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BACKGROUNDER

The U.S. Threats Against Europe's GMO Policy and The WTO SPS Agreement

To date there have been several WTO challenges of countries' domestic food safety and quarantine laws. The latest challenge in this area is by the U.S. against Europe's policy on Genetically Modified Organisms (GMOs.) Below we describe the background and issues in this new WTO challenge. This will be a highly political case.

First, European reaction to this case will be intense. This U.S. action will exacerbate anti-U.S. sentiment in the European public generated by the U.S. Iraq war approach. Second, such an aggressive move is likely to harden the resolve of the EU member governments with the greatest concerns about GMOs. Third, many developing country members of the WTO—led by the African bloc—also oppose GMO seeds and foods being released without further testing and strong regulation. The U.S. already has generated ill will among many of these nations by unilaterally blocking a late 2002 proposal on the WTO's intellectual property rules and access to medicines.

Finally, this case raises many of the issues regarding democracy and the appropriate scope of the WTO rules that have undermined the institution's legitimacy with the public in many countries and with a growing number of developing country governments. Polling shows that a majority of Europeans and Americans want GMO foods to be segregated from non-GMO foods and labeled so that the consumers will have a choice. This case poses the specter of public will and its democratic enactment in Europe being undermined by a tribunal of three trade experts meeting behind closed doors at the WTO's Geneva headquarters.

The moratorium that U.S. has challenged is an interim measure while the individual EU countries debate the implementation of that policy. Because the Europeans apply these same rules domestically—in the same manner that they do to imports—there is no trade discrimination and thus there really is no trade issue here.

However, although there is no trade discrimination in this situation, there is a viable WTO case to be made in attacking the EU GMO moratorium. The agreement on Sanitary and Phytosanitary Standards (SPS) is one of the Uruguay Round Agreements enforced by the WTO. The agreement provides strict limits governing countries' permissible food safety policy goals and the means by which nations can pursue even the permitted goals.[1] The WTO rules empower member countries to challenge each other's policies and regulations as exceeding these limits.

No country's SPS measure challenged in the WTO has ever been upheld. In past cases, WTO panels consistently have interpreted WTO member countries' food and quarantine measures to be barriers to trade that must be weakened or eliminated, rather than as public health safeguards or prudent measures aimed at avoiding the spread of pests or plant or animal disease.

Yet, as scientific innovation outpaces the ability of regulators to anticipate the adverse human health effects of new technologies, the potential threat WTO trade rules pose to cutting-edge domestic public health and safety policies will increase. For instance, barely discussed at the time the SPS Agreement went into effect, but of vital importance, were the potential human health and environmental threats posed by new biological technologies. More and more commodities for human consumption are being genetically altered to improve appearance or enhance resistance to agricultural chemicals. Agribusiness and biotechnology companies are pushing for the unregulated sale and trade of these genetically modified organisms, yet consumer, health and environmental exports demand regulation until a full understanding of their impacts on human and environmental health over the long term can be known.

I. US Challenge Against EU's GMO Policy

While the EU and many other countries have proceeded cautiously before exposing their publics to GMOs, the U.S. biotech industry and agribusiness interests have been leading advocates for GMOs, and have successfully pressed the case with US government and trade officials.

Industry views requirements for process-based labeling and tracking or "traceability" of GM foods from farm to table as being without basis in any known health risk—and thus in violation of the WTO SPS rules.[2] Industry also argues that the practical difficulties and huge costs involved in segregating and documenting GM foods would greatly hamper U.S. trade and could potentially encourage skeptical European consumers to avoid GM food products, effectively discriminating against U.S. exports.[3] Therefore, the industry view is that even labeling and traceability requirements also constitute unnecessary restrictions on trade under the WTO's Agreement on Technical Barriers to Trade, claiming that labeling GMO products is unnecessary "in the absence of an identified and documented risk to safety or health."[4]

U.S. consumer and environmental groups take the position held by their counterparts worldwide and by many governments: too little is known about the long term health and environmental risks of GMOs. Some groups oppose any use of GMO seeds or foods. At a minimum these groups call for segregation and labeling of GMOs from non-GMO seeds and foods so that consumers can choose whether they will eat GMOs.

The U.S. government policy carefully follows the industry line and considers the EU's resistance to GMOs to be a trade barrier.[5] In November 2002, newspapers in the U.S. reported that the Bush Administration was actively laying the groundwork for a Cabinet-level decision on whether to bring a GMO suit against the EU in the WTO.[6] Government officials were said to be focusing on solidifying their WTO case and Aseeking the best way to frame the initiation of a WTO dispute in terms of public perception."[7] The case was delayed for political reasons on the brink of the Iraq war. On May 13, 2003, the U.S. announced it would file a case against the EU moratorium. (In its news releases, the U.S. Trade Representatives Office announced that its was challenging the moratorium. USTR has not made public its brief, so it is not clear if the case also covers the underlying law.)

The EU Law and Moratorium: The EU's precautionary approach to GMOs was reflected as early as 1990 when the EU regulated release of GMOs into the environment, such as by planting, ranching or marketing (sale).[8] Another directive regulated "contained uses" of GMOs in laboratories.[9] About a dozen GMOs were approved under the 1990 directive. However, as public opposition to GMOs intensified in Europe in 1999, a *de facto* moratorium applied to new approvals of GMOs.

On February 14, 2001, the European Parliament voted to approve new rules governing the testing, planting and sale of domestic and imported GM crops and food products.[10] The directive regulates the "deliberate release" of genetically modified organisms into the environment, such as by cultivation or ranching, as well as the "marketing" of GMOs as food or food products.

The new rule lacked some key provisions for labeling and traceability of GMOs and included no framework for liability if a GMO causes injury to consumers or the environment. Therefore, six EU member states indicated that they will maintain the *de facto* EU-wide moratorium on new GMO approvals until those issues are adequately addressed in additional legislation[11] that is still in the pipeline.

No new GMOs will be approved for cultivation or marketing until the moratorium imposed by individual EU member states is lifted. Under both the existing rules and the new regulation, an approval for the marketing of a GMO can be temporarily blocked and contested by any EU member state.[12] Although such a temporary hold is designed to allow for resolution of the dispute, a sufficient number of countries could prevent the entire EU from ending the temporary hold, thereby resulting in a de facto moratorium.

