilize in making domestic regulation. Together, international treaties and institutions push domestic policy-makers towards keeping in step with their international neighbors. The concern that follows, as will be discussed below, is whether such pressure drives a race to the bottom.

Domestic politics naturally reflect significant agreements at the international level. For instance, the US recently addressed global harmonization of food standards in

~ The Statement of Administrative Action, submitted by the US House of Representatives to the President, and recommending ratification of the WTO agreements: US sovereignty is fully protected under the WTO. WTO dispute settlement panels will not have any power to change US law or order such a change. Only Congress and the Administration can decide whether to implement a WTO panel recommendation and, if so, how to implement it. US Statement of Administrative Action, 3. While this is technically true because of the legal and practical limitations on WTO enforcement, its implication of free reign is exaggerated, as this paper is intended to show.

10 The International Standards Organization (ISO) also sets standards that are increasingly important in
international trade, but its role is beyond the scope of this paper. See Covington and Burling, Short Summary of FDA Modernization Act of 1997, at 33 (12 January 1997).

The FDA Modernization Act of 1997. In 6410(b) of the Act, Congress instructs FDA to support reduced regulation, and increased harmonization of regulatory requirements, so long as doing so is consistent with consumer protection; FDA should also generally facilitate mutual recognition and harmonization agreements. Since these obligations arise from a purely domestic political command, they, of course, leave significant room for agency discretion in interpretation and application. Realistically, FDA’s own commitment to 6410 will likely be more determinative of its effect than the language of the statute. While Congress may have legitimately intended to shift FDA’s stance on regulation and/or harmonization, it must surely also have been motivated by a desire to show good faith in meeting its international treaty obligations, and it would not likely expect FDA to satisfy the mandate in a way contradictory to larger US food policy. In contrast to such purely domestic mandates complementary to international agreements, the treaties themselves may impose real limits on sovereignty in deference to the agreed goal of free trade and harmonization. A treaty’s bilateral nature creates enforcement incentives that do not exist between Congress and an administrative agency. WTO trade treaties also naturally err on the side of free trade and the WTO dispute settlement body has indicated that it will narrowly construe exceptions for trade restrictive national action.

A. The World Trade Organization

The WTO is an international member organization that administers the General Agreement on Tariffs and Trade (GATT) and a host of other treaties. The United States, the European Community, Canada, and Japan are the WTO’s Big Four members (the
Quad), and 128 other developed and developing countries belong to the organization. The WTO officially replaced the provisional GATT body as administrator of the GATFi’ treaty and became administrator of the other WTO treaties on 1 January 1995 in accord with the Marrakesh Agreement Establishing the World Trade Organization. The US Congress accepted the agreement on 30 Dec 1994, two days prior to its entry into force.

In accordance with their founding principles, the WTO performs three main functions. The WTO:

1. facilitates and maximizes free trade between member countries through removal of trade barriers and requirement of transparent domestic rules;
2. provides a forum for trade negotiations; and
3. resolves trade disputes through treaty interpretation.

These functions are evident in the structure of the organization, which is run by its member governments. WTO agreements are interconnected and clearly directed toward the single goal of maximizing freedom of trade. The membership as a whole makes major decisions, normally by consensus, either through ministers at their biannual meetings or

12 The WTO’s website is an excellent resource for historical information, documents, and dispute settlement reports. Their website is located at <http://www.wto.org>.

13 States become members by signing and enacting the WTO treaties. See WTO, The Organization:


14 The term GAIT is confusing to most people because of its history. The original GATT treaty set up a provisional body to conduct oversight of the treaty, which was simply referred to as GATT on the assumption that a more permanent body would soon be created. The provisional body, however, existed from 1947 — 1994, partially due to the failure of the International Trade Organization (ITO). In modern parlance, GAIT refers only to the specific trade agreement signed in 1948, while WTO refers to the member organization that administers the GAIT and related trade treaties. WTO agreements refers to the whole host of treaties administered by the WTO.

~ The statutory approval and entry into force of the Uruguay Round Agreements, including the GAIT, the SPS Agreement, and the Dispute Settlement Understanding, is located at 19 U.S.C. 53511, Pub.L. 103-465, 108 Stat. 4809 (8 Dec 1994).


8
through officials at their regular Geneva meetings. The WTO’s dispute settlement mechanism, created to fulfill the WTO’s third function, is unique in international law.

**B. Member Obligations Under the Treaties**

**The GATT.** The most well-known and long-standing agreement that WTO administers is the GAFF, which currently has 132 signatories. All WTO members are contracting parties to the GAFF and, as such, experience four major substantive obligations in formulating domestic policy. Members must:

1. grant most-favored-nation (MFN) status to all other WTO members under Article I, so any trade privileges extended to one member are extended to all;
2. afford the same treatment to like products whether domestic or imported (a.k.a. national treatment);
3. generally eliminate quantitative restrictions under Article XI (e.g., a zero quota on tropical hardwoods would be inconsistent); and
4. notify all GAFF members upon the grant or maintenance of any subsidy that directly or indirectly affects trade and discuss limiting it if necessary in accord with Article XVI.

WTO agreements are not static and may be amended by signatories during the multiyear negotiations called rounds. WTO member nations most recently amended the GAFF during the intensive Uruguay Round of negotiations, conducted between 1986-94, and during which members made further commitments to creating a more level playing field for trade.

Perhaps the most obvious way to reduce barriers is to eliminate exceptions. The original GAFF allowed, for instance, some notable exceptions for quotas and subsidies in
agricultural trade, which will be phased out as a result of the Uruguay negotiations.\textsuperscript{7} The GATT contains some more permanent exceptions, however, included in the treaty to balance the benefits of free trade with Members’ understandable demands for retained sovereignty. For instance, GAFF Article XXI recognizes deference to sovereignty in the event of conflict between Member obligations and national security. More relevant to this discussion, however, is GAFF Article XX, under which Members may maintain measures that would otherwise be inconsistent with the GAFF so long as they arise from particular sovereign rights and do not offend basic principles of the GAFF. These police power-type exceptions generally relate to health, safety and welfare. If a dispute arises, the complaining member will first try to establish that the measure-imposing Member is in violation of one of the GAFF provisions; if successful, the measure-imposing Member then tries to defend by showing that the measure is excepted by Art. XX and the Member is thus acting consistently with the GAFF after all.\textsuperscript{8}

For the purposes of this paper, the relevant portions of GAFF Art. XX are the introductory chapeau, (b), and (g). Article XX provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(b) necessary to protect human, animal or plant life or health;


18

For example, Member Y might note that the general rule under Art. 111:4 is that measures may restrict trade in like products only so long as they do not treat imports less favorably. Y might then say that Member Z does not subject its domestic like products to an equivalent, corresponding restriction as imports. If so, Z is prima facie acting inconsistently with the GAIT. However, Z may be able to justify its measure by showing that an Art. XX exception applies, in which case the measure is inconsistent with Article 111:4 but not inconsistent with the GAIT as a whole.
relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.

Article XX(b) is obviously relevant to food safety regulations since they are precisely intended, as FDA proclaims, to protect pregnant women and children. Article XX(g) relates to food regulation because food production and harvesting inherently affects the environment and as a result may implicate conservation, as I will discuss in Section II-C, infra. The chapeau establishes the context of the exceptions the GAFF as a whole.

**Other Agreements.** In addition to the GAFF, the WTO administers a variety of related trade agreements, such as the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (ThT Agreement). These related agreements are typically understood as elucidating particular aspects or requirements of the GAFF, but it is important to recognize that they are technically independent of the GAFF in that they are binding treaties in themselves. The most important GAFF-related treaty for the purposes of this paper is the SPS Agreement. Its meaning and relationship to the GAFF are considered at length in the Meat Hormones reports discussed below.

**C. Trade Disputes Between WTO Members**

Unlike most international regimes, WTO notably includes a dispute settlement process created under the original GAFF to resolve trade disputes between member states. The Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), located in Annex 2 of the GAFF, is the implementing document of the dispute.
settlement body (DSB) and lays out the process of dispute settlement. Figure 1 below provides a flow chart of the dispute settlement process including timelines and WTO commentary.

Structure of the Dispute Settlement Process, if two or more WTO Members are engaged in a dispute related to trade measures and cannot successfully negotiate a settlement amongst themselves within sixty days, either or both Members may request convention of a WTO panel. The panel considers the case and issues an official report, usually recommending, if appropriate, that the complaining Member request the offending Member to align their trade measures with treaty obligations as interpreted by the panel. Any Member party may appeal the decision to the Appellate Body (AB), a creation of the Uruguay Round. The AB may uphold, overturn, or modify the panel’s findings and conclusions of law. The WTO cannot actually force a Member to alter measures found inconsistent with WTO obligations as interpreted by the DSB. If a Member refuses to abide by the findings of a panel and/or the Appellate Body by 60 days after final disposition, the offending Member must submit to arbitration to determine what retaliatory trade measures may be employed against it until it chooses to act consistently. The inability of WTO to actually force compliance with its agreements is typical of international law and should not be construed to indicate weakness on the part of WTO. In fact, the very existence of the dispute settlement body indicates unique strength.

20 Working Procedures for Appellate Review; the full text of which is available on the VIT's website at <http://www.wto.org/wto/dispute/ab3.html>.
There are several peculiar aspects of the WTO dispute settlement process that deserve attention before turning to actual disputes. First, panel decisions are persuasive, not authoritative, so they are not technically binding on future panels. It does seem unlikely though that a WTO panel in practice would deviate wildly from a previous report without justification, especially given the WTO’s dependence on administrative efficiency and predictability to maintain the international legitimacy fundamental to a successful treaty regime.

Secondly, the Appellate Body does not have authority to remand to the original panel for further consideration once the Appellate Body clarifies interpretations of law. This creates interesting challenges for both the panels (who cannot come back to issues which they do not reach in their considerations) and the Appellate Body (who relies on the panel to do complete fact-finding in case it is wrong on a legal interpretation, and who cannot simply clarify law but must apply it). Finally, the Uruguay round changed the rules for adoption of reports. Previously, WTO Members had to officially adopt reports by consensus, providing an opportunity for nations to block adoption through obstinacy and/or political pressure. Under the revised agreement, a report will now be automatically adopted unless there exists a consensus against its adoption.\textsuperscript{22}

\textsuperscript{21} For a discussion of the relative usefulness of adopted versus unadopted reports, see Shrimp Panel Report, infra note 136, at fns. 623 & 662.

The panel process

**NOTE:** The various stages a dispute can go through in the WTO. At all stages, countries are encouraged to consult each other in order to settle “out of court”.

- **some binding** At all stages, the WTO director-general is available to offer his good offices, to mediate **some not** or to help achieve a conciliation.

60 days

**Consultations**

(Art 4)

<table>
<thead>
<tr>
<th>Days</th>
<th>Termu S referens. (Art 7)</th>
<th>During 11 duges</th>
<th>Punel cxu.unio. (Art 8)</th>
<th>Composition (Art 9)</th>
<th>Interim review tug.</th>
<th>Descriptive pan of report</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>20 days</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>+</td>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

**PunS established by Dispute Settlement Body (DSB) (Art 6)**

- **Interim report** sent to parties for comment (Art 15.2)

- **Expert review**
NOTE: a panel can be composed (i.e., 08'S de puns) if urgent.
Types or Disputes Relating to Food. Two general categories of food product-related disputes have occurred to date within the WTO framework. The typical class of cases are traditional trade disputes in which the import or export at issue happens to be a food article. Sample trade disputes involving food articles include complaints filed against the EU regarding its official favoritism toward former colonies for purposes of banana importation (WTJDS27), against Brazil for imposition of duties on desiccated coconut imports (WTIDS22),24 and against the EU concerning export subsidies on 25 processed cheese (WT/DS 104/1). The second, rarer class of food disputes relate to trade measures that reflect policy decisions made and implemented by one WTO member to advance larger social goals, particularly consumer and environmental protection, but that impact international trade and that other Members disagree are warranted. In the context of food regulation, only the Meat Hormones, Tuna, and Shrimp disputes belong to this class at present. In each of these cases, the WTO dispute settlement body agreed that certain measures could not be sustained consistently with one or more WTO agreements.

Unlike traditional trade disputes, the Meat Hormones, Tuna, and Shrimp cases implicate peculiar health, environmental, and philosophical concerns. Governments and private citizens are growing more aware of some potential health concerns associated with new food technologies, as well as some environmental impacts of modern food production. As a result, relatively advanced governments like the US and the EU may be inclined to change their laws to reflect these concerns and to accommodate public demand, especially since their strong economies can likely withstand any resulting


~ See id.
disruption. Under the WTO agreements, however, unilateral resolution of the conflict between trade interests and other values may not be consistent with international obligations. Environmental and moral considerations which place a perceived imperative on an individual country to take action before seeking an international consensus may result in trade sanctions that the measure-imposing Member considers unjust. To retain legitimacy and voluntary compliance, the WTO is now struggling with striking the balance between sovereignty and free trade in the manner most agreeable to Members while still complying with the letter and spirit of the GAFF and the other WTO agreements.

The ability of the WTO to balance these considerations to the satisfaction of its sovereign members may determine the ultimate success of the WTO.

Caseload. The GAFF was signed in 1948. The Tuna dispute was brought before the WTO dispute settlement body over forty years later in 1991. Six years later, in 1997, a panel convened to consider the Meat Hormones dispute. Only one year later, Shrimp followed. These issues are obviously not resolved. Further, the WTO’s caseload is notably increasing due to some combination of expanding world trade, the stricter rules laid down in the Uruguay round, and improved legitimacy of the WTO process. Given the Uruguay round’s changes to the rules regarding panel report adoption, the WTO’s generally increasing caseload, and recent and ever-faster advances in biotechnology, the likelihood of future cases pressing upon the tension between free trade and sovereignty seems high. Questions about the role of WTO agreements in formulating domestic food

The treaties themselves reflect a rudimentary awareness of these issues. For instance, the GAIT tries to reconcile sovereignty with free trade interests in GAIT Art. XX, while the SPS Agreement Art. 3.3 affirms sovereign decision-making as well.
policy, and whether the limitations the agreements create are appropriate, are ripe for discussion and deserve immediate attention.