The EU policy is the world's most comprehensive regulatory regime to date for GMOs, and includes a number of safety features demanded by consumer groups,[13] including explicit incorporation of the Precautionary Principle, environmental risk assessment, monitoring of GMO effects on human health or the environment, and information on control, remediation methods, waste treatment and emergency response plans.[14] It also provides for public input to the approval process.

WTO and the Precautionary Principle

As described in section III of this backgrounder, the WTO contains extensive subjective, value-oriented rules constraining signatory countries' domestic food safety policies that limit the subject matter, level of protection and design of domestic food safety policies. One such WTO rule puts the burden of proof on countries seeking to regulate a product to show it is dangerous. This WTO rule means that policies based on the Precautionary Principle **B** for instance requiring that a manufacturer show a product to be safe over the long term before it goes on the market **B** are threatened.

As described in section IV of this Backgrounder (where the WTO SPS cases are reviewed), in past cases the WTO has turned the sensible Precautionary Principle on its head. Asking the government to prove a product is dangerous is almost impossible for new or emerging technologies. Cases in which the WTO has ruled against the Precautionary Principle include the EU's consumer protection ban on artificial hormone-treated beef, and Australia's quarantine on raw salmon imports (which was designed to protect the health of indigenous fish population). The WTO's rulings on the EU beef hormone case are described in detail in this section because this is the case most closely related to the U.S. challenge of the EU's GMO policy.

II. Political Context of US WTO Challenge on GMOs

Many Countries Regulate GMOs

Egypt has decided not to import GMO wheat.

Brazil's Supreme Court ruled that untested release of GMOs violated that country's Constitutional provisions on public health. Planting of GMOs is forbidden in Brazil.

Saudi Arabia has banned GMO food and will not import GMO wheat.

India bans GMO corn and all other edible crops and only recently approved GMO cotton after a heated debate.

In **Japan** in 1997 the leading food retailer initiated plans to label GMO foods in its stores.

The **Chinese** Government banned the commercial planting of GMO rice, wheat, corn and soybeans and requires labels on GMO imports.

Sri Lanka has banned the import of all GMO foods from May 2001.

Since late 2000, **Algeria** has banned import, distribution, commercialization and use of GMO plant material

Australia has banned GMO rape-seed in Tasmania, and has banned commercial planting of GE crops in Western Australia (Australian States have been given the right to declare themselves GE-free).

In **New Zealand** the Government has blocked trials of GE salmon. Some local bodies in Wellington and Auckland are GMO-free.

In 1996 in **Germany** the physicians' association issued a statement demanding labelling of GMO foods. Germany banned Novartis Bt corn. Several Protestant Church groups have banned GE crops from their land.

In **Austria** in 1997 the Government stated that it wanted to be a "Biotech-Free Zone". Austria has banned three varieties of GMO corn.

Norway prohibited the release of genetically modified corn, tobacco, chicory and rape-seed, stating that anti-biotic resistance was already a serious enough problem without adding anti-biotic resistant genes into the food supply. Norway has imposed a ban on the import of six GMO crops and products that contain anti-biotic resistance.

In **England,** the Church of England has refused permission for GMO crop trials on 60,000 hectares of land. Dozens of local authorities supply GE-free school lunches and the House of Commons banned GMOs from its catering.

In **Italy** there are bans on GE crops in four regions and 25 provinces.

This U.S. WTO case is against the EU, yet its target is significantly broader. There is growing concern in U.S. industry about the number of other nations that are taking the precautionary approach to biotechnology. Because plaintiffs almost always win WTO challenges, mere threats of challenges often result in the challenged country changing its policy. A U.S. calculation in this case is that if the U.S. succeeds in the EU case, mere threats against other countries might suffice. Already, mere threats of WTO action under the SPS Agreement have resulted in Japan and South Korea lowering food standards.

Significant U.S. trading partners such as China and Brazil have moved to restrict biotech imports.[15] African and Asian countries have banned or restricted GMOs. Even in Australia and New Zealand, popular concerns about GMOs has caused new regulations to be implemented.

"We are not a nation of guinea pigs [but] the entry into the country of genetically engineered crops and food products…may just as well make us one."

- Philippine Rep. Prospero Pichay Jr. Aug. 24, 2001.[16]

While increasing food security and food availability is the main argument for promoting

GMOs, ironically recent research is showing that there is no significant yield in transgenic crops, only increased safety risks.[17] Southern Africa was facing a significant famine by the end of 2002, with nearly 15 million people facing

starvation in Lesotho, Malawi, Mozambique, Swaziland, Zambia and Zimbabwe.[18] Yet, in October 2002, Zambia refused U.S. food and aid that came in the form of 18,000 tons of U.S. GM corn.[19] Malawi, Mozambique and other southern African countries joined Zambia's refusal to accept U.S. food aid if it was GM grain.[20]

Other countries followed suit. In November 2002, India froze U.S. GM shipments of corn and soy food aid shipments.[21] In January 2003, two U.S. relief agencies approached the Indian Genetic Engineering Approval Committee (GEAC) to gain permission for them to import U.S. GM corn and soy food aid that could not be certified as GM-free.[22] As of early 2003, GEAC has only approved the importation of GM cotton, but disallowed GM food imports.[23]

In early 2003, an unhinged U.S. Trade Representative Robert Zoellick lashed out at Europe for preventing GMO crops from entering their market and thus creating a disincentive for developing countries to allow GMO food imports, calling Europe "luddite" and "immoral."[24]

Yet, the opposition from Africa was not based on an EU effort, as the U.S. already had witnessed at the Earth Summit in Johannesburg in 2002. The U.S. sought to use the Summit to further promote biotech especially for Africa—cynically in the name of fighting hunger.

Many African governments expressed outrage over U.S. pressure on African countries to accept GMO imports. The Catholic Bishops of South Africa issued a statement, that "It is morally irresponsible to produce and market genetically modified food."[25]

At the Summit itself, one civil society representative, representing hundreds of African farmers and government presented a statement:

"We, African Civil Society groups, participants to the World Summit on Sustainable Development, composed of more than 45 African countries, join hands with the Zambian and Zimbabwean governments and their people in rejecting GE contaminated food for our starving brothers and sisters. We refuse to be used as the dumping ground for contaminated food, rejected by the northern countries. Our responses is to strengthen solidarity and self-reliance within Africa, in the face of this next wave of colonization, through GE technologies, which aim to control our agricultural systems, through the manipulation of seed by corporations. And we are enraged by the emotional blackmail of vulnerable people in need, being used in this way. We will stand together in preventing our continent from being contaminated by genetically engineered crops, as a responsibility to our future generation."[26]

The fight back against the U.S. from African countries and civil society at the Summit has not deterred USTR Zoellick from continuing to press the U.S. agribusiness agenda on GMOs. Indeed, filing the WTO case against Europe is viewed as a sign of how extreme his feelings on this subject are: the case poses significant risks to U.S.-EU relations.

Summary of Concerns about GMOs

Emerging data indicate that some GMOs cause allergic reactions in humans (for instance genetically engineered soybeans containing Brazil nut genes) and that some are fatal to benign insects that feed on GMO crops. In addition, the environmental dangers of open-air crop trials, cross pollination, and on-the-

ground and in-the-silo contamination of non-GMO crops with GMOs has been amply demonstrated on numerous occasions. For example, in November 2002, U.S. officials announced that an experimental plant that was genetically modified to make a pharmaceutical product had nearly slipped into the nation's food supply, even though it is not intended for human consumption.[27]

GM crops that are not approved for human consumption already have made it onto the U.S. food market. In 2000, consumer group U.S. PIRG detected Starlink**7** corn, produced by Aventis but only approved for use as animal feed, in taco shells for sale in grocery stores, prompting a voluntary recall by the U.S. Food and Drug Administration.[28]

Plus, there are numerous environmental and development issues to consider. First, crops engineered to resist pesticides and herbicides perpetuate reliance on those chemicals, threatening the environment.[29] In fact, increasing demand for such products may be a goal of some corporations producing GMOs. For example, Monsanto, manufacturer of the popular Roundup line of herbicides, also genetically engineers Roundup Ready cotton seeds designed to resist its herbicides.

Second, scientists believe that crops engineered to resist pesticides and herbicides could pass those traits on to weeds, resulting in herbicide- and pesticide-tolerant "superweeds".[30] Scientists in the U.S. and Denmark have shown that the herbicide-tolerance gene can be readily passed from cultivated canola plants to closely related wild plants, like wild mustard, in nearby fields.[3132] The widespread use of Roundup Ready crops and the herbicide Roundup for the last 30 years has engendered at least two weeds that can survive being sprayed directly with Roundup **B** mare's tail and water hemp.[33] If pesticide resistance were transmitted to pest plants, it would force farmers to use more and more herbicides to control plant pests, with unknown effects on the environment and added threat to public health.

Additionally, the emergence of resistance in pests like Bollworm and creation of superpests is another inevitable consequence of Bt. cotton. Researchers at North Carolina State have found that the corn earworm (also known as the cotton bollworm) develop resistance to Bt. corn **B** and that the moths that develop Bt. resistance in the Midwest cornfields fly south to U.S. cotton Bt. cotton fields.[34]

Third, GMOs may upset biological diversity. According to a report written for the British government, if GMOs eradicate weeds and insects, species that depend on them for food or habitat, including such birds as the corn bunting, partridge and skylark, will suffer.[35] Furthermore, crops engineered to resist insect pests also may be toxic to harmless or beneficial insects, such as green lacewings and springtails, thereby reducing insect diversity.[36]

The creation of genetic uniformity leading to genetic erosion in centers of genetic diversity and monoculture agriculture threatens food security. Aggressive marketing of the products protected by intellectual property rights can lead to the displacement of hundreds of local varieties of crops and breeds of livestock.[37] Mono cropping stamps out the diverse crop and animal varieties that are useful to maintaining balanced ecosystems. The end product - the so-called "mono-culture" - is a dangerously unstable ecosystem that has lost its diversity and hence its resistance against pests, diseases and environmental stresses. In 1970, a corn blight epidemic ravaged at least 15% of the U.S. corn crop due to homogeneity making the entire crop vulnerable to the same fungus.[38]

Fourth, genetically modified foods may run afoul of consumers with allergies and those who have specific

dietary requirements because of ethical, religious or cultural beliefs. People allergic to fish could have a reaction to tomatoes with transplanted fish genes; vegetarians and persons of the Islamic and Jewish faiths may be averse to eating food containing pig genes.

Fifth, GMOs might pose human health risks. British scientist Dr. Arpad Pusztai first suggested this following a study on the effects of consumption of genetically modified potatoes on rats, in which subjects fed the altered potatoes suffered stunted internal organ growth and weakened immune systems.[39] The Monsanto-funded[40] Rowett Research Institute suspended Dr. Pusztai, despite his stellar reputation, claiming the researcher went public without sufficient scientific evidence to substantiate his findings.[41]

A specially convened group of U.K. scientists later concluded that Dr. Pusztai's study, though possibly "flawed," underlined the uncertainty as to the safety of genetically modified foods.[42] Indeed, the British Medical Association, representing Britain's doctors, promptly called for a moratorium on the planting of genetically modified crops in the U.K.[43]

IV. What Are the Requirements of the WTO Food Rules (SPS Agreement)?

The provisions of the SPS Agreement can be viewed as setting constraints in four areas. First, it limits the policy goals a country can seek using SPS measures. Second, the level of protection a country chooses for its citizens is also a matter for WTO review **B** even when the standard is applied equally to domestic and foreign goods.[44] Third, even for policies that meet the constraints regarding goals and level of protection, the means by which WTO-legal policy goals may be achieved is subject to another test. The SPS Agreement requires that a policy not be any more restrictive to trade than is necessary to obtain its WTO-allowed goal.[45] Additionally, domestic laws cannot treat goods differently on the basis of how they are harvested, processed or manufactured. Thus animal humane slaughter laws, which distinguish physically similar products according to the conditions under which they were produced, could be deemed to go beyond the constraints. Fourth, the WTO SPS Agreement contains affirmative obligations for WTO countries to harmonize their domestic standards to international ones and to find other countries' differing standards to be 'equivalent' to U.S. standards.[46] These last two mechanisms are the primary engines of the race to the bottom in public health and consumer protection. This tautological provision is often cited by WTO defenders to misleadingly argue that countries may set any standard desired.