III. The WTO Treaties and Domestic Food Regulation

A. Case Study. BGH and Scientific Uncertainty

The Meat Hormones case is in some ways a watershed for the WTO Settlement Body, beginning to define the edges of WTO’s legitimacy and its role in domestic policymaking based on science. The Tuna and Shrimp cases raise serious questions about the relationship between seemingly conflicting policy commitments, i.e., free trade and protection of sea creatures; however, in contrast to the Meat Hormones case, the US animal protection measures at issue in Tuna and Shrimp clearly accomplished their stated goal of protecting dolphin and turtle life respectively. In Meat Hormones, the precise issue is whether a ban on hormone-treated meat in fact protects human life or health at all. While the Tuna and Shrimp measures were held to violate the GAFF despite their effectiveness, the WTO found that the Meat Hormones measures were only consistent with the SPS if they were shown to be effective.


In 1981 the EU Council adopted Directive 81/602/EEC, a Council Directive Prohibiting the Use in Livestock Farming of Certain Substances Having a Hormonal Action, essentially requiring all EC members to ban the administration of certain 27


hormones to farm animals. The adoption in 1988 of Directive 88/146/EEC
expanded the ban to cover five additional hormones used to promote growth in
farm animals (with narrow exceptions for therapeutical and zootechnical treat-
ments), as well as requiring member countries to ban importation from third
countries of animals and meat products

to which such hormones had been administered. The EU Council confirmed
and extended the policy directives on 29 April 1996.～～

According to evidence produced during the dispute settlement that ensued,
at the time of the ban only four or five EC member states allowed any use of
the hormones in question;31 one of these, the United Kingdom, estimated on the
basis of anecdotal evidence that only about 40% of UK meat-producing animals
received any hormone treatment. In contrast, the FDA had already approved use of the three
natural hormones (estradiol, progesterone, and testosterone) and the three synthetic hormones
(zeranol, trenbolone acetate, and melengestrol acetate (MGA)) for growth pro-
motion purposes?3 The US established during the dispute settlement that an
average of 70% of American beef cattle were being treated with one or more of
the hormones in question by the time the ban entered force.34 Thus, although
the EU directive was facially neutral, applying

VITO panel report on the US complaint (WT/D526). The facts and arguments
apply equally to the companion complaint by Canada however (WTIDS48).

29 See id. at 2.3 — 2.4.
30 The EU Council replaced the two existing directives with Directive 96/22/EC. See
id. at 2.5.
～’ See BGH Panel Report at 8.205.
32 See id.
～ All six hormones, except MGA, which is supplied as a feed additive, are ad-
ministered through a slow-
release ear implant pellet; the ears are discarded at slaughter. All six hormones remain
available today in the
US as over-the-counter animal drugs approved for administration to beef cattle and
sheep. See FDA Center
for Veterinary Medicine, The Use of Hormone for Growth Promotion in Food-
Producing Animals, May
1996 <http://www.cvm.fda.gov/fda/infores/consumer/con I 3.html>. More infor-
mation on the approvals is
available in 21 CFR 6522, 6556, 6558.
～ See BGH Panel Report at 8.205. The US noted that trade American beef and veal
exports to the EU was
in the hundreds of millions of dollars between 1986 - 1989 and was increasing at a rate
of approximately 30% each year, but American imports plummeted to nearly zero after the ban took effect in 1989. See BGH
equally to domestic and imported meat and meat products, the ban in fact had a disproportionate impact on importers that spurred the US and Canada to action. Both Members brought WTO complaints against the EU, claiming that the ban, as it related to six specific hormones administered to cattle for growth promotion purposes, violated the SPS Agreement, the TBT Agreement, and the GAFF.

In response to the US and Canada’s allegations, the EU argued that its measures were justified under the Art. XX(b) exception to the GAFF, which pertains to the protection of human life or health, and were thus consistent with all three agreements. After studying the relevant texts, the WTO panel concluded that the SPS Agreement creates obligations additional to the GAFF for Members who adopt sanitary and phytosanitary measures, and that nothing in the WTO agreements required consideration of GAFF consistency prior to SPS Agreement consistency. The panel found the TBT Agreement inapplicable because the TBT Agreement specified that it did not apply to sanitary measures. In the interests of administrative efficiency, the panel chose to first consider whether the EU standards violated the SPS Agreement.36

The SPS Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade.37 Such measures are essentially a subset of measures that qualify for consideration under GAFF Article XX(b), so measures consistent with the SPS Agreement are presumed consistent with the GAFF. Parties to the Meat Hormones dispute conceded that the EU ban constituted sanitary measures. In the interests of administrative efficiency, the panel chose to first consider whether the EU standards violated the SPS Agreement.36

Panel Report at 4.10. The US introduced retaliatory trade measures on the same day the ban went into effect. The US eliminated some of the retaliatory measures following an EC/US agreement to allow American meat certified as not violating the ban into the EU market. See BGH Panel Report at 2.35. 13 See BGH Panel Report at 8.29.

36 See BGH Panel Report at 8.40 — 8.42.
measures and that a ban could affect trade, so the panel concluded that the SPS Agreement was applicable to the dispute. Under the SPS Agreement, WTO members agree to enact sanitary and phytosanitary measures that affect trade only to the extent necessary...based on scientific principles. Measures that conform to international standards are presumed consistent with the SPS (and GAFF), although the presumption is rebuttable. If an international standard does not exist or is lower than the proposed standard, then the member country may impose the standard only if it is based on scientific evidence or a demonstrated risk assessment. SPS Article 5 lays out the risk assessment process with relevant factors in the assessment including not only health and environmental concerns (Art. 5.2), but potential economic (Art. 5.3) and trade (Art. 5.4) impacts as well.

The panel allocated the initial burden of proof to the United States to make a case against the EU measures that, if unrebutted, would establish a prima facie violation. Of the six bovine hormones in dispute in the Meat Hormones case, five of the steroids had Codex standards at the time of the ban and three naturally occur in cattle. The panel found that the EU’s standards for the five steroids differed significantly from the Codex standards and so were not based on international standards and could not be presumed

~ SPS Article 1.1.
38 SPS Article 2.2.
~ See SPS Articles 3.1 and 3.2.
~ See id. at 8.58 & 8.62. The hormone without a Codex standard at the time was MGA.

See id. at 8.77. Codex Alimentarius is a joint commission of the United Nations Food and Agriculture Organization (FAO) and the World Health Organization. Created in 1962 to establish voluntary international food standards, Codex serves as an international resource and is especially invaluable to countries that do not have sufficient resources to research food safety. The Codex standards are not binding of themselves, but are practically so with the advent of the WTO. Annex A of the SPS agreement specifically defines international standards as Codex standards, and the BGH panel found that where Codex standards exist, Members must follow them or justify not doing so. See BGH Panel Report at 8.56 — 8.57. For information on Codex standards generally, see the FAO website at <http://www.fao.org>.

20
in accord with the SPS Agreement. Once the US established that the EU standards were not based on international standards, the panel shifted the burden of proof to the EU to justify its measures scientifically under Art. 3.3. This burden of proof assignment to the EU treats SPS Art. 3.3 in the same manner as a GAFF Art. XX affirmative defense.\textsuperscript{42}

The panel found both procedural and substantive flaws in the EU’s standardsetting, and ultimately struck down the ban as it applied to each of the six hormones when administered for growth promotion purposes. Procedurally, the panel concluded that the EU had successfully demonstrated that it did carry out the necessary risk assessment under SPS Article 5, but believed that the EU failed to meet a minimum procedural requirement of 5.1 to showing that it used the risk assessment when creating the measures.\textsuperscript{43}

The substantive failures were more damning though. The panel concluded that the EU’s scientific conclusion about the danger of BGH, as reflected in the measure, had no basis in any of the evidence referenced by the EU, and thereby exceeded international standards in violation of Art. 3.1 without any Art. 3.3 justification. Further, the panel concluded that the measures, even if the EU had proved them scientifically justified, also failed to meet the other requirements of the SPS Agreement. In this regard, the panel found that the measures violated Art. 5.5 because of the EU’s different treatment of hormones in comparable situations, which created arbitrary distinctions and resulted in

\textsuperscript{42}See BGH Panel Report at 8.50 — 8.55; see also Figure 2, infra.

\textsuperscript{43}See id. at 8.134 & 8.137.
discrimination or disguised restrictions on trade.\textsuperscript{45} Specifically of concern to the panel was the EU’s differential treatment of (1) endogenous hormones and hormones administered for therapeutic and zootechnical purposes \textit{compared to} natural hormones administered for growth promotion purposes, (2) natural hormones \textit{compared to} synthetic hormones, and (3) all disputed hormones \textit{compared to} the anti-microbial growth promoter carbadox.\textsuperscript{46} This SPS interpretation is complementary in principle to the GAFF’s Art. 111:4 provision on process distinctions—Art. 111:4 requires that Members treat like products alike and does not allow trade distinctions between final commercial products based on their process or production methods (PPM) in manufacture. In this case, interpreting SPS, the panel concluded that the EU, by not placing any limit on levels of the naturally occurring hormones in meat, was tacitly admitting that they were safe at their natural levels. The EU’s zero tolerance policy for administered hormones, which cannot be differentiated from exogenous ones in the cattle’s bodies, thus effectively created an arbitrary process distinction.

Figure 2 below summarizes the BGH panel’s interpretation of the appropriate method of determining whether measures are consistent or inconsistent with the SPS Agreement. Note that the panel’s allocation of burden of proof is also indicated.

\textsuperscript{46} See id. at 8.213.
\textsuperscript{47} See id. at 8.185.

Examples of process and production method (PPM) distinctions include whether plastic is recycled, whether wood comes from tropical or temperate forests, whether timber is sustainably cut, whether gas is formulated for reduced emissions, etc. The difference between PPMs that are reflected in the final product and those that are not is critical for purposes of the TBT Agreement and its labeling standards. The TBT does not apply to sanitary measures though.
2.3  
Fajia r&i. BGH Panel’s Interpretation of the SPS Agreement.

**Does the measure constitute a sanitary measure?**

/ *Burden of proof on complainant* /

IYES

**Do international standards exist?**

/ *Burden of proof on complainant* /

IYBS

**Is measure based on international standards?**

/ *Burden of proof on complainant* /

†

YES, or less strict  
Presumed consistent  
With SPS  
NO~J,  
SPS inapplicable

NO

if

**Is measure based on scientific evidence or a demonstrated risk assessment?**

(procedural & substantive inquiry)

/ *Burden of proof shifts to and remains with respondent* /

NO~J,  
NO, stricter

**Has the member adopted different Levels of protection in situations where the same substance or the same adverse health impact is involved?**

Inconsistent with SPS  
Inconsistent with SPS

**Is the distinction in level of protection arbitrary or unjustifiable?**

†YES

**Does the distinction result in discrimination or a disguised restriction on international trade?**

4YES

Consistent with SPS  
Consistent with SPS  
Consistent with SPS  
Consistent with SPS

N04,
Are measures more restrictive than necessary to provide adequate protection?

| YES  | NO 4, |

Inconsistent with SPS
Consistent with SPS
Since the decision was appealed, detailed consideration of the panel’s findings is inappropriate here. However, the BGH panel report raised a number of important questions about scientific uncertainty, the precautionary principle, and consumer information. Two particular elements of the Report are worth noting in some detail, especially since the Appellate Body addresses them as well: (1) the panel’s discussion of the difference between risk assessment, as the term is used in SPS Art. 5, and the concept of risk management; and (2) the panel’s indication, or lack thereof, of what would constitute, for WTO purposes, adequate scientific justification to allow deviance from international standards in the face of scientific uncertainty.

**Risk Assessment vs. Risk Management.** In interpreting the obligations that arise under the SPS Agreement, the BGH panel distinguishes the risk assessment function (a scientific assessment of available data) from the risk management function (a political process by which science becomes policy by way of social judgments). The SPS Agreement requires that Members base their sanitary measures on risk assessments, which the panel interpreted as meaning that the Member should first conduct a risk assessment to determine the actual risks to human health that a substance poses, if any. Once some risk is so established, the panel goes on to state, a proper risk assessment also requires an evaluation of the potential or probability of occurrence of these effects. The Member then moves to the second phase—the political process of risk management—to establish an appropriate level of protection and determine how to act.

---

See BGH Panel Report at 8.91 et seq.  
*See id.* at 8.98. The latter requirement moves the risk assessment closer to a quantitative cost-benefit analysis. See footnote 76, infra, and accompanying text regarding the Appellate Body’s treatment of this characterization.
See BGH Panel Report at 8.160.

on the now-available scientific information. The panel characterizes the process as follows:

Once the risks have been assessed, i.e., once the risks and their probability of occurrence identified, a Member will need to decide, on the basis of its own value judgments, whether it can accept these risks. In so doing a Member sets its appropriate level of sanitary protection. The determination and application of the appropriate level of protection by a Member is part of risk management.50

SPS Articles 5.4, 5.5, and 5.6 particularly relate to risk management. The first sets the minimization of negative trade impacts as a general goal, the second requires some degree of internal consistency in making risk management decisions (i.e. considers the Member’s treatment of comparable risks that may or may not be subjects of the dispute), and the third forces Members to choose the least trade-restrictive means of implementing their risk management decision. Note that Figure 2 above reflects the panel’s understanding of the relationship between the risk assessment-risk management process and Member obligations under the SPS Agreement.