Since every WTO member country has agreed to conform to the SPS rules, it is worth reviewing them more closely. Article 2.1 defines WTO member nations' basic rights: "Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement."[47]

Article 2.2 defines WTO members' basic obligations, requiring SPS measures to be applied "only to the extent necessary to protect human, animal or plant life or health, . . . based on scientific principles, . . . and not maintained without sufficient scientific evidence…"[48] Thus, a country could not, for example, have in its food safety law a ban on a pesticide that poses an unknown human health threat but that causes wild bird eggs to have thin shells, as was the case with DDT.

Article 3 requires WTO member countries to harmonize their domestic food safety and animal and plant protection policies by basing them on international standards, such as the food safety and pesticide residue level standards set by the Codex Alimentarius Commission. Policies based on such international standards

are presumed to be WTO-legal. However, policies that achieve a higher level of human, animal, or plant protection than relevant international standards must pass a series of tests in order to be proved *not* to be illegal trade barriers. One such test requires a "scientific justification."[49] A Member has scientific justification only if it can analyze available scientific data to determine that the international standard is insufficient to attain the country's "appropriate level of sanitary or phytosanitary protection."[50]

A country's "appropriate level of protection" is defined as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."[51] This definition suggests that WTO Members have unfettered discretion to set their own level of protection. Yet, in setting this level of protection, countries must comply with SPS Article 3, which requires Members to base their SPS measures on WTO-legal international standards. If a Member wishes to maintain an SPS measure that provides more consumer protection than the relevant international standard, it must prove "scientific justification." Since the burden of proof falls on the Member with the more protective standard, that Member must invest time and resources in proving a negative that the international standard is unsafe. The phrase "appropriate level of protection" obviously leaves the door open to such a challenge.[52] If a country's level of protection is not based on international standards, it is automatically subject to challenge as not "appropriate."

In addition, in setting a level of protection, countries are required under Article 5 to base their SPS measures on a "risk assessment," using techniques developed by relevant international organizations. This requirement places enormous burdens on developed and developing nations alike to have conducted extensive studies and to develop scientific proof *before* taking any regulatory action. While this requirement is difficult enough for developed nations, where science is increasingly an expensive private sector endeavor, it is extraordinarily difficult for nations that are not able to put significant government resources into scientific studies or independent analysis of available studies.

The SPS elevates trade concerns above all others in the risk assessment process, specifically requiring Members to "take into account the objective of minimizing negative trade effects.[53] Article 5.6 adds: "Members shall ensure that [SPS] measures are not more trade-restrictive than required." Though zero-tolerance standards are theoretically permissible under the wording of the agreement, these two requirements place yet another burden on nations that want to ban dangerous products rather than roll the dice and "regulate" the risk. Finally, Article 4 requires member countries to accept the SPS measures of other WTO countries as equivalent, even if they are different, if the exporting country can prove to the importing country that its measures reach the importing countries' "appropriate level" of protection.

Combined, these provisions of the SPS Agreement effectively eviscerate the Precautionary Principle, an internationally recognized theorem of public policy embedded in many local laws and international environmental treaties, such as the 1992 Rio Declaration on Biodiversity. It is generally understood to mean that in cases where there is scientific uncertainty, governments have an obligation to take action to avoid harm to the public health, safety or the environment by seeking out less harmful alternatives. Proponents of new products or technologies must demonstrate that their activity will not cause undue harm to human health or ecosystems. The Precautionary Principle is based on the premise that science does not always provide the information necessary to take protective action effectively or in a timely manner, and that undesirable and potentially irreversible effects may result if action is not taken until science does provide such insights.

Proponents of the SPS Agreement argue that Article 5.7 specifically allows nations to take precautionary measures in the face of scientific uncertainty. In fact, this provision only covers "provisional" or time-limited emergency measures. This is extremely problematic given that many scientific problems, such as the dangers of mad cow disease, the public health ramifications of endocrine disrupters, and the threat of global warming, have taken generations to understand and do not lend themselves to easy cause-and-effect analysis and short timelines.

V. WTO RECORD ON FOOD SAFTEY AND QUARANTINE LAWS CHALLANGED

After eight years, a trend in the food arena has emerged. WTO panels have ruled against all food safety regulations under review on the grounds that they restrict trade more than necessary.

The WTO also has ruled repeatedly that the Precautionary Principle cannot be implemented in a manner consistent with WTO rules, thus eviscerating the ability of any nation to safeguard against significant potential risks. The SPS Agreement declares WTO-illegal measures that are based on "insufficient" scientific evidence. Yet, under the Precautionary Principle, the burden is on a company to prove that a potentially dangerous substance is safe before it is put on the market -- governments are not required to prove a substance dangerous.

For instance, in the 1960s U.S. regulators refused to approve the sale of the morning sickness drug thalidomide because U.S. law put the burden on the manufacturer to prove a drug was safe. In relying on this precautionary approach, the U.S. averted a disastrous epidemic of birth defects. In other countries, thalidomide is estimated to have caused deformities in more than 10,000 babies. At the time of its approval in Europe and Canada, tests in laboratory animals showed no negative effects.[54] Thalidomide's damage was revealed only over time and not in the drug's users, but in their children.

The WTO has set an unusually high standard which countries must meet to protect the integrity of their food and farms from non-indigenous and hazardous pests and diseases. Countries free of these pests legitimately wonder who will pay to combat or eradicate new pests that arrive on imported food once their quarantine measures are eroded by the WTO. These cases include Japan's testing requirements designed to keep fruit pests out of the country, Japan's efforts to keep aggressive orchard-attacking bacteria off its shores and the recent effort by the U.S. to keep Mediterranean Fruit Flies from entering the country in Spanish Clementines.

Case 1: The WTO Rules Against European Ban of Artificial Hormone-Treated Beef

"As you recommended, we have initiated action against the EU ban under the dispute settlement procedures of the World Trade Organization." - Letter from U.S. Trade Representative Mickey Kantor to the National Cattlemen's Association Feb. 18,1996.[55]

In a major defeat for health and safety policies based on the Precautionary Principle, a WTO panel ruled in 1997 against an EU ban on artificial growth hormones used in beef. The decision was the first involving the WTO SPS Agreement, and amply illustrates the danger of shifting decisions on public health policy to the WTO.