Sufficient Scientific Evidence. The question naturally arises upon reading the panel report: how much scientific evidence does a Member need to justify a policy decision under SPS Art. 3.3. Clearly an international scientific consensus, usually in the form of a Codex standard, is not necessary or there would be no point to SPS Art. 3.3, which allows the application of measures that do not conform to international standards but are nonetheless scientifically justified. The panel’s interpretation of the sufficient
scientific evidence language in that provision is admittedly limited by the facts of the case. The panel summarizes:

[W]e recall that all scientific experts advising the Panel..., stated that, as of today, no scientific evidence is available which concludes that an identifiable risk arises from the use of any of the hormones at issue for growth promotion purposes in accordance with good practice.... In our view, the scientific conclusion reflected in the EU measures in dispute...does not conform to any of the scientific conclusions reached in the evidence referred to by the European Communities.51 (emphasis added)

While the panel attempted to parse out the relative functions of risk assessment and risk management, both in general and in the WTO context, it fails to reach the more interesting and challenging question of what constitutes sufficient scientific evidence since it has an easy case in this regard, i.e., no evidence. Footnote 2 of the Agreement merely refers to justification being based on an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement. This language is not particularly enlightening. Further, neither the treaty language nor the anel directly address how conflicting scientific evidence should be weighed—with deference to the WTO member, or with de novo review by a WTO panel. Since the latter questions are really the ones of interest to the EU as it pursues scientific evidence in its favor, it is fortunate that the Appellate Body gave some better guidance.


The EU appealed the panel decision. The Appellate Body (AB) affirmed the panel’s principle holding that the EU ban is inconsistent with SPS Art. 5.1. However, the

~’ See BGH Panel Report at 8.134 — 8.137.


26

31
AB also made a number of other relevant findings, particularly important for predicting how the WTO dispute settlement body will review questions involving scientific uncertainty in the future. One such critical holding relates to the panel’s findings under Art. 5.5. The panel found that the following aspects of the EU measures were in themselves arbitrary or unjustifiable: (1) the treatment of endogenous hormones compared to added hormones, and (2) the treatment of hormones administered for therapeutic and zootechnical purposes compared to hormones administered for growth promotion purposes. In this context, the AB made the important precedential statement:

We consider there is a fundamental distinction between added hormones (natural or synthetic) and naturally-occurring hormones in meat and other foods.

The following table summarizes the findings of the AR, not all of which are raised in this discussion.


<table>
<thead>
<tr>
<th>Panel</th>
<th>Appellate Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>(EC challenge that the Panel did not objectively assess the facts of</td>
<td>Panel acted properly.</td>
</tr>
<tr>
<td>the case as obligated by DSU Art. 11.)</td>
<td></td>
</tr>
<tr>
<td>(EC challenge to several procedural methods adopted by the panel,</td>
<td>Panel acted properly.</td>
</tr>
<tr>
<td>including its selection and use of experts.)</td>
<td></td>
</tr>
<tr>
<td>(US and Canadian challenge to panel’s failure to make findings</td>
<td>Panel exercised appropriate judicial</td>
</tr>
<tr>
<td>regarding Art. 2.2 and Art. 5.6.)</td>
<td>economy.</td>
</tr>
<tr>
<td>Standard of review.</td>
<td>Upheld.</td>
</tr>
<tr>
<td>The precautionary principle cannot override Arts. 5.1 and 5.3 but</td>
<td>Upheld.</td>
</tr>
<tr>
<td>is incorporated into Art. 5.7.</td>
<td></td>
</tr>
</tbody>
</table>

Despite the fact that the AR upheld the panel’s decision on the ban, many people recognized the potential import of the appellate decision. See, e.g., WTO Ruling on EU Hormone Ban is a Victory for European Consumers, RAPID Press Release (16 January 1998).

~' See BGH Panel Report at 221

See id. at 225.

56 See id. at 221.

~' See id. at 253.
<table>
<thead>
<tr>
<th>Statement</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>The SPS Agreement applies to measures enacted prior to its entry into force that remain in force thereafter.</td>
<td>Upheld.</td>
</tr>
<tr>
<td>A measure must comply with Art. 5 to be consistent with Art. 3.3.</td>
<td>Upheld.</td>
</tr>
<tr>
<td>Assignment of burden of proof.</td>
<td>Reversed.</td>
</tr>
<tr>
<td>The meaning of &quot;based on international standards in Art. 3.1 and Art. 3.3.</td>
<td>Reversed.</td>
</tr>
<tr>
<td>The EU ban is inconsistent with Art. 3.1.</td>
<td>Reversed.</td>
</tr>
<tr>
<td>Being based on a risk assessment entails a minimum procedural requirement.</td>
<td>Reversed.</td>
</tr>
<tr>
<td>Interpretation of risk assessment.</td>
<td>Modified.</td>
</tr>
<tr>
<td>Findings and conclusions on Art. 5.1.</td>
<td>Modified.</td>
</tr>
<tr>
<td>Findings and conclusions on Art. 5.5.</td>
<td>Reversed.</td>
</tr>
</tbody>
</table>

The Appellate Body’s interpretation of the meaning of based on and their assignment of burdens of proof are critical reversals. First, the AR clarifies that having measures based on international standards, within the meaning of Arts. 3.1 and 3.3, is different than having measures that conform to international standards, within the meaning of Art. 3.2. While conforming measures enjoy a rebuttable presumption of consistency with the SPS Agreement under Art. 2.4, a Member can adopt measures more loosely based on the international standards, which are still consistent with Art. 3.1. The AR also concludes that the panel must have misconceived the relationship between Articles 3.1, 3.2, and 3.3 of the SPS because Art. 3.3 is not an exception to Art. 3.1 in the sense that Art. XX is to the other provisions of the GAFF. Under the AR’s interpretation, the initial burden of proof is on the complainant to show each element of inconsistency with the SPS Agreement, including inconsistency with Art. 3.3, rather than shifting to the respondent to prove consistency with Art. 3.3 by means of a scientific approach.

58 See id. at 177.

Due to their interpretation, the AB later reverses the panel’s conclusion that the EU acted inconsistently with Art. 3.1 by acting inconsistently with Art. 3.3. Since there is not a general rule-exception relationship...
justification for not basing the measures on international standards. The AR's interpretation of based on and their assignment of the burden of proof recharacterizes the burdens of the parties in such dispute. The interpretation of based on also reaffirms the sovereign right of states to establish their own appropriate levels of consumer protection through sanitary measures.

The AR also addresses the important issue of standard of review that the panel failed to adequately address. The EU contested the panel’s lack of deference to its scientific assessment and risk management decisions regarding the six hormones, arguing that a deferential reasonableness rather than de novo standard is appropriate. After noting that neither the SPS Agreement nor the DSU provide a specific standard of review for SPS matters, the AR goes on to say that DSU Art. 11 does articulate with great succinctness but with sufficient clarity the appropriate standard of review for panels in respect of both the ascertainment of facts and the legal characterization of such facts under the relevant agreements. That standard is neither totally deferential nor de novo, according to the AR, but rather calls for an objective assessment of the facts.

Several guidelines emerge from the AR’s discussion of the EU’s complaints that the panel’s actual assessment of the scientific evidence in this dispute was not objective. These basic guidelines are at least worth noting here:

between the two articles, inconsistency with the one does not itself create inconsistency with the other. See id. at 157.

~ See id. at 108 — 109; see also id. at 172 (referring to the right to set appropriate levels as an important right and an autonomous right...not an exception from a general obligation under Art. 3.1). For a look at how the DSB has comparatively interpreted the GAIT exceptions, see, e.g., Shrimp Panel Report, infra note 136, at 7.40. Given the nearly identical introductory language of the two provisions, the AB’s distinction in Meat Hormones is somewhat slippery.

61 See id. at 100—119.

62 Id. at 116.

63 Id. at 117.
(1) Panels do not have an obligation to gather or request submission of scientific data. M

(2) Panels may utilize scientific experts as it deems appropriate and best suited to

the dispute at hand, e.g. requesting a range of opinions from individual experts

rather than establishing an expert panel to provide a consensus opinion. 65

(3) Panels should not disregard scientific evidence offered by a party, but may

66 conclude that it is not relevant in nature. In the same vein, a panel may distinguish between general scientific evidence relating to a substance (e.g., one hormone) and specific scientific evidence regarding application (e.g., residues of that hormone in meat after administration to cattle for growth promotion purposes). 67

(4) Panels generally has discretion in deciding which evidence to utilize in making

its findings. 68

(5) A single divergent scientific view is not per se reasonably sufficient to

outweigh contrary scientific information.

(6) Harmless error does not invalidate a panel’s findings. 70

These guidelines provide some guidance to future panels regarding the handling of scientific evidence, as well as alerting future parties to panels’ obligations in handling scientific evidence. 

~ See id. at 136.

65 See id. at 146—147.

See id. at 137.

67 See id. at 141.

68 See id. at 135.

69 See id. at 198.

70 See id. at 138.
The AR further clarifies the demands of scientific justification in its consideration of the precautionary principle, its interpretation of Art. 5.1, and its discussion of the nature of a risk assessment. Together, these elements of the AR Report provide much greater flexibility to nation states in conducting risk assessments and making risk management decisions. I will discuss each respectively.

While passing on the question of whether the precautionary principle is now a general principle of international law (referring to it as an important, but abstract, question), the AR does address the role of the precautionary principle in assessing a Member's compliance with the SPS Agreement. The AR upheld the panel's conclusion that the principle could not override explicit obligations arising from the SPS Agreement, given that it had not been incorporated into the SPS Agreement as a justification for maintaining otherwise inconsistent measures. Indeed, it seems logical that such a general holding would undermine the purpose of the Agreement, especially given the difficulty of proving that the precautionary principle was the motivating factor behind a policy decision. However, the AR continued, stating: We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. According to the AR's interpretation, the SPS

The Member may only adopt such measures provisionally and must seek additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time. The EU stated that their measures are not provisional, so the panel did not apply Art. 5.7. But what if the EU mistook the meaning of provisional? It is unclear what constitutes provisional measures or a reasonable period of time. At first it seems unlikely that a Member could just adopt measures without sufficient scientific evidence until there is sufficient evidence, even if they kept reviewing the science at reasonable time intervals. But the text is intriguing since it allows such adoption on the basis of available pertinent information, and the reasonable period of time language seems to only refer specifically to the requirement that the Member seek more evidence and review the measure accordingly. If no more conclusive evidence comes in for an

72

72 Id. at 124. Article 5.7 relates to provisional measures adopted by Members in the face of insufficient scientific evidence. The Member may only adopt such measures provisionally and must seek additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time. The EU stated that their measures are not provisional, so the panel did not apply Art. 5.7. But what if the EU mistook the meaning of provisional? It is unclear what constitutes provisional measures or a reasonable period of time. At first it seems unlikely that a Member could just adopt measures without sufficient scientific evidence until there is sufficient evidence, even if they kept reviewing the science at reasonable time intervals. But the text is intriguing since it allows such adoption on the basis of available pertinent information, and the reasonable period of time language seems to only refer specifically to the requirement that the Member seek more evidence and review the measure accordingly. If no more conclusive evidence comes in for an
Agreement explicitly recognizes the sovereign right of Members to establish their own appropriate level of sanitary protection, which may be higher (i.e., more cautious) than that implied in existing international standards. Further, the AR takes the important step of specifically addressing one element of how a panel should evaluate the sufficiency of scientific evidence:

[A] panel charged with determining, for instance, whether sufficient scientific evidence exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g., life-terminating, damage to human health are concerned. (emphasis added)

This mandate to panels is potentially much more flexible and responsive to reality than the BGH panel’s approach.

The AR’s conclusions as to Art. 5.1. complement their comments on the precautionary principle. The AR concludes that Article 5.1, read properly in conjunction with Art. 2.2, requires that the risk assessment reasonably support the SPS measure in dispute. However, the AR explicitly states that the risk assessment can properly reflect divergent scientific views and uncertainty rather than coming to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure.

Lastly, the AR disagreed with the panel on what it saw as the introduction of a required quantitative element into the risk assessment. The AR felt this quantitative element arose from the panel’s language regarding the second step of a Member’s risk.

unreasonable amount of time, despite the Member’s efforts, can the Member’s measures still be considered provisional and therefore consistent with the SPS Agreement? It would have been interesting to how the dispute settlement body interprets Art. 5.7 if the EU had not effectively dismissed this potential argument.

\[ \sim Id. \text{ at } 124. \]
\[ \sim Id. \]

32
assessment—that the Member should evaluate the potential or probability of occurrence.

of such effects (emphasis added). The AR explains: Neither Articles 5.1 and 5.2 nor Annex A.4 of the SPS Agreement require a risk assessment to establish a minimum quantifiable magnitude of risk. Rather, the AR explicitly states that consideration of non-qualitative factors is entirely appropriate and that the panel was in error to the extent it relied purely on matters susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences. In sum, the AR explains:

It is essential to bear in mind that the risk that is to be ascertained in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.

3. Other Applications of the SPS Agreement

Despite the fact that the Appellate Body’s interpretation of the SPS Agreement is more flexible than the BGH panel’s was, and even though the exact nature of scientific evidence to support sanitary measures is still unclear, it is clear that SPS members must pass some minimum scientific threshold for their measures to be consistent with the SPS Agreement. Any number of existing national regulations might be affected by this requirement. Some US laws were actually changed in deference to Uruguay round conclusions, but these changes were mainly modifications and only a few directly impact

1d. at 194.
1d at 184; see also supra note 49 and accompanying text.
~ BGH Appellate Report at 253(j).

1d. at 187.
~ Id.

33
food. Examples of food laws which could come under WTO scrutiny include the FDA’s food definitions and standards of identity, \(^8^1\) filth standards, \(^8^2\) and good manufacturing.

\(^8^0\) See generally Statement of Administrative Action, supra note 4 (listing modifications to current US laws believed necessary for full compliance with the VITO agreements in light of the results of the Uruguay round negotiations).

\(^8^1\) Definitions and standards are promulgated pursuant to FFDCA 6341. For an argument that this is the area of US food law most ripe for dispute in the WTO, see John S. Eldred & Shirley A. Coffield, What Every Food Manufacturer Needs to Know: Realizing the Impact of Globalization on National Food Regulation, 52 Food & Drug L.J. 31, 36 (1997).