Since 1988, the EU has banned the sale of beef from cattle treated with six artificial hormones that are linked to cancer and premature pubescence in girls[56] and have been shown to have genotoxic (damaging to DNA) effects.[57] The ban has been applied in a nondiscriminatory fashion to both domestic and imported beef products.[58] The risk to humans of artificial hormones' residues in the meat they consume is uncertain. On the basis of the known risks from direct consumption and strong public demand for a ban on meat from cattle treated with artificial hormones, the EU adopted a "zero risk" standard. Rather than trying to assess a tolerable amount of an indeterminable risk or waiting for negative human health affects to accrue over time, the EU chose to eliminate public exposure to the risk altogether.

The U.S. beef and biotechnology industries have long opposed this EU policy.[59] In January 1996, at the behest of the U.S. Cattlemen's Association, the U.S. challenged the EU policy at the WTO.[60] In 1997, a WTO panel ruled that the beef hormone ban was an illegal measure under SPS rules in part because it was not based on international standards developed at the Codex Alimentarius, nor on a WTO-approved risk assessment,[61] and in part because the hormones had never been shown to be dangerous in the context of residues on beef.[62]

A vital element of the original WTO Panel ruling against the EU's ban was the requirement that the EU standard needed to conform to international standards set by the Codex.[63] The Codex standard, which is extremely controversial and was issued only after a high-pressure, four-year campaign by the U.S., allows for residues of artificial hormones in beef.[64] The U.S. forced two votes on the issue, even though second votes are almost unheard of at Codex (usually, the body sets standards by consensus). The U.S. lost the first vote, then forced a second vote and won by a slim majority.

In January 1998, the WTO's Appellate Body narrowed the basis of the initial ruling, but did not alter the outcome of the case. The WTO Appellate Body stated that the WTO SPS rules would allow the EU to set standards different from the Codex standard, but only if such an EU decision was based on a risk assessment that "sufficiently warranted" the difference.[65] Although the WTO SPS Agreement in Article 3.3 technically allows countries to have set levels of protection that exceed Codex, another provision of the SPS Agreement effectively undermines the flexibility that Article 3.3 **B** would seem to confer.[66] Under SPS Article 5.1, it is allowed to maintain that higher standard only if the higher standard is based on a risk assessment done pursuant to WTO-condoned risk assessment rules.[67] As the Appellate ruling in the Beef Hormone case, explicitly notes, the contradictory mandates in the WTO SPS Agreement operate to make it nearly impossible for a country to maintain a standard that provides more regulatory safeguards than the Codex standard.[68]

While the tone and logic of the Appellate Body ruling sounded more reasonable than the extreme lower tribunal decision, it led to the same bottom line. The EU was ordered to begin imports of U.S. artificial hormone-treated beef by May 13, 1999 or to have conducted a WTO-legal risk assessment to justify not doing so by that time.[69]

The EU began to implement the WTO ruling by initiating a risk assessment analysis that could be used to justify the ban under WTO rules. The U.S. objected to the EU's move to do a risk assessment, arguing that the WTO ruling meant that the EU's beef ban was *prima facie* incompatible with SPS rules because there was no scientific evidence that artificial hormone residues are not fit for human consumption.[70] Regardless of the U.S. contention, in 1998, the EU launched 17 studies into the risk of the hormones in question. The

EU also asked the European Commission's Scientific Committee on Veterinary Measures Relating to Public Health (SCVPH) for an assessment of the risk to human health.

The EU's full risk assessment was not complete by the WTO deadline. Thus, the U.S. argued, the EU was required to lift the import prohibition.[71] When the EU failed to comply with the WTO panel ruling by the May 1999 deadline, the WTO on July 12, 1999, approved a U.S. request to impose retaliatory sanctions, but lowered the amount from the $200 million requested by the U.S. and authorized trade sanctions against $116.8 million worth of European-made products.[72] To avoid the U.S. being free to choose what EU goods would be hit with the sanctions, the EU offered to compensate the U.S. for maintaining the beef hormone ban until the assessment was done and the issue could be judged on the basis of more complete evidence.[73] Then-U.S. Trade Representative Charlene Barshefsky responded that the U.S. would accept a deal only if the EU pledged to open its beef market soon.[74] No deal was struck, and the U.S. levied 100% tariffs totaling $117 million annually on a variety of key EU exports including truffles, mustard, cheeses and foie gras.[75]

Meanwhile, the EU risk assessment established that the artificial hormone 17 beta-oestradiol, one of the six artificial growth hormones at issue in the case, was a 'complete' carcinogen, meaning that it had both tumor initiation and tumor promotion properties.[76] In the cases of the other five hormones, the committee found that, though there was insufficient evidence for a quantifiable risk assessment, there was identifiable risk to the consumer of those products,[77] especially pre-pubescent children.[78] In April 2000, the SCVPH was asked to re-examine its findings in light of additional studies, and found no reason to change its earlier conclusions.[79] The European Scientific Committee (SCVPH) working group on the issue had included four U.S. and five EU scientists. Once the SCVPH report was presented, the European Commission recommended a permanent ban on 17 beta oestradiol and provisional prohibition of the other growth hormones. The European Parliament adopted those proposals on February 1, 2001.[80]

Trade Bureaucrats As Scientists: Many observers thought that the WTO panel had imposed its own assessment of the scientific evidence, ignoring evidence of cancer risk related to the use of the hormone MGA and testimony from experts. Indeed, the WTO seemed uninterested in any science outside of that provided by the Codex Alimentarius. Public Citizen submitted an affidavit to the WTO highlighting the body of research collected by a Northwestern University public health physician, which demonstrated that the use of natural and synthetic anabolics in meat production posed serious carcinogenic and other hazards to consumers.[81] But the affidavit was returned with a terse note explaining that the WTO did not accept submission from the public in its dispute resolution process.

In the face of the new findings, the U.S. refused to address the scientific merits or faults of the risk assessment, sticking to the initial position that the WTO Appellate Panel's ruling found the ban to be indefensible. Indeed, in the 2002 National Trade Estimates Report on Foreign Trade Barriers, the USTR noted the existence of the new studies, but commented that Anone of these studies presented any *new* evidence to support the EU's hormone ban.[82] Thus, the tariff trade sanctions remain in place and the EU ban remains in place. However, this is the only WTO ruling **B** with two wealthy nations each of whom can afford continuing WTO litigation and bear sanctions **B** which has resulted in such an outcome.