\(^8^2\) have not seen this issue raised by other commentators, so I will explore it a bit. Section 342(a)(3) of the FFDCA provides that a food shall be deemed adulterated... [i]f it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. The courts have almost unanimously interpreted filthy, putrid, or decomposed as independent of unfit for food, although the extreme harshness of this interpretation is tempered in practice by the administrative tolerances observed by the FDA during enforcement. See US v. 484 Bags, More or Less, 423 F.2d 839 (5 Cir. 1970); see also US v. 1,5000 Cases...Tomato Paste, 236 F.2d 208 (7k Cir. 1956). Introduction into interstate commerce of an adulterated food is a prohibited act under FFDCA 6331, which can result in the seizure of the food under 6 334, and in civil or criminal penalties under 6333.

The filth regulations are arguably based solely on an amorphous consumer gross-out factor; the FDA admits they are not based on food safety concerns. See Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard, 37 Federal Register 6497 (30 March 1972) (stating that filth in excess of administrative tolerance renders the product adulterated, even though no health hazard is presented (emphasis added)). As such, the filth standards are not subject to the SPS Agreement nor do they qualify under GAIT Art. XX(b). Given the courts’ interpretation, it seems unlikely that the standards are consistent with the GAIT. The first question is whether not filthy and filthy products are like under Art. 111:4. The US would argue that a domestic X-rat hair candy bar is treated the same as an imported X-rat hair candy bar (allowed), and that a domestic X+ 1-rat hair candy bar is treated the same as an imported X+ 1-rat hair candy bar (illegal). A complainant would counter-argue that a domestic X-rat hair candy bar is treated more favorably (legal) than an imported X+1-rat hair candy bar (illegal), on the argument that the X-rat hair candy bar and the X+1 rat hair candy bar are like products. Without going into the complexities of GAIT like product analysis over the years, I merely note that, given that the candy bars compete directly in the market and are literally indistinguishable to consumers as to filth content (barring an extreme circumstance likely far in excess of both the technically zero statutory tolerance and the administrative tolerance level), this argument seems persuasive. In its extreme, the filth standards would actually allow no food onto the market, in which case they are equally restrictive to domestic...
goods and imports. In practice, however, they may discriminate against foreign producers who cannot live up to American sanitary requirements. Alternately, not allowing filthy candy bars may constitute an Art. XI quantitative restriction without Art. XX(b) justification.

In practice, the question is probably academic. The US could likely justify some level of filth regulation (e.g., the administrative tolerances) on the grounds that filth may indicate an increased likelihood of the presence of other contaminants, even if the language of the statute needed to be reinterpreted to incorporate otherwise unfit for food into the meaning of filthy. (Of course, that would likely bring the standards within the scope of the SPS Agreement!) But it seems highly unlikely that any nation will publicly demand in an international forum the right to import filthy food—a public relations nightmare—even if individual defendants to FDA actions would like to raise the defense. The fairness of this situation to importers is difficult to evaluate objectively given the difficulty of making objective policy decisions about the filth content of the foods that the policy-maker consumes along with everyone else.
process (GMP) standards; and the EU’s laws pertaining to genetically modified organisms (GMOs). In this section, however, I would like to focus on one rather infamous US food law to consider the potential application of the SPS Agreement: the Delaney Clause. This law is only one example—the real effects of WTO decisions on US policymakers and the market will largely depend on what measures are actually challenged before the WTO dispute settlement body.

The SPS Agreement. The BGH panel held, and the Appellate Body upheld, that measures taken prior to the SPS Agreement’s entry into force, but which remain in place after its entry into force, are subject to the requirements of the Agreement. SPS Annex A. 1(b) defines sanitary measures as including any measure applied to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or

83 Good manufacturing process is a blatant process distinction. I can only think of two reasons why it stands: (1) The statutory provision specifically applies to goods that appear to be contaminated (as a result of process) based solely on the examination of such samples. (The statutory language by examination or otherwise has no real meaning in conjunction with the word appears). This physical inspection-based standard may narrowly avoid the process problem. In fact, the statutory language almost invalidates the process aspect, so long as the product is not adulterated. (2) No one has challenged it. Arguing for the right to export food produced under unsanitary conditions is sensitive from a public relations, if not political, standpoint. To the extent that only foods that appear contaminated can be rejected by FDA, the economic losses to importers may not be excessively high anyway.

~ A dispute actively brewing right now between the US and EU on this issue is strikingly similar to the Meat Hormones dispute. Genetically modified organisms like root worm-resistant corn and soybeans impervious to pesticides, which are already being marketed by US companies, have raised significant political opposition in some parts of the EU. Commission Directive 90/220/EEC (8 May 1990) requires compulsory labelling of products containing or consisting of GMOs, with directed adoption by individual countries due in 1997. See European Commission, Press Release on GMO Labeling (IP/97/528) (18 June 1997); Edmund L. Andrews, Europe’s Banning of Treated Beef is Ruled Illegal, Boon for US Industry, New York Times (9 May 1997). The US has responded severely to the EU’s actions. US Trade Representative Charlene Barshefsy said, We made it clear to [the EU] that at a minimum, at a minimum, were our exports being restricted, we would use VITO dispute settlement. But that is the minimum. See Barshefsky Warns EU of Trade War Over Genetically Modified Products, 15 Inside US Trade 16 (20 June 1997). For a general discussion of GMOs and trade issues, see Thomas P. Redick, Biotechnology, Biosafety, and Sustainable Development, 12 Nat. Resources & Env’t. 114 (Fall 1997) (discussing GMOs).
US Sen. Richard Lugar (R-In), Chairman of the US Senate Committee on Agriculture, went so far as to indicate that the EU needs to get over its hang-up about GMOs. See id. Unless Sen. Lugar is a scientist or
particularly well-informed for a senator, this kind of comment seems highly inappropriate and blatantly protrade (at least when the exporter is the US).


Feedstuffs. Footnote 4 further defines contaminants to include pesticide and veterinary drug residues and extraneous matter. Since the WTO dispute settlement body concluded that the imposes obligations additional to the GAFF, it can be considered alone.

The Delaney Clause. Arising from consumer concern about increased cancer rates in the previous two decades, Congress enacted the Delaney Clause in 1958, creating what one casebook on the subject refers to as one of the most notorious and least frequently invoked passages in the FD&C Act.85 FFDCA 6348(c)(3), commonly known as the Delaney Clause for food additives, disallows FDA approval of any food additive as safe that has been found in human or animal tests to be carcinogenic, unless GRAS or a prior sanction. This standard is considered unduly strict by some economists, commentators, and food regulators, and it effectively preempts the FDA’s authority to make determinations about food safety on this matter. Ironically, the first notable invocation of the Clause related to an FDA ban on diethylstilbestrol (DES) use in animals, the same issue which triggered the EU concern about food additives that eventually led to their ban on bovine growth hormones.86

The Delaney Clause might be quite vulnerable to an SPS attack on the grounds that, at least as applied to some additives, it bans products without sufficient scientific justification. The Clause does require that there be at least one human or animal study that concludes the substance is a carcinogen. However, while the FDA may make reasonable judgments in applying the law, the Delaney Clause technically does not require consideration of the scientific merit of the study or studies, let alone require
international agreement on carcinogenicity, or speak to the degree of scientific uncertainty about the substance’s risks. Few scientific studies definitively conclude anything, especially standing alone.

Assuming that the Delaney Clause is not based on international standards (in which case it would be prima facie consistent with the SPS Agreement), there are nonetheless a few facts that at least reduce the likelihood of a WTO challenge. First, many common substances are GRAS or subject to a prior sanction. Further, the law came into effect in 1958, almost four decades prior to the SPS Agreement, so many foreign producers/importers have likely already adapted to it regarding non-exempted substances.87 Secondly, the Clause was recently amended in regards to pesticide residues in processed foods, probably the area of most concern to producers and importers.88

Nonetheless, the Delaney Clause seems apt for challenge after Meat Hormones, especially since there are many natural carcinogens in food which, arguably, the US is arbitrarily distinguishing from added carcinogens. Certainly, the Delaney Clauses as they relate to certain substances could be challenged as not based on scientific evidence. The larger question is whether the Clauses could be challenged as a whole. In fact, although neither the BGH panel nor AR commented on the record, the EU actually compared their meat hormones ban to the Delaney Clause several times in their arguments before the WTO. The EU argued that the Delaney Clause was a perfect example of an inflexible,

87 Importantly, this hypothesis may be less true of many growing markets, including developing countries.
zero-tolerance policy. The EU also noted that the US had specifically interpreted the SPS Agreement, in its Statement of Administrative Action, as allowing WTO members to set zero-risk levels of protection that cannot be challenged by the WTO, with only the measures used to achieve those levels of protection open to challenge.

The US Statement of Administrative Action states:

[The Delaney Clauses, in the first instance, establish a level of protection. They reflect a decision by Congress that there should be no risk of cancer to humans from the substances those clauses cover... A determination that a particular food additive poses a health risk is made on scientific grounds....Based on scientific principles, the United States has determined that if a substance induces cancer in animals, it poses some risk of human carcinogenesis. And since the level of protection under Delaney requires that there be zero risk of carcinogenesis, the [US] prohibits the substance. (emphasis added)]

The US’s distinction between levels of protection and methods of achieving those levels is supported by the DSB’s interpretation of the SPS Agreement. In the emphasized part of the quote, however, the US seems to draw a problematically fine line—it does not explain why the US can behave differently as to the substances the legislation does and does not cover. This shortcoming goes directly to the issue of national consistency, which the US used against the EU in the Meat Hormones dispute, pointing to carbadox. Further, the US’s decision to extrapolate from animal to human data may seem perfectly logical, but if an international consensus does not exist as to this methodology, or if it breaks down in the future,


~ Statement of Administrative Action, supra note 4, at 94 — 95.
then the Clauses as a whole are theoretically based on unsound scientific principles for SPS purposes.  

B. Scientific Uncertainty and Food Policy within the US

Issues like those raised in Meat Hormones, particularly scientific uncertainty, are obviously not purely international concerns. As seen in Meat Hormones, the WTO framework raises questions about the sovereignty of nation states and the limitations on government responsiveness to consumer demand. Cases in which individual states in the US attempt to regulate foods more strictly than the FDA or USDA raise similar questions.

Cancer is an excellent example of a phenomenon the causes of which are scientifically uncertain. The evaluation of whether substances are carcinogenic, or helpful in preventing cancer of one type or another, has occupied many American laboratory hours. In a world of such imperfect information, governments must decide how much safety they want to try to guarantee their citizens. At the same time, citizen consumers can make food choices, among the foods the government permits, based on their own beliefs about what foods are good or bad for them and in what combinations. Inevitably, citizens

91 People in the US who believe the Delaney Clause is too strict might welcome a successful VITO challenge that might force Congress to leave carcinogenic risk assessment in the hands of the expert agency they themselves created precisely to develop expertise on such matters, the FDA. On the other hand, cancer is a very politically hot topic among consumers in the US, so the government would likely stand firm even in the face of a negative WTO holding, much like the EU has done regarding meat hormones. Plus, the US never likes to lose generally.

92 The status of political subdivisions under the VITO agreements is, not surprisingly, fairly unsympathetic to domestic politics. A panel concluded in 1992 that the US had not demonstrated that its federal constitutional structure prevented it from removing trade restrictive measures imposed by individual states. See Report of the Panel on US Measures Affecting Alcoholic and Malt Beverages, 16 March 1992, 1992 VIL 799397 (G.A.T.T.), D523/R — 398/206, at 5.78 —5.80. Although a detailed analysis of the possibility is beyond the scope of this paper, the interpretation at least suggests that the GAIT could potentially be more restrictive on states than the US Dormant Commerce Clause. The US created the position of WTO Coordinator for State Matters under the US Trade Representative to deal with such issues. See Statement of Administrative Action, supra note 4.
sometimes want the government to do more to protect them. Sometimes they also want more information, perhaps in the form of labels, so that they can protect themselves by avoiding certain foods or additives based on their own, more or less informed, evaluations of the evidence. Several debates relating to scientific uncertainty have raged in the US in recent years. I will touch on just two of them—pesticides and bovine somatotropin (growth hormone) residues in dairy products.

**Pesticides.** Recently, pesticides have come under increasing scrutiny in terms of both the risks they pose to children and other sensitive populations, as opposed to the average healthy adult in a scientific study. The cumulative risks of exposure to multiple pesticides and sources in an aggregate diet, as well as over the course of a lifetime, are also debated both within the scientific community and between industry and consumer advocates.

In the US, EPA is responsible for assessing the toxicity of individual pesticides, while FDA monitors foods for pesticide residues. Pesticides are primarily regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). FIFRA explicitly preempts some pesticide regulation by individual states, including imposition of additional labeling requirements. Thus, most US pesticide policy is made at the federal level.

One recent policy shift is evident in the Food Quality Protection Act of 1996, FIFRA provides in 7 U.S.C. 6136v(b): Uniformity. Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

This is not to say that the states do not maintain interest in the subject. The Massachusetts state legislature is currently taking a national lead on pesticides by considering a bill (Ma. Senate Bill 1970) that would require manufacturers to provide information on toxic content in products, including pesticide residues on foods above a certain threshold. FIFRA preemption necessarily limits the scope of the pesticide aspect of the bill, but it appears that the residue threshold for providing information could be lower than EPA’s current threshold for labeling as long as the bill does not technically require labeling. Case law suggests that information could be provided near the product but could not be required directly on it. Conversation with Paul Burns, MASSPIRG Toxics Division, 29 January 1998. The legislation is currently in the
which creates new standards for pesticide residues. The Act forges a single standard for raw and processed foods (resolving the so-called Delaney paradox regarding pesticides), bases risk assessments on children rather than adults, and requires large retail grocers to provide brochures that identify pesticide risks and ways to avoid exposure.95 The final element of the Act resounds to the clamor of consumer advocates for right-to-know information about residues on the food they buy so that they can make choices about the chemicals to which they may otherwise unknowingly expose themselves.