Even far less stringent regulatory approaches to food safety than a ban could run afoul of the WTO. A possible alternative to a ban on artificial hormone-treated beef sales in the EU and elsewhere is labeling of meat raised with the artificial hormones. The U.S. argues that this relatively weak strategy may also be WTO-illegal. The Agreement on Technical Barriers to Trade (TBT), which governs all non-food safety,

plant or animal health product standards, requires technical regulations to be based on the performance of a product, rather than its design or descriptive characteristics. This could be interpreted to prevent labeling based on the manner in which cattle are raised, since the presence of hormone residues does not change the end use of the product. In addition, in the beef hormone case, the WTO already has ruled that artificial hormone residues on food have not been shown to pose a danger to human health. Thus, under the TBT Agreement, mandatory labeling of beef hormones could be determined to serve no legitimate WTO human health objective and thus could be ruled to be an unjustifiable discrimination against U.S. beef.

V. The Implications of the Beef Hormone Ruling

The WTO Appellate Body ruling toned down some of the more controversial aspects and anti-regulatory findings of the initial WTO panel ruling. In addition, it cut out an array of findings the lower panel had made on issues not directly raised in the case. However it confirmed the basic findings: 1) that nondiscriminatory domestic regulations must either be based on international standards; 2) or if they depart from international standards, they must be based on an extensive risk assessment. Revealingly, the WTO Beef Hormone Appellate decision confirmed that nondiscriminatory health and environmental measures, those that apply equally to domestic food as well as imports, could still be held WTO-illegal, and that domestic laws must overcome a variety of hurdles to be held consistent with WTO rules even if they are non-discriminatory.

Precautionary Principle Severely Undermined: The WTO Appellate body also clearly subjugated the Precautionary Principal to the WTO's SPS requirements, severely limiting the ability of nations to enact health regulation in advance of scientific certainty.[83] The WTO tribunal did so by dismissing the EU's arguments that it took action on the artificial hormones based on the Precautionary Principle. The Appellate Body ruled that a government's reliance on the Precautionary Principle did not override the obligation of WTO members to base their measures on a risk assessment.[84]

Confirmed Opposition to Zero Tolerance: Even when scientific data is robust, value judgments and social priorities play the central role in policymaking. People make judgments about whether exposure to a risk is avoidable (whether there are acceptable, affordable substitutes) and how much risk is reasonable in exchange for whatever rewards a new product promises. Legislatures may decide to allow zero risk from a particular hazard, rather than establishing an allowable level of risk. The WTO Appellate ruling does not leave space for such policy judgement.

The implications of the interpretation of WTO rules are far reaching. For example, Chile has a zero tolerance level for *salmonella* in poultry, which applies to both foreign and domestic poultry, and which, when implemented, has successfully prevented contamination.[85] The U.S. considers the Chilean policy to be unnecessarily severe and thus enumerated the *salmonella* policy in the USTR's 2002 National Trade Estimate Report on Foreign Trade as a barrier to trade,[86] and has raised it at the WTO.[87] Under the WTO SPS Agreement, the Chilean *salmonella* regulations could be challenged as illegitimate trade restrictions.

Case 2: Australian Salmon – WTO Adds Difficulty, Cost to Animal Health Protections

In addition to creating prohibitive obstacles to the adoption of human health safeguards, rulings on the WTO SPS Agreement also have set strict requirements on when and how countries can create or maintain policies regarding the protection of plant and animal health. In 1998, the WTO Appellate Body ruled that an

Australian quarantine on raw salmon imports, instituted in the 1960s[88] to protect the nation's indigenous fish population, was an illegal barrier to trade.[89] (The rule required Australia's director of quarantine to ban raw salmon imports unless they have been subjected to treatment that would prevent the introduction into Australia of any infectious or contagious diseases affecting persons, animals or plants.)

When Canada and the U.S. requested access to Australia's uncooked salmon market in 1994, Australia conducted a risk assessment as required by the WTO SPS Agreement. In 1996, on the basis of the risk assessment, the Director of Quarantine concluded that Australia should not permit uncooked salmon imports.[90] In response, Canada filed a complaint with the WTO in 1997, arguing that the salmon ban violated the SPS Agreement.[91] The United States reserved its third party rights to participate in Canada's complaint.

Among other findings, the Australian risk assessment revealed that some 20 bacteria not present in Australia were present in Canadian salmon. The Australian government concluded that the introduction of these contaminants to its salmon population could cause disease and found that Canada had not developed a treatment to eliminate the bacteria. Moreover, the Australian risk assessment found that bacteria can remain in animals after they have been killed and that food prepared for human consumption has in a number of cases ended up in the animal food supply, thus creating a risk of exposure to the Australian fish. The risk assessment report thus confirmed that it was possible that Canadian uncooked salmon could infect live Australian salmon.[92] Indeed, Australia noted in its WTO filings that Canada had not disagreed that there was a risk of disease spread through uncooked salmon[93] and further that Canada had refused to produce relevant scientific data pertaining to the diseases particular to Canadian salmon.[94]

Despite these findings, in June 1998, a WTO panel ruled that the Australian ban violated WTO requirements because it was not based on sound science, exceeded international standards and therefore was arbitrarily and unjustifiably discriminatory.[95] Australia appealed, arguing that its risk assessment, which was conducted as required by the SPS Agreement and which established that there was a risk of disease from uncooked salmon, allowed it to determine for itself the *level* of risk to which it would expose its fish stocks[96] in accordance with the SPS. In its November 1998 ruling on Australia's appeal, the WTO Appellate Body concluded that Australia's risk assessment was unsatisfactory because it failed to calculate the *likelihood* of salmon disease entry and transmission.[97] "It is not sufficient that a risk assessment conclude there is a possibility of entry, establishment or spread ... A proper risk assessment ... must evaluate the likelihood, i.e. the probability, of entry, establishment and spread."[98] Thus, the Appellate decision expanded the WTO requirements by demanding that a risk be quantifiable and found significant, rather than 'merely' present. The Appellate Body's ruled that a country must show not just a risk, but a serious risk. This ruling replaced a democratically elected government's policy judgment with the WTO's definition of what constitutes serious risk.