Given the strength of the pesticide industry in the US, it seems unlikely that extremely precautionary measures would suddenly be adopted by Congress, unless consumer demand was extraordinarily high. If such an event occurred, despite the Appellate Body’s adoption in Meat Hormones of a relatively tolerant approach to conservative risk assessment, it seems clear that purely consumer demand-driven legislation would not meet the scientific threshold of the SPS Agreement, unless it was fortuitously backed by hard (or at least firm) science. Again though, it appears unlikely in the present political climate that sufficient evidence would accrue to overrule the objections of the US pesticide industry without meeting the threshold of sufficient scientific evidence in the SPS Agreement.

The more germane question then is the SPS as it relates to current pesticide regulation. Some evidence suggests that a significant number of modern US standards exceed international standards and so are open to challenge in the WTO. One Massachusetts Senate Ways and Means Committee, having successfully passed out of the Natural Resources Committee.

Government Accounting Office study noted that, among American pesticide standards it
96 reviewed, 55% were more protective than existing Codex standards. A study published in 1994 by the Environmental Working Group and Public Citizen concluded that the US
barred 1,539 of the 3,285 pesticide/crop combinations for which Codex had standards at the time and banned residues of 40 pesticides for which Codex had 569 different standards at the time (including eight ranked as highly hazardous by the WHO, for which Codex had 116 standards).97 While the fact that this report was released prior to recent pesticide-related amendments to the Delaney Clause should be taken into account, it is nonetheless at least eye-catching that the report concludes that the adoption of existing Codex standards for pesticide/food combinations would result in a twelve-fold increase over existing American regulations in allowable cancer risk for American
98 consumers.

**Bovine Somatotropin in Dairy Products.** This interesting debate relates quite
nicely to the debate between the EU, Canada and the US regarding bovine growth
hormones in meat. In 1993, Monsanto sought FDA approval of Posilac, a genetically
～See id. at 72. Legislation has been introduced into Congress to create a presumption for Codex standards unless the EPA can demonstrate formally that deviation is justified. See id.
Interestingly, BGH residues in milk have drawn considerably more public attention in the US than residues in meat. Consumer concern about BGH in meat appears to have remained relatively steady in the US over the years, although there may have been some increase during the time between the BGH panel and AB reports. The following table summarizes Roper opinion polls conducted on the issue of BGH in meat during the period up to 1994.
engineered counterpart of a natural bovine pituitary hormone, for injection into dairy

cows.1~ Studies show that the drug can increase milk yields between 10—

40%. 101 While the drug was pending FDA approval, many consumers and consumer advocates publicly opposed market introduction of milk from cows administered BGH—questioning both whether the product should be allowed on the market at all and, if so, whether it should be labelled. Consumer and environmental advocates questioned the necessity and wisdom of (1) administering the hormone to animals who may experience serious side effects, (2) selling their milk to humans upon whom the health impacts remain uncertain, and (3)

Figure 4 Annual US Consumer Surveys on Hormones. *

Question: The following substances may or may not present a health hazard. How much of a hazard do you consider (antibiotics C and hormones in livestock)?

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>#Surveyed</td>
<td>1007</td>
<td>1019</td>
<td>1031</td>
<td>1005</td>
<td>2000</td>
<td>2006</td>
<td>2018</td>
</tr>
<tr>
<td>Serious hazard</td>
<td>57</td>
<td>61</td>
<td>61</td>
<td>56</td>
<td>53</td>
<td>55</td>
<td>50</td>
</tr>
<tr>
<td>Something of a hazard</td>
<td>34</td>
<td>28</td>
<td>26</td>
<td>33</td>
<td>36</td>
<td>34</td>
<td>37</td>
</tr>
<tr>
<td>No hazard</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Unsure</td>
<td>3</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>6</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>

* Survey sponsored by the Food Marketing Institute and conducted by Opinion Research Corporation. The surveys were conducted in the US by telephone and administered to adults who had gone shopping within the previous two weeks. Compilation of data available in LEXIS-NEXIS Market (library) Rpoll (file), a database containing methodology and results of public opinion polls.

For our purposes, the inclusion of antibiotics in the question undermines the value of this data.

In August 1994, Roper conducted a telephone survey of 1014 adults and asked respondents how high they

ranked a number of environmental problems on a scale of 1 — 10. The mean response to food additives and hormones was 6.4. Public Opinion On-Line (September 8, 1994). Exactly three years later, (coincidentally?) after issuance of the BGH panel report, when Roper polled another 1040 adults on the same question, the mean response was 7.1. Public Opinion On-Line (October 10, 1997).

Meanwhile in Europe, although I have no evidence of a relationship between the BGH dispute and fluctuations in the EU meat market, it just to note that beef consumption fell 7% in the EU in 1996 in contrast to the 2% increase that had been projected for that year. See World Beef Market on Recovery Track: WTO, Business Line, 17 September 1997, at 13.

~Note that Posilac is identified by several monikers in the debate: BGH, rBGH, bovine somatotropin, bST, and rbST.

101 See Hutt & Merrill, supra note 85, at 982. The OTA found that milk output increases 12% on average. See US Office of Technology Assessment, U.S. Dairy

43
creating an even larger milk surplus than already exists in the US. If FDA refused approval to Posilac, effectively banning it from the market, or instituted a mandatory labeling scheme, could the US have justified its actions to the WTO? The WTO has not formally considered issue (1), which would fall under GAFF Art. XX(b) to protect animal life and health. As for (3), the US could not discriminate against importers solely because it produced an overabundance of milk domestically. Finally, issue (2) is nearly identical to the subject of Meat Hormones.

In reality, the FDA did approve Posilac, requiring only the normal labeling for a prescription veterinary drug which consumers never see. FDA approval did not quell consumer concern about the issue though, which continues at least among some consumers and environmentalists today. A number of consumers even brought suit, challenging the FDA action in approving the drug, failing to require consumer labeling.

102 See Peter Montague, Is BGH in Trouble?, Rachel’s Environment and Health VWeakly #483, Environmental Research Foundation, 29 February 1996, at 1. 103 Thereby providing a perfect opportunity for the US to either be completely hypocritical or suddenly reinterpret the SPS Agreement. Without conducting a thorough analysis of the scientific evidence on both sides of the debate, however, it is impossible to suggest whether there is sufficient scientific evidence for purposes of the SPS Agreement to justify negative FDA action on the substance. 104 The fact that BGH residues in milk is no longer a frequently cited consumer issue may relate more to media tastes and human psychology than changes in objective perception of safety. Human nature, and the media (who need stories), tend to discount risks over time when they do not obviously manifest themselves. Given that bovine somatotropin could create risks that are not readily identifiable, decreased consumer interest therefore may have no relationship whatsoever to the state of science. It may suggest something about the effectiveness of labeling over time though.

There is some evidence that consumer concern over BGH may relate directly to basic awareness of the issue’s existence. An April 1996 Roper survey asked consumers: Has the synthetic hormone that causes cows to produce more milk caused you to avoid certain foods? Twenty-two percent (22%) of respondents replied affirmatively, 76% negatively, and 2% did not know. (Of course, without labeling it is exceedingly difficult for consumers to know how to shop with the BSE factor in mind.) In an earlier Roper survey, conducted February 1994, the food product which the most consumers identified as remembering hearning2 about in the context of biotechnology was milk, yet relatively few consumers were aware of the issue then either. Twenty-four percent (24%) remembered seeing or hearing about genetically engineered milk (compared, e.g., to 20% for vegetables, 16% for medicines/drugs, 8% for fruit, and 3% for meat/beef/cattle/livestock). See Public Opinion On-Line (June 30, 1994). If the 22% of concerned respondents from the 1996 survey overlap significantly with the 24% of aware consumers from the 1994 survey (as intuitively suggested by the fact that people cannot worry well about things that
they are unaware of), then the concern among consumers who know about BSE is potentially quite high.
and failing to conduct an environmental impact assessment.\textsuperscript{105} Although the district court granted summary judgment to the government on all counts, the judge stated in the undisputed facts section of his opinion: Scientists, economists, farmers, and environmental and animal welfare organizations have questioned the safety and quality of rbST-derived products... FDA received thousands of letters from consumers asking it either to deny approval of rbST or require labeling of rbST-derived products.\textsuperscript{1}\textsuperscript{14} In fact, a USDA-commissioned study calculated that 94\% of 1900 consumer respondents favored labeling to help them make dairy choices. While the US’s lack of responsiveness to consumer concerns raises other issues beyond the scope of this paper, it is sufficient to note in this context, that, if challenged, the US could have been forced to defend a more protective measure to the WTO dispute settlement body.

In a related story, but confined to the US, the Vermont ice cream manufacturer Ben & Jerry’s, a company that actively cultivates its natural image, recently settled a notable dispute concerning BGH residues in dairy products. The case arose from the following facts. Although FDA had refused to require consumer labeling of milk products from rbST-treated cows when it approved Posilac, FDA did eventually issue voluntary guidelines on consumer labeling. However, the city of Chicago and the state of Illinois refused to permit any rbST-related labeling of products. Since national manufacturers can rarely afford to produce multiple labels for different markets, the Illinois laws effectively stymied BGH labeling nationwide. Ben & Jerry’s initiated a First Amendment suit in

\textsuperscript{107} See Stauber v. Shalala, 895 F.Supp. 1178 (VI.D. VIis. 1995)
\textsuperscript{14} Id. at 1183.

\textsuperscript{14} See Ben & Jerry’s, Press Release (14 August 1997): Legal Settlement Clears Way For National AntirBGH Label, Ben & Jerry’s Homemade Inc. website (14 August 1997)

federal district court, joined by Stonyfield Farm (a New Hampshire-based yogurt and ice cream manufacturer), Whole Foods Market (the largest natural food supermarket chain in the US), and Organic Valley (a Wisconsin farmers cooperative that sells dairy products). The suit recently settled, allowing the natural food companies to go forward with voluntary negative content labeling (e.g., BGH-free). In light of the settlement, Ben & Jerry’s now explains sympathetically explains on its Web page:

We’ve always wanted to tell you that the family farmers who provide our milk and cream do not treat their cows with recombinant bovine growth hormone (rBGH), but until now we just weren’t allowed to. Since 1994 Illinois has forbidden Ben & Jerry’s, Organic Valley and Stonyfield Farm from adding anti-rBGH labels to their products and threatened to seize any such products that were sold there.

In a press release, all four companies made statements definitively linking the settlement with consumer rights. Gary Hirshberg, CEO of Stonyfield Farm, concluded:

This win signifies a great step for freedom of speech, consumer rights and the survival of family farms. Our dedication to using pure, all natural ingredients and our fight against labeling bans shows [sic] our commitment to supporting our customers right to know about the food they eat.110

The issue of labeling is considered in more depth later. At this juncture, it is enough to note the apparently strong public support for labeling, at least in some situations, in the absence of conclusive scientific evidence.110 It is also important to recognize that this win was the result of a settlement and so is not an answer from the courts.

In conclusion, the political tug-of-war between US federal and state governments illuminates the even greater difficulty of dealing with sovereignty issues at the international level. Federalism, and the necessary loss of state sovereignty that results, is well established by the US Constitution, and yet disputes still arise regarding the division of power between two levels of government in a unified country. At the international level, nation states are each at the top of their own totem pole. Although they sometimes agree to accept limits on their sovereign power in order to receive the benefits of multinational agreements, the degree of sovereignty forfeited is a delicate political issue.

C. Case Studies: Tuna, Shrimp, and Environmental Decision-Making

The Tuna/Dolphin dispute well illustrates the critical overlap between food policy and environmental policy. While the Marine Mammal Protection Act (MMPA) at the heart of the dispute is not what would traditionally be termed a food regulation, it does have ramifications on the food supply arising directly out of the fact that all food comes

International perception of the inherent rights of sovereigns has changed somewhat over time with increasing globalization. For example, while absolute sovereignty within one’s own border was once a vital tenet of international law, evolving international public and political opinion has created a more balanced approach to sovereignty—including, e.g., the idea that sovereign rights may be partially tempered by a responsibility to protect the environment. See, e.g., The Stockholm Declaration on the Human Environment (1972) (recognizing a limit on sovereign rights when domestic activities affect states or jurisdictions beyond their borders); see also Trail Smelter Arbitral Tribunal Decision, 35 Am.J.Int’l L. 684, 716 (1941) (essentially relying on US original jurisdiction Supreme Court case in holding that sovereignty does not extend to a right of states to emit transboundary pollutants); The Law of the Sea Convention (1982) (allowing states to exploit domestic natural resources pursuant to their environmental policies and in accordance with their duty to protect and preserve the marine environment (emphasis added)).

As one commentator summarizes, while the clairvoyant may have anticipated it earlier, the policy struggle between environmental protection and liberal trade effectively began in August 1991 [with Tuna I]. See William J. Snape III & Naomi B. Lefkovitz, Searching for GATE’s Environmental Miranda.~ Are Process Standards Getting Due
Process?, 27 Cornell Int’l L.J. 777, 777 (1994). Given the parallel rise of trade treaties and environmental treaties, the lack of international awareness of their potential collision course is actually somewhat astounding and should hardly have required the services of a clairvoyant to anticipate.
from the environment. The subsequent corollary is that the harvesting of food products may have direct negative impacts on the environment.

1. Tuna I (1991)\textsuperscript{114}

In 1990 Mexico requested convention of a WTO panel to hear its complaint regarding two US environmental statutes that Mexico claimed inhibited free trade in violation of the GAFF. The two statutes at issues were the Marine Mammal Protection Act (MMPA) and the Dolphin Protection Consumer Information Act (DPCIA). Both statutes came into law in response to consumer concern about dolphin mortality and injury incidental to use of the purse seine fishing technique. The MMPA required all importers of tuna to demonstrate that their country has an overall regulatory regime regarding the taking of marine mammals comparable to the US regime; evidence of an incidental kill rate at or below \textit{1.25} times the average US rate for the same time period demonstrates comparability. The complementary DPCIA specified voluntary labeling standards for tuna products sold in or exported by the United States. It permitted the placement of a Dolphin Safe label on tuna products caught in the Eastern Pacific Tropical Ocean (EPT) only if certain conditions were met regarding incidental dolphin kills.\textsuperscript{5}

Of course, this reality could partially or wholly shift in the future if artificial means of generating food are developed in response to world hunger and/or other food availability concerns. Biotechnology raises a host of issues that tend to shift the discussion from Tuna back to Meat Hormones.