In this case, the WTO established strict guidelines for conducting risk assessments relating to non-human disease. It ruled that a risk assessment must be conducted *prior* to a WTO Member's introduction or enforcement of a regulation relating to plant and animal pests and diseases.[99] This interpretation of the WTO rules imposes a significant financial burden on countries wishing to put into place such regulations and thus discourages countries from doing so. Under WTO rules, a country cannot quickly act to avert an outbreak, but rather must decide if it has the resources and/or expertise to perform a WTO-compliant risk assessment and then do so. According to an Australian government official, AThere are not a lot of

scientists around who are able to do these (types of risk assessments). A thorough assessment requires a lot of time and resources.[100]

In light of the WTO's Appellate ruling, in May of 1999 the U.S. exercised its third party rights, and requested a panel to rule on Australia's quarantine. Australia was given a deadline of July 1999 to lift the ban. In July 1999, the Australian Quarantine and Inspection Service (AQIS) issued a decision that lifted the import ban but increased the quarantine requirements for several species of fish, in line with risk assessments undertaken.[101] Australia contended that these changes met the requirements of the Appellate Body.

In late July 1999 Canada asked the WTO to authorize sanctions on the basis that the new quarantine measures were not compliant with the WTO panel ruling.[102] It requested that the original panel rule on this question of whether Australia's new measures were WTO-consistent. Australia made a counter-request that the WTO panel determine how much Canada was actually harmed by the Australian quarantine.[103] A Recourse Panel, which would determine whether the measures taken by Australia had brought them into compliance with the previous WTO rulings,[104] was established in June 1999.[105]

In February 2000, the Recourse Panel ruled on the Canadian challenge that, although Australia had performed a WTO-compliant Import Risk Assessment (IRA),[106] the quarantine measures were nonetheless in violation of WTO SPS requirements because it was not the least trade restrictive way to achieve the goal of the risk assessment.[107] The Recourse Panel put the burden on Australia to prove that there was no other means than the one used, that had a lesser trade impact. In other words, the WTO Recourse Panel demanded not just that Australia show that its concerns were based on a real risk, and that the proposed rules would meet those concerns, but also that Australia prove a negative or accept the judgement of a WTO tribunal of trade experts about the proper way to meet safety thresholds for the judgement of the Australian government and scientists.

In light of the ruling by the Recourse Panel, Australia negotiated a settlement with Canada on May 17, 2000 and extended it to the U.S. on October 27, 2000. The settlement removed the provision that only consumer-ready salmon, as previously defined by Australia, could be imported.[108] Thus, Australia was forced to choose between changing its quarantine law and facing potential sanctions.

The WTO Appellate Body ruling made clear that countries are strictly constrained in their policy options to protect against pests and animal disease and certainly have no latitude to err on the side of caution. The Appellate Body's ruling against the original guidelines, in concert with the Recourse Panel's ruling against the updated guidelines, set four precedents. The first requires WTO Members to adopt SPS standards relating to plant and animal health only when precise risk to animals or plants can be quantified. Additionally, the likelihood of infection or infestation must be able to be established with scientific certainty. Third, the risk must be judged serious by the WTO panel. Finally, the means used to deal with the risk must be the least trade restrictive. Together, these requirements place countries in a straitjacket, with their wild flora and fauna and domesticated plants and animals at risk.

In its ruling against Australia's salmon measure, as in the beef hormone case, the WTO panel shifted the entire burden **B** financial and scientific **B** to the country whose law was being challenged, requiring it to show that prohibited products were unsafe. Exporting countries - or companies located therein - on the other

hand, cannot under WTO rules be asked by importing countries to demonstrate that their products are disease-free before they are allowed into the country.

Canada and the U.S., on the other hand, are not required to do anything to ensure that their salmon exports are free of bacteria that are known to afflict North American salmon. Only after Australia conducts research on aquatic disease spread and conduct tests on Canadian and U.S. salmon and calculates a precise probability of spread to live Australian salmon and releases an authoritative assessment that successfully quantifies a risk of disease transmission to its salmon stocks can it impose any requirements on Canada and the U.S. under WTO rules.

Case 3: A Blight on Japan's Diet: U.S. Moves to Limit Japan's Efforts to Protect its Agriculture from Fire Blight

Japan has long sought to protect its farmland from new and dangerous pests. Japan's geographic isolation has provided a natural barrier to invasive species and agricultural diseases which cause considerable damage to crops in other parts of the world. In the U.S., for example, efforts to control invasive species and losses in the agriculture and timber industries cost $137 billion annually. More than half of these costs are associated with plants, animals and diseases that are subject to phytosanitary regulations.[109]

Japan's agricultural quarantine rules successfully have prevented the introduction of many hazards and pests which are not indigenous to Japan, including diseases such as rabies and pests such as codling moths and Mediterranean Fruit Flies. Japan imports 20,000 times more agricultural products from the U.S. than it exports to the U.S., making it susceptible to invasive species introduction.[110] Typically, biological invasions are irreversible and given the tremendous cost of combating invasions, it is easier, cheaper and more effective to focus on preventing the introduction of invasive species.[111] In its annual report on agricultural trade in 2002, Japan noted its exposure to invasive pests was increasing every year as a result of the increases in and diversification of its agricultural imports.[112]

Japan's efforts to combat introduction of Fire Blight on apples and pears and other invasive species also go back more than 50 years to the enactment of Japan's Plant Protection Law in 1950.[113] Japan imposed the Fire Blight quarantine rules in 1994, after it first opened its markets to apples.[114] The U.S. has been trying to fight them ever since.[115]

Fire Blight, caused by the bacterium *Erwinia amylovora*, can be spread by wind, rain and insects to fruit blossoms.[116] It damages and kills trees in nurseries and young trees in the orchard, can delay fruit-bearing in young trees and can kill older trees through girdling blight cankers.[117]

Fire Blight is one of the class of diseases caused by bacteria called prokaryotes which have rapidly reproducing outbreaks, are likely to occur during wet weather when orchards are less likely or able to be tended and are too far below the bark to be easily treated chemically. Because diseases like Fire Blight are so difficult to treat, the best approach is prophylactic management to ensure the infestation never occurs.