Note that this report, like Tuna I, was never officially adopted by a WTO consensus.

\textsuperscript{5} \textit{See} id. at 5.6. For information on recent developments pertaining to the Dolphin Safe label, see Public Citizen Global Trade Watch, \textit{GA7î'zîllazFlipper Round 111: Threat of WTO Challenge Pressures US}
The panel examined four aspects of the US measures to determine whether either violated the GAFF, and if so whether any Article XX exceptions were applicable. The two legal aspects of the report that are most relevant to this discussion include (1) the provisions of the MMPA on which prohibition of Mexican tuna was based and (2) the voluntary labeling provisions of the DPCIA.6

The MiVIPA. Recall that the GAFF explicitly permits internal taxation and regulation under Article III, as long as the Member affords national treatment, while disallowing quantitative restrictions under Article XI. The panel first considered which Article applied to the MMPA provisions regarding foreign kill rates. Mexico complained that the MMPA constituted an Art. XI quantitative restriction on the product tuna. 117 Further, Mexico argued, the regulations were less favorable to importers than domestic producers under Art. Ill because the Act based foreign compliance on a retroactive variable dependent on the actual US domestic kill rate; consequently, Mexico could not know whether it was in compliance during the year until the end of the year when the US calculated its own average. The US disagreed, arguing that the product at issue was actually tuna-caught-by-certain-fishing-methods and that treatment of such products was identical. In other words, the US argued that the MMPA provisions were Art. Ill internal regulations that did provide national treatment. The panel rejected the American argument, agreeing with Mexico that the product at issue was tuna and that the MMPA provisions were an Art. XI quantitative restriction in nature.8 The panel noted that the


117 See id. at 5.8.

118 See id. at 5.14.
MMPA could not be a internal regulation since the regulation had nothing to do with the actual product tuna (a typical GAFF product-process distinction).

Mexico having established a prima facie case of inconsistency between the MMPA and the GAFF, the panel proceeded to consider the US’s arguments that the MMPA was excepted by Arts. XX(b) or (g). Recall that Art. XX(g) pertains to measures necessary to protect human, animal or plant life or health. Since dolphins live in the high seas, the panel first studied the jurisdictional question—whether XX(b) is intended to cover animal life beyond a Member’s land or territorial waters. After admitting genuine ambiguity in the GAFF, the Tuna I panel nonetheless concluded that the GAFF’s drafting history suggests the drafters intended only to except measures to protect health of animals located within a Member’s jurisdiction. But even if XX(b) does apply to extra-jurisdictional protection, the panel continued, Mexico was correct that the measures were not necessary within the meaning of Articles XX(b) and (g) for two reasons. First, the 1.25 x actual US domestic kill rate method was too unscientific and unpredictable to be necessary. Secondly, international cooperation was both a more desirable and a more appropriate option to pursue first. The panel also rejected the US’s XX(g) argument. Article XX(g) provides an exception for measures relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption. Again, the extra-jurisdictional nature of the measures and the arbitrariness and uncertainty of the 1.25 calculation defeated this US argument.
The **DPCIA.** The US fared better when the panel considered the voluntary labeling provisions of the DPCIA. The panel first rejected Mexico’s argument that these provisions constitute unfavorable product-marking requirements under GAFF Article IX: 1; it found as a matter of law that Art. IX: 1 only applies to marks of national origin. The panel then concluded that DPCIA’s labeling provisions do not restrict tuna sales since tuna can be sold freely with or without the label and because the only competitive advantage gained by labelled products arose solely from consumer preference. The panel also rejected Mexico’s argument that the labeling option violated Article 1:1 by discriminating against countries that fished in the Eastern Pacific Ocean (ETP). The panel found that the voluntary labeling measures related specifically to the ETP simply because of the unique fact that tuna had been documented to swim in schools below dolphins solely in that region, resulting in intentional deployment of purse seine nets in the ETP to encircle dolphins and corresponding high incidental dolphin kill rates. Further, the panel reasoned, US customs law considers the origin of fish products to be the fishing vessel’s country of registry, so any country fishing in the ETP is subject to the DPCIA. Since the complainants in Tuna 11 did not challenge the DPCIA, the Tuna I panel report provides the WTO dispute settlement body’s only guidance thus far as to food labeling.

**2. Subsequent Events and Tuna II (1994)**

Two events of note occurred in 1992 pertaining to the Tuna/Dolphin dispute. In June, the US, Mexico, and ten other countries negotiated an international agreement in
June under the auspices of the preexisting Inter-American Tropical Tuna Commission (IAFFC). The signatories agreed to reduce dolphin mortality below 5000 by 1999. In October, despite the IIATC agreement and with little regard to the panel’s findings in Tuna I, Congress amended MMPA. The amended act provided for suspension of the US tuna embargo, but only against those countries that entered into formal agreement with the US to (1) implement a global moratorium by March 1994, (2) reduce dolphin mortality in the meantime, and (3) require observers. If a country promised to meet the requirements and failed, the ban would be reinstated. If the ban was unsuccessful after 60 days in bending offending countries to the US’s will, further trade sanctions would be brought against those countries. Finally, a ban was scheduled to go into effect on all dolphin-unsafe tuna beginning June 1994. At the time of the MMPA amendments, the EU and the Netherlands had already filed WTO co-complaints, alleging that the MMPA was inconsistent with the GAFF, and a panel had convened. Following a pause requested by the co-complainants to evaluate the US amendments, and after consultation between the parties, the panel decided that it would consider the new legislative provisions during the proceeding. Thus the panel addressed the amendments as well as many of the issues raised in Tuna I.

The Tuna II panel essentially agreed with the reasoning of the Tuna I panel with one important exception, although it did not cite the unadopted report as an authority. The Report of the Panel on United States Restrictions on Imports of Tuna, 16 June 1994, 1994 VIL 907620 (G.A.T.T.), D529/R [hereinafter Tuna II Panel Report]. Note that this report, like the Tuna I panel’s, was never officially adopted by the VITO.


128 See Tuna II Panel Report at 1.4.
Tuna 11 panel agreed that GAFF Art. III did not apply to the US measures because the product at issue was tuna was not regulated at the point of importation. It also agreed that the national embargoes constituted prohibitions or restrictions on trade in contravention of GAFF Art. XI since they banned tuna imports from other Member nations that did not share US policy. The US again argued for exceptions based on Arts. XX(b) and (g), but the Tuna 11 panel rejected those arguments as the Tuna I panel had before them. The Tuna 11 panel importantly disagreed with the Tuna I panel as to the jurisdictional issue though. In their consideration of the applicability of Art. XX(g), the panel concluded quite succinctly that there was no valid reason to conclude that the provision applied only to conservation measures related to domestic natural resources.

The panel nonetheless rejected both of the US’s Art. XX arguments, reasoning that measures aimed at forcing other nations to change their purely domestic policies (and which, in fact, could only be effective by accomplishing such a result) are inappropriate in the context of the basic principles and objectives of the GAFF. Thus, such measures could not be necessary (Art. XX(b)) or primarily aimed at conservation (Art. XX(g)). Referencing the desirability of narrow interpretation, the panel predicted:

If Article XX were interpreted to permit contracting parties to deviate from the obligations of the [GAFF] by taking trade measures to implement policies, including conservation policies, within their own jurisdiction, the basic objectives of the [GAFF] would be maintained. If however Article XX were interpreted to permit contracting parties to take trade measures so as to force

29 See id. at 5.8—5.9.
30 See id. at 5.10.

Writting before Tuna II, Charnovitz heavily criticized the Tuna I panel’s extra-jurisdictional argument. He questioned the panel’s adoption of the fuzzy term extra-jurisdictional and pointed out that the MMPA is clearly not extraterritorial in the legal sense—the Act covers imported food products, as opposed to extending legal jurisdiction to the behavior of foreign parties (such as forbidding American companies in foreign countries to buy Mexican tuna or foreign fisherman to fish with purse seine nets).
other contracting parties to change their policies within their jurisdiction, including conservation policies, the balance of rights and obligations among contracting parties, in particular the right of access to markets, would be seriously impaired. Under such an interpretation, the General Agreement could no longer serve as a multilateral framework for trade among contracting parties.\footnote{32}

Accordingly, the panel adopted the former approach, focusing on the distinction between forcing foreign government policy-making and influencing commercial activity abroad.\footnote{33}

From a policy perspective, the Tuna 11 panel’s rejection of the Tuna I panel’s extra-jurisdictional analysis bodes well for environmentalists concerned with the ability of their governments to enact conservation measures. It is unclear from the panel’s report though, what measures would fall within the panel’s narrow permissible range of ones that create trade incentives to do what the Member wants but do not try to force other Member governments to adopt policies in their own jurisdictions. For instance, the US cannot actually pass laws in other jurisdictions; a ban at the border on tuna caught in an offensive manner would be unenforceable, as well as an impermissible process distinction; and under the Tuna 11 panel’s interpretation the US cannot require other nations to adopt certain policy measures as means to accomplish the US’s ends. What precisely is left? The panel comments in its concluding observations: [T]he issue in this dispute was not the validity of the environmental objectives of the United States to protect and conserve dolphins. The issue was whether, in the pursuit of its environmental objectives, the United States could impose trade embargoes to secure changes in the policies which other contracting parties pursued within their own jurisdiction.\footnote{132 Tuna II Panel Report at 5.26.}

The tuna ban was lifted on 15 August 1997, and there have been some changes to the dolphin safe labelling scheme. See generally Public Citizen Global Trade Watch, supra note 115, at 5. \footnote{Id. at 5.42.}
panel does not illuminate what trade measures would be permissible. Despite the panel’s distinction between commercially attractive and policy-forcing measures, the only types of regulations that are clearly permissible are ones that are purely domestic. A ViTO document dated only four days after the Appellate Body’s report on BGH is no more helpful, stating, Subject to [the requirement of nondiscrimination] being met, WTO rules place essentially no constraints on the policy choices available to a country to protect its own environment against damage either from domestic production or from the consumption of domestically produced or imported products. ~ This statement does not illuminate the question of the non-jurisdictional areas which Tuna 11 implies it is permissible for Members to worry about conserving.


The very recent dispute over US embargoes on shrimp based on turtle protection measures bears a striking resemblance to the Tuna dispute. Although the neither Tuna panel report was adopted, the Shrimp panel refers to the Tuna 11 panel report as relevant and useful.37 It should be noted that the Shrimp decision is only a few weeks old and has not even been made public yet. While the US has indicated it will appeal,38 the dispute settlement body’s unsympathetic approach in Tuna I and 11, as well as in the

136 Report of the Panel on United States Restrictions on Imports of Shrimp, — 1998. 1998 VIL — (V.L.T.O.), D558/R [hereinafter Shrimp Panel Report]. I encountered great difficulty in trying to obtain the panel report on this dispute. The WTO was prompt but unhelpful when I emailed them about the report— telling me only that it was unofficial as yet but would be available on their website within hours of release (whenever that might be—the WTO only releases DSB reports upon the request of a Member). I particularly mention this difficulty because it is illustrative of some later points I make regarding secrecy in the WTO process. My analysis of the Shrimp panel report is therefore, by necessity, based upon the Findings section of an unofficial copy of the final report that I obtained from an NGO in Washington, D.C (who got it from the Office of the US Trade Representative).

Shrimp panel report, necessarily generate some pessimism about the US’s chances for a successful appeal. The Appellate Body could conceivably take a different view than the panels though, and, at any rate, is at least likely to clarify some of the panel’s GAFF interpretations.

Sea turtles encounter a variety of risks in their modern environments. The animals are exploited by humans for their meat, eggs, and shells; they are impacted by ocean pollution and habitat destruction; and they are at serious risk of incidental capture by fisherman.39 All species of sea turtles are listed as threatened or endangered species under both the US Endangered Species Act of 1973 (ESA) and the 1973 Convention on International Trade in Endangered Species (CITES)). In response to this situation, the US National Marine Fisheries Service developed turtle exclusion devices (TEDs) which allow shrimp to pass through while quite effectively excluding turtles and other larger sea creatures.

Since 1987, US shrimp trawlers have been required to use TEDs, or else observe certain tow time restrictions, to reduce incidental sea turtle kills. The ViTO dispute centered on a complementary US law, enacted in 1989, referred to as Section 609. Section 609(b)(l) reads:

The importation of shrimp or products from shrimp which have been harvested with commercial fishing technology which may affect adversely [sea turtles] shall be prohibited no later than May 1, 1991, except as provided in paragraph (2) [i.e., the exporting nation is certified].


~ Although all the parties to this dispute are parties to CITES, the US did not pursue a CITES challenge because, as the panel notes, CITES applies only to trade in endangered species, and the turtles are not being traded. See Shrimp Panel Report at 7.58. The ViTO dispute settlement body has yet to address the implications of non-VITO multilateral environmental agreements for the ViTO framework.

56
The US initially implemented Section 609 only against countries located in the Caribbean/Western Atlantic region, but the US Court of International Trade (CIT) ruled in 1996 that the law required the government to apply Section 609 to all countries.\textsuperscript{141}

The CIT also ruled that the embargo is nation-based rather than catch-based, so an embargo must cover shrimp actually caught with TEDs if the trawler is from an embargoed country. The US Secretary of State responded with revised Section 609 guidelines in April 1996, requiring governments to supply documentary evidence that they have a regulatory program comparable to the US’s pertaining to sea turtles, and that their national average kill rate is comparable to that of US vessels.\textsuperscript{142} India, Pakistan, Malaysia, and Thailand requested convention of a VTO panel on the matter.

All four complainants argued that Section 609 violates GAFF Article XI: 1, and three argued that it violates Articles 1:1 and XIII: 1 as well. The US raised an affirmative defense under Articles XX(b) and (g). With some variations, but essentially relying on the same rationales given by the panels in Tuna I and 11, the panel concluded that the measures do violate GAFF Art. XI and that an Art. XX defense is unavailable.\textsuperscript{1} In evaluating the Art. XX argument, the panel focused more narrowly on the chapeau to Art. XX than the Tuna panels had done. Where the Tuna panels had argued that the US measures regarding tuna were not necessary within the meanings of Arts. XX (b) or (g)—because their unilateral nature was inappropriate and threatening to the multilateral

“The plaintiffs sought to compel the US to enforce the turtle-shrimp provisions of the ESA, and included Earth Island Institute, the Sierra Club, the Humane Society of the US, and the American Society for the Prevention of Cruelty to Animals.\textsuperscript{42} See Shrimp Panel Report at 7.16.

\textit{Id.} at 7.5. A showing that the country has a TED-based program comparable to the US scheme constitutes prima facie evidence of a comparable kill rate.
regime—the Shrimp panel concluded that the US’s unilateral measures regarding shrimp are not in accord with the general principles of the GAFF, as expressed in the term unjustifiable in the Art. XX chapeau—and so inappropriate and threatening to the multilateral regime. The Shrimp panel characterized its finding as an interpretation of the scope of Art. XX exceptions. By rejecting Art. XX’s applicability on the basis of the chapeau, the panel avoided the Art. XX(g) extra-jurisdictionality question.

The Shrimp panel concluded, like the Tuna panels before it, that the US environmental measures threatened the principles of GAFF and the ViTO agreements generally by relying on unilateral action. Adoption of similar measures by multiple ViTO members, the panel concluded, would undermine and unravel the entire WTO framework. The panel predicted that, under an alternative interpretation of Art. XX, GAFF 1994 and the ViTO Agreement could no longer serve as a multilateral framework for trade among Members and that market access for goods could become subject to an increasing number of conflicting policy requirements for the same product which would rapidly lead to the end of the ViTO multilateral trading system.

The most interesting question raised by the Shrimp panel relates to the ViTO’s preference for multilateral environmental agreements in accord with its general principles of international cooperation and free trade. The panel noted that MEAs are a long recognized method of achieving environmental protection, that the US did not claim to be allowed or required by a non-ViTO multilateral treaty to impose the ban, and that the

The panel did not reach the Art. 1:1 or XIII: I challenges. See id. at 7.18 —7.23.

's See id. at 7.25 — 7.29.
146 id. at 7.24 & 7.64—7.65.

47 Id. at 7.45.
CIT interpreted Section 609 as requiring comprehensive requirements (emphasis added) for nations. The panel stated:

[W]e are limiting our finding to measures—taken independently of any such international obligation—conditioning access to the US market for a given product on the adoption by the exporting Member of certain conservation policies. In this regard, we note that banning the importation of a particular product does not per se imply that a change in policy is required from the country whose exports are subject to the import prohibitions. 8 (emphasis added)

The panel provided several examples: (1) a Member may ban unsafe products while accepting similar safe products, but it may not refuse all imports from an exporting Member on the grounds that the exporting Member allows some production of unsafe products for domestic use or export elsewhere; 9 (2) a Member may set minimum characteristics for entry of a product into its market, but it may not require Members to set policies comparable to their own for domestic production or export to other countries.

The intriguing question raised by the Shrimp panel report is what constitutes multilateral action for purposes of the ViTO agreements. More specifically, can agreement among less than the whole membership of the ViTO establish international standards for environmental protection which Members may then act upon against all Members. If less than a consensus, how many Members must agree to a multilateral action—a significant number less than half, a majority, a supermajority? Does it matter whether there are a significant number of non-Members who have adopted similar policies? The panel cites a number of international treaties in support of the basic idea.
that environmental decision-making which affects international affairs and trade should be pursued in a multilateral manner, including the Rio Declaration on Environment and Development (1992) and the Convention on Biological Diversity (1992). ‘~’ But how international? Hopefully, the Appellate Body will flesh out this important question.

One determination of the panel does not bode well for a more relaxed interpretation of multilateral by the AR. The US actually did attempt to argue that use of TEDs to protect sea turtles is an international standard. The US argued three points:

first, that the international community has long recognized the importance of protecting endangered species; secondly, that a number of existing international conventions, including the 1982 United Nations Convention on the Law of the Seas and the 1992 Agenda 21 on Sustainable Development, require signatories to adopt conservation measures and urge resource management such as prevention of incidental takings during fishing operations; and, thirdly, that 19 countries already required TEDs on all shrimp trawl vessels in their jurisdiction, having acted either on their own initiative or under the Inter-American Convention on the Protection and Conservation of Sea Turtles. The Shrimp panel concluded that the US’s citation to only regional agreements and voluntary use of TEDs failed to establish that the use of TEDs constituted a recognized multilateral environmental standard applicable to the complainants’ (emphasis added). If the AR upholds the panel’s seemingly high threshold for establishing an international

Rio recognizes the sovereign right of states to set environmental policy in light of their own situations and values while stressing the importance of international cooperation and multilateral action. See id. at 7.52. The Convention on Biological Diversity also proposes international cooperation through competent international organizations as to manners outside national jurisdiction. See id. at 7.53.

See id. at 7.51.

See id. at 7.57.

See id. at 7.59.
environmental standard, then it seems unlikely that anything short of a ViTO consensus, perhaps facilitated by the ViTO Committee on Trade and Environment, could justify imposition of measures to the dispute settlement body.

IV. Concluding Remarks: The Potential Impact of the WTO Treaties on Domestic Food Regulation

A. Issues for Consideration

ViTO treaty interpretation is an evolving process, and as such there will always be opportunities to alter (through negotiation rounds) or reinterpret (through the dispute settlement mechanism) the ViTO treaties to fit the needs of member nations. WTO members are currently engaged in a process of determining how to balance the competing, but not necessarily conflicting, goals of strong environmental/consumer protection policies and maximized free trade. Accordingly, and surely at least partially in deference to firm stances taken by the US and EU (both Big Four members) regarding sovereignty in these matters, the ViTO dispute settlement body appears to be adopting a somewhat more flexible approach to environmental and consumer protection measures. This increased flexibility, demonstrated in the two week old Shrimp panel report and the six month old BGH appellate report, are at least partially responsive to strong criticism of the earlier decisions. Given the single case regarding scientific uncertainty, it is particularly difficult to tell where the ViTO will go with this issue. The Shrimp panel report appears to be a definite improvement on the Tuna reports in that it suggests that conservationist measures that go beyond national boundaries are not per se impermissible under the GAFF, nicely following up on the extra-jurisdictionality finding in the unadopted Tuna II.
Sensitivity to sovereignty issues is very important for the ViTO in general and the dispute settlement body in particular. Responding to significant Member anxiety about loss of sovereignty over such fundamental issues as consumer and environmental protection not only increases the ViTO’s legitimacy, which is fundamentally necessary for a successful international regime, but it recognizes the complicated nature of many real world policy decisions including those that relate to food safety. However, both the BGH appellate report and the Shrimp panel report suffer from a critical flaw—while they each suggest that there is a perfectly reasonable way to achieve the desired level of consumer and/or environmental protection by means other than the chosen measures that are completely consistent with the ViTO agreements, they fail upon inspection to give any real guidance as to what those alternatives might be. Given the relative infrequency of ViTO dispute settlements on these matters and given the lengthy political processes necessary to enact such measures, especially in democratic nations, it is unlikely that ViTO members will be willing to use a trial and error approach perhaps somewhat more tenable in a domestic adjudicative setting. Without better guidance, at least some important Members with much to lose economically will eventually either (1) leave the WTO regime rather than obey the DSB’s interpretations of the ViTO agreements or (2) give in to the pressure towards downward harmonization, which might lead to eventually disastrous, non-sustainable development.

A number of areas are in particular need of evaluation and development, as indicated by the ViTO dispute settlement body’s interpretations to date regarding environmental and consumer protection. Important areas for discussion include ViTO
procedure, the product-process distinction, Codex standards, labeling, US leadership, and the risk of downward harmonization

WTO Procedure. Several elements of the ViTO process, including the provisions of the DSU, have been heavily criticized by consumer and environmental advocates who feel that, among other problems, the ViTO process offers far too few, if any, significant opportunities for public participation. Public Citizen has identified a number of what it considers biases, which potentially undermine any public legitimacy in the ViTO result:

1. ViTO requirements for membership on DSB tribunals favor trade liberalization over other policy values;
2. the DSB operates in secret with oral arguments and documents visible only to national government representatives;
3. the DSB does not accept amicus briefs from NGOs or other outsiders unless officially submitted by a participating government;
4. NGOs have received only minor concessions to allow some presence in the US’s official trade advisory system while industry has much more extensive access to information and many opportunities to give input due to the structure of the system; and
5. the ViTO system promotes only increased trade and better economies without due consideration to other goals such as improved democratic accountability, distributive justice, or promotion of consumer and environmental protection.

Earth Island Institute, an American NGO working on conservation issues, has argued that the ViTO regime is basically offensive to democracy and sovereignty, particularly noting the make-up of the

's—The Shrimp panel actually noted rather grudgingly in its report that it received submissions from American NGOs that it did not ask for and would not consider as such. The US was permitted to submit the NGO’s material if it wished to do so. In this case, the US attached one section of a document submitted by the Center for Marine Conservation and the Center for International Environmental Law to its second panel submission. See Shrimp Panel Report at 7.8.

~Public Citizen, Harmonization, supra note 4, at 3 — 5. Public Citizens argues that these imbalances derive at least partially from the fast track approach taken to the ViTO agreements (and NAFTA), which provided Congress with an extremely limited role in developing treaties that were negotiated largely in
panel in the Shrimp dispute: two persons from nations that were named as interested parties and had openly sided with the challengers plus one person from a nation that had previously been embargoed under US law. A situation Earth Island refers to as a classic case of the fox watching the hens.\textsuperscript{56} In the wake of the BGH panel report, EU Agricultural Commission raised a political stir by stating that the ViTO lacked clear democratic controls.\textsuperscript{57} Meanwhile, a number of academic commentators have suggested that the dispute settlement process is clouded by political considerations which undermine the process.\textsuperscript{58} 

The \textbf{Product-Process} Distinction. From the standpoint of an environmental or consumer advocate, the product-process distinction is one of the most difficult aspects of the ViTO agreements. It almost inescapably impedes the enactment of regulations related to labor standards (including child labor), environmental standards (such as factory emissions), and other consumer protection measures. The basic principle behind generally not allowing process and production method (PPM) distinctions is that Members do not have a right to force their personal policies onto other Members and that international issues should be approached and resolved multilaterally. If international standards (which may or may not be less than a consensus) cannot be achieved then a WTO member who secret by unelected and largely unaccountable government agents. See id. at 4.

\footnote{Earth Island Institute, \textit{News Release: Environmentalists Blast Free Trade Panel for Conflict of Interest} (4 June 1997). Todd Steiner, director of the Institute’s Sea Turtle Restoration Project, echoes loudly Public’s Citizens concerns about the VITO generally: [The VITO] consists of secret meetings, conflicts of interest, and no public participation. In this age of democracy, the VITO is an international embarrassment. See Earth Island Institute, \textit{News Release: Environmentalists Blast International Trade Panel Decision} (16 March 1998).}

wishes to impose non-conforming measures must either pay the price in retaliatory measures or leave the ViTO. As the Tuna I panel notes, a Member could have chosen only to sign trade agreements with countries having similar standards.\footnote{Production processes for food and other goods are an increasingly sensitive issue for consumers though. Both the ViTO membership and individual nation states need to deal squarely with the process-product distinction, perhaps revisiting whether allowing process distinctions is not appropriate in certain instances.}

The Codex Commission. The SPS Agreement makes Codex standards the international standards which over 130 nations, including the most advanced democracies, must either conform to (to avoid any challenge), base their standards upon (to prevent the burden of proof shifting to them in a challenge), or be prepared to justify deviating from (based on a potentially high threshold of scientific information). Similar to procedural fairness concerns about the ViTO process, the increasingly important international role of Codex necessitates greater attention to its procedures, scientific methods, and transparency. Public Citizen and the Environmental Working Group complain that: (1) Codex does not have minimum requirements for study design or for content/completeness of data sets in studies it uses in standard-setting; (2) Codex has no minimum requirements for contents and completeness of data sets it uses to establish standards; (3) Codex does not consider varying dietary exposure in different cultures when setting standards; and (4) Codex meetings are closed to the general public so their positions can only be presented to the Commission through a sympathetic governmental participant, unlike industry. These organizations recommend in their report that Codex
act as an international science data center rather than an international standard-setter.\textsuperscript{160}

Labeling. While nondiscrimination in international markets, in the words of the ViTO, guarantees consumer choice, \textsuperscript{61} those choices cannot be made intelligently without information, which is the strongest argument in favor of labeling. When consumers demand information on process, and the ViTO agreements refuses to allow Members to give it, there is a conflict between consumer expectations and the ViTO agreements that citizen consumers may or may not accept in the long run. And if there is consumer market demand for labelled food products, then an interpretation of the ViTO agreements that prohibits that information entering the market seems more protectionist of trade than merely facilitative of it, since such an interpretation prevents consumers from making informed market choice according to their actual preferences.\textsuperscript{62}

The ViTO Committee on Trade and the Environment (CTE) has rightly identified eco-labeling as a hot issue.\textsuperscript{164} While noting that the preferred approach for governments to take in tackling transboundary or global environmental problems is

\textsuperscript{\textasciitilde} See Patti Goldman & Richard Vliles, Public Citizen & the Environmental Working Group, \textit{supra} note 95.

\textsuperscript{166} The US noted in its statement to the President regarding the CTh, however, that much division existed among Members, particularly between developed and developing countries, regarding the consistency of eco-labeling with the ViTO agreements. The US stated to the President that it did not interpret the TBT Agreement as per se invalidating eco-labeling schemes, but did not elaborate on the circumstances of perceived consistency. \textit{See} US Statement of Administrative Action, \textit{supra} note 4, at 56 — 57.
cooperative, multilateral action, CTE acknowledges that eco-labeling programmes are important environmental policy instruments.\textsuperscript{166} However, CTE is, not surprisingly, concerned about PPM-based labelling. The TBT Agreement addresses eco-labeling of products with non-identical final characteristics (e.g., automobile emissions, energy economy information). As the CTE recognizes, the issue of PPM-based labeling for identical end products under the TBT Agreement must be explored. Guidelines for labeling of food products in the face of scientific uncertainty about the safety of one or more ingredients should also be investigated. Since the TBT specifically does not cover sanitary measures as defined in the SPS Agreement, the ViTO needs to clarify whether such labelling is subject to the TBT Agreement’s lower threshold (legitimate purposes) or the SPS Agreement’s higher one (based on science).

Consumer labeling cannot cure the ills of the world. The cigarette warnings, for instance, have hardly eradicated tobacco-induced lung cancer. But labeling may be an alternative when a Member wants to be cautious in the face of scientific uncertainty without taking more trade restrictive measures. In this situation, labeling actually seems to fit quite well with the spirit of the SPS Agreement. Labels may also be appropriate in response to consumer demand for process information. The dispute settlement body has not said enough about labeling to date. Voluntary Dolphin Safe labels were held consistent with the GAFF in the unadopted Tuna I panel decision, and the BGH panel.


\textsuperscript{165} WTO, Eco-labeling, \textit{supra} note 135. I state earlier that food policy and environmental policy are intimately related and what looks like the latter may also be the former. The argument runs both ways: ecolabeling obviously refers to the environment and may be misconstrued to refer only to conservation issues, but no BGH labels on meat would almost certainly be considered eco-labels too.

\textsuperscript{167} \textit{See id.}

\textsuperscript{67}
alluded to voluntary natural labels on meat. In a different type of environmental case,

the ViTO DSB upheld mandatory point-of-sale labelling providing automobile fuel economy information on the grounds they were nondiscriminatory. While these facts are promising, labelling should be addressed more squarely. Food products could be a perfect test case for an experiment in process labeling, should the ViTO find such an experiment useful, since the FDA already has fairly extensive labeling requirements.

US Consistency. The US has behaved rather schizophrenically to date. It is particularly unfortunate that it and the EU are standing firmly on opposite sides of the Meat Hormones and GMO debates. While standing firm about more traditional environmental regulations pertaining to conservation, decreeing the sanctity of sovereign rights and an international moral imperative, the US has acted rather abysmally when it comes to consumer protection standards that threaten the US’s multi-billion dollar meat and dairy industry. When the US was ruled against in a ViTO case against

168 [T]he ability of any Member to enact measures which are intended to protect not consumer health but other consumer concerns was not addressed. In this regard, we are aware that in some countries where the use of growth promoting hormones is permitted in beef production, voluntary labeling schemes operate whereby beef from animals which have not received such treatment may be so labelled. BGH Panel Report at 8.274.


170 Section 403 of the FFDCA requires every packaged food to be labelled with at least the following: (1) the common name of the food, (2) the foods ingredients, (3) an accurate statement of net quantity, (4) the manufacturer or distributor’s name and address, (5) and specified nutrition information. The country of origin requirements come from 8304 of the Tariff Act of 1930, 19 U.S.C. 81304. For an argument that these requirements should be extended to ingredients in otherwise domestic foods, see Country-of-Origin Labeling Requirements for Imported Meat and Other Food Products, Hearing before the Subcommittee on Trade of the House Committee on Ways and Means.

171 The EU refuses to repeal its measures and is submitting to arbitration to determine appropriate retaliatory measures. See Request for Arbitration by the European Communities regarding EC Measures Concerning Meat and Meat Products (Hormones), April 16, 1998 (WTIDS26/14). The EU has insisted that it will not lift the ban ever since the original panel decision. See, e.g., Peter Blackburn, EU’s Fischler Defiant on
Meat Hormone Ban, Reuter European Community Report (Brussels, 26 January 1996) (discussing the EU Farmer Commissioner’s reaction to the BGH panel report); France Urges EU to Appeal WTO Meat Hormone Ruling, Reuter European Business Report (20 May 1997) (citing statements by the French Farm Minister that these [VITO panel] conclusions are totally unacceptable and that they place
Japan regarding trade in photography equipment, 72 US Sen. John Ashcroft (R-Mo) expressed that the ruling raises serious questions about the credibility of this international body and of the US trade representative’s capacity to secure and defend trade agreements. 73 Yet Sen. Lugar, Chairman of the Senate Committee on Agriculture, declares that the EU needs to get over its concern about genetically modified organisms. 7

**Downward harmonization.** Finally, I would like to touch again on the threat of

Downward harmonization. The SPS Agreement tentatively establishes a floor, albeit an unenforceable one, for sanitary measures. I say unenforceable because, while Members are supposed conform to or base their standards on the Codex, the structure of the SPS Agreement suggests that it is extremely unlikely that a Member will be challenged in the ViTO for having less stringent standards. Meanwhile, ViTO members with superior food safety and environmental protection regulations, e.g., have economic incentives to reduce their levels of protection to the minimum required unless they cannot get a sufficient number of other Members to adopt their policies or they are under strong and sustained consumer pressure. The presumption of SPS and GAFF consistency for measures conforming to Codex standards alone creates a strong downward force, promising a trade interests ahead of public health concerns. The EU also declared in January that it will conduct another risk assessment in light of the AB decision. See *Europeans Press Their Beef Ban*, N.Y. Times (17 January 1998), at D3. Following the BGH Appellate Report, market analysts have predicted that the complicated nature of the multimillion-dollar case and the wording of the [AB] finding...leaves [sic] no doubt that a long legal wrangle between the two top trading powers lies ahead. See *EU, US Both Claim Victory in WTO Ruling*, Washington Post (16 January 1998), at A16. 172 See Report of the Panel on Japanese Measures Affecting Consumer Photographic Film and Paper, 31 March 1998, 1998 VIL 208716 (W.T.O.), VIT/D544?R.

174 See *USA Still Ahead Despite Kodak’s Defeat*, USA Today (10 December 1997), at 24A.

---

69
buffer against a ViTO challenge. This enticement to conformity reduces the likelihood that a Member will impose a higher sanitary standard solely in an effort to gain covert trade advantages, but the problem is actually the very strength of the incentive it creates. The incentive to downward harmonize creates additional pressure on Members seeking to establish higher levels of protection, who are likely to already be under pressure from industry and political groups. The EU actually argued that the different levels of protection adopted by it and the US reflected the BC’s precautionary approach [which placed attainment of a high level of consumer protection before the commercial interests of farmers and pharmaceutical companies].

One European professor of agricultural economics implores, The trouble with the ViTO agreement is that it does not provide for any measures that are based on consumer concern. It only provides for measures that are based on scientific concerns. This statement appears quite true in light of the DSB’s interpretation of the SPS Agreement. The EU, the US, and all the other members of the ViTO must determine whether that is tolerable or appropriate.

Reminder. Finally, I would like to bring attention back to the issue of the ViTO treaties as creatures of international law. Although it is important to consider the potential limitations on food regulation created by the ViTO treaty obligations, it is equally important to remember the limits on the ViTO. Nations are not bound by decisions of the ViTO dispute settlement body in the way that, for instance, the US federal and state

See generally Charnovitz, supra note 114, at 478 (arguing that the WTO agreements may result in downward harmonization of public health and safety standards); Public Citizen, Harmonization, supra note 4 (making stronger version of same argument).


Andrews, supra note 84 (quoting Stefan Tangermann, professor of agricultural economics at the
legislative bodies are bound by the decisions of the US Supreme Court. Rather, parties to the different agreements are contracting parties. As with most contracts, parties may violate their obligations so long as they pay the price. DSU Art. 22.6 provides that Members who are parties to disputes can elect to retain measures that have been found by the dispute settlement body to be inconsistent with the ViTO agreements. At that point, the Member must submit to arbitration to determine what countervailing trade sanctions may be imposed on it by the Members affected by its decision not to act consistently with the Agreements. Nonetheless, the price of retaliatory measures can be high, and it is perhaps naive to believe that nations will be willing to pay forever in the name of ethics.

B. Recommendations

In light of the ViTO dispute settlement body’s interpretations of the GAFF and the SPS Agreement, I would like to suggest possible areas of action for the different constituencies in the ViTO universe. The list is by no means exhaustive, but raises some of the more difficult issues and recommends potential methods of easing their resolution.

The WTO

- Actively consider the relationship between trade and environmental measures pertaining to world food supplies, including the role of eco-labelling and whether, and if so how, to allow Members to take PPM-related measures. CTE should be clear about its recommendations and the ViTO clear about what is allowed under the WTO.

University of Gottingen in Germany).

Few international treaties include hard enforcement tools. In creating a treaty, nations may offer each other a variety of carrots as incentives to abide by the treaty, which in conjunction with political realities may assure adequate compliance, at least with the spirit of the treaty. The inclusion of actual sticks in a treaty, however, is extremely rare given politics, lack of a larger entity with authority over all signatories (in contrast to a situation like the United States where the federal government and the courts can generally resolve state disputes), and fear on the part of each drafter that the stick could someday be turned on them.
agreements so that Members may either attempt to change the agreements, change their interpretation, or leave the ViTO.

- Regarding the SPS Agreement, continue to apply a more flexible approach when interpreting the relationship between a risk assessment and sovereign risk management. Clarify what constitutes sufficient scientific evidence. Minimizing intrusion into domestic policy-making will reduce the likelihood of a consumer backlash against the ViTO and contribute to the legitimacy of the ViTO dispute settlement process.

- In light of the designation of the Codex standards as international standards for purposes of the SPS Agreement, assure that the Codex Commission is and remains apolitical. Since the Appellate Body concluded in BGH that conservative risk management decisions are permissible under the Agreement, consider the possibility of incorporating a factor into the Codex standards to reflect scientific uncertainty.

  Doing so could make the state of the science more clear to panels when determining whether measures that do not conform to the Codex standards are nonetheless based on them. If Codex cannot act objectively and apolitically, it should revert to a purely voluntary status as it was originally conceived.

National Governments

- Establish a list of important national policies that touch on trade. In the future, before signing any new multilateral agreement, or agreeing to revisions to an existing one,

  The EU raised the issue in the panel proceeding that the Codex standards for the five hormones at issue in the dispute were formally adopted by a very narrow margin (33 for, 29 against, 7 abstentions), an especially noteworthy occurrence given that Codex proposals are normally adopted by a consensus. See BGH Panel Report at 8.67. In cases of such significant scientific disagreement, the inability of even the Codex to reach a consensus may weigh in favor of giving deference to a Member’s risk assessment.

  72

  83
consider the treaty’s potential impact on those policies. For example, conduct an environmental assessment of the treaty before signing. If the government official does not, then Congress must demand an opportunity for thorough review before approval.

- Meanwhile, enter into multilateral agreements with major trading partners and other nations with similar sanitary, labor, and environmental standards. By doing so, individual nations can assure that there will not be a race to the minimum standards while also decreasing the economic impact in the international market of voluntarily maintaining higher standards.

- To maintain consistency with the SPS Agreement, and to reduce the likelihood of a ViTO challenge, conduct well-documented risk assessments when implementing sanitary measures. Make these risk assessments available to other Members in the interests of transparency and harmonization. Although the burden of proof is initially on the complainant, having a clear scientific justification for regulating before having to defend the measure will increase the likelihood of successfully showing consistency with the SPS Agreement, as well as making better policy at home.

- Be receptive to consumer concerns and make scientific evidence readily available to consumers. Educate consumers on how the FDA and USDA make food safety decisions. Demonstrating that a regulation is not warranted by a conservative risk assessment will go a long way toward preventing a citizen backlash against the government for not implementing food standards in response to consumer demand.80

~ The SPS agreement clearly indicates that bowing to public or political pressure alone will not withstand ViTO scrutiny, for instance if public fear of a food, food additive, or food-producing technology is founded on the National Enquirer rather than science.
• Consider consumer labeling programs and how to implement them in a way that provides adequate information without creating an unnecessary panic or, conversely, deadening consumers to labels.

• Decide whether your political body and your citizens can live with the limits on sovereignty imposed by the ViTO agreements, particularly as they relate to health risk assessments, environmental policymaking, and process distinctions generally. In all likelihood, the benefits of belonging to the ViTO far exceed the burdens, but long-term maintenance of offsetting retaliatory trade measures against you may not be politically feasible.

• Free trade without reference to conservation increases risks of unsustainable growth and consumption, as well as providing an effective subsidy to non-conservationist nations whose lower standards provide them a competitive edge and threaten the world environment and consumers with downward harmonization. The United States should take the lead on environmental conservation and sustainable development measures.

**Consumer and Environmental Advocates**

• Help governments consider the implications of trade agreements for hard questions.

• Monitor, publicize, and educate citizens about international developments that may impact their sovereign’s ability to pass legislative in accordance with the precautionary principle or a higher environmental ethical standard. The complex, unfamiliar nature of treaties may mean that citizens are significantly less likely to understand or predict the implications of treaties than traditional federal, state, or local legislation, let alone mobilize to discourage treaty signature or ratification.
• Continue to question the procedural fairness of the ViTO, Codex, and other international treaty regimes and organizations. Given the ViTO’s repeatedly stated goal of transparency, your experience in shedding light on bureaucratic and political injustice and revealing important conflicts of interest can do much to improve the ViTO process and could even ultimately be what makes it compatible with the values of the real people behind the WTO member governments.