To date, Japan has not had a sustainable fire blight outbreak.[118] Even if it had, weakening the quarantine against Fire Blight would still create additional risks, such as introducing the disease to new areas or presenting new genetic varieties which could be harder to control.[119]

Japan's quarantine requirements for Fire Blight have been targeted by the U.S. for removal. In its 2001 and 2002 lists of trade barriers, USTR has catalogued Japan's program to prevent Fire Blight infestation as being overly burdensome because the quarantine rules "raise costs and reduce competitiveness of U.S. apples."[120]

On March 1, 2002, USTR requested WTO consultations with Japan regarding Japan's import restrictions on U.S. apples to prevent the introduction of Fire Blight.[121] The U.S. was unhappy with Japan's quarantine rules, which among other things prohibit importing apples from orchards where any Fire Blight is detected, require three annual inspections of orchards seeking to export to Japan for the presence of Fire Blight, the disqualification of orchards within 500 meters of Fire Blight infestation, and require post-harvest treatment of apples with chlorine, which the U.S. contended is not supported by scientific evidence.[122]

Japan insisted that its quarantine rules are necessary to prevent a dangerous pest from being introduced to its domestic farm sector. Japan maintained that its restrictions on Fire Blight are based on scientific evidence and that these restrictions have succeeded in keeping Japan free of Fire Blight.[123] On May 7, 2002, the U.S. formally requested that a WTO dispute panel be convened to consider Japan's import restrictions on U.S. apples.

In May 2002, Japan used the one-time stalling maneuver allowed in WTO dispute resolution rules to block the U.S. request to convene a dispute panel over Japan's Fire Blight quarantine measures. In doing so, Japan argued that the U.S. WTO complaint lacked necessary scientific basis and that Japan's quarantine measures are consistent with its SPS obligations.[124] In July 2002, the WTO convened a dispute panel to rule on Japan's quarantine measures, and Australia (which also has a Fire Blight quarantine measure), Brazil, Chinese Taipei, the EC and New Zealand (who all oppose the quarantine) reserved their right to participate as third parties.[125]

The USTR submissions to the WTO in the dispute made one basic argument: that there is no evidence that Fire Blight can be transmitted on mature, symptomless apples. USTR noted that billions of apples have been exported worldwide without a single documented case of Fire Blight transmission; USTR stated that Fire Blight bacteria are Ararely@ found on mature, symptomless apples; claiming that cold storage, handling and transport would make the bacteria's survival unlikely and that there is no mechanism for the bacteria (should it exist and survive export) to be transmitted to orchards.[126] Moreover, the U.S. argued that Japan has failed to present a risk assessment that meets the tests from the Australia salmon case: identify the risks, evaluate the likelihood of entry, and demonstrate that Japan's Fire Blight measures are the least trade restrictive alternatives.[127] Japan's risk assessment focuses on the possibility of entry, but not the probability, according to USTR.[128]

Although opponents of Fire Blight quarantine barriers contend Fire Blight transmission cannot occur from healthy fruit, there is no proof of this contention. USTR itself admits that some studies have found Fire Blight bacteria on mature fruit at harvest.[129] Researchers from the Horticultural and Food Research Institute of New Zealand (which favors eroding Japan's Fire Blight quarantine) could only show that it is *difficult*, though possible, to infect healthy apples with Fire Blight and that healthy apples are *unlikely* to transmit Fire Blight across national borders through trade.[130] The difference highlights a significant problem with the WTO's risk analysis rules: a country is not permitted to maintain a policy that makes the introduction of invasive pests impossible, only one which makes an infestation unlikely. The U.S. does not dispute that the Japanese Fire Blight regime will prevent the introduction of Fire Blight. Instead it contends that under

WTO rules, Japan cannot maintain a policy that ensures that there will not be a Fire Blight introduction, but that Japan can only have a WTO consistent policy that keeps the probability of an introduction low.[131]

The U.S. wants Japan to significantly ease its requirement that imported apples come from orchards more than 500 meters from trees infected with Fire Blight. In its annual report on trade barriers in 2001, USTR proposed that a Fire Blight buffer zone over 10 meters **B** one-fiftieth the distance Japan considers safe **B** constituted a trade barrier.[132]

However, the 10-meter limit may be insufficient to ensure that fruit will be uncontaminated by Fire Blight bacteria. The Australian government's interim risk assessment for its Fire Blight quarantine recommended a buffer between 50 and 500 meters from Fire Blight outbreaks to ensure a low risk of introduction.[133] Indeed, one of the ways that Fire Blight can be transmitted is through the wind, and 10 meters might not be sufficient to prevent wind transmission.[134]

If the WTO rules in favor of the U.S. it will have significant effects on the global capacity to prevent the spread of invasive plant, animal and disease species. To date, the WTO has ruled against every effort to prevent the entry of agricultural pests and invasive species. In each ruling, the WTO has progressively raised the bar for what policies are WTO-legal, making future efforts to keep out these agricultural pests, diseases and invasive species increasingly difficult. For instance, other countries, including Australia and South Africa, who have successfully used quarantines to remain free of the Fire Blight bacteria might have to lower their safeguards and increase their risk of exposing their crops to Fire Blight.

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[79] EU, Review Of Specific Documents Relating To The SCVPH Opinion Of 30 April 99 On The Potential Risks To Human Health From Hormone Residues In Bovine Meat And Meat Products, May 3, 2000, at 1-3.
[80] Official Journal of the European Communities, "Substances having a hormonal or thyrostatic action and beta-agonists," February 1, 2001, at C267/53-C267/56.
[81] Affidavit of Professor, Samuel S. Epstein MD, University of Illinois Medical Center, Sep. 27 1996.
[82] USTR, 2002 National Trade Estimate Report on Foreign Trade, at 113
[83] WTO, European Communities - Measures Affecting Meat and Meat Products (Hormones) (WT/DS26/AB), Report of the Appellate Body, Apr. 16, 1998, at paragraph 253(c).
[84] WTO, European Communities - Measures Affecting Meat and Meat Products (Hormones) (WT/DS26/AB), Report of the Appellate Body, Apr. 16, 1998, at paragraph 253(c).
[85] WTO, International Trade of Chile in Poultry Products, G/SPS/GN/3, at 1.
[86] USTR, 2002 National Trade Estimate Report on Foreign Trade, at 38.
[87] WTO, Committee on Sanitary and Phytosanitary Measures - Specific Trade Concerns - Submission by the United States Regarding G/SPS/GEN/204/Rev.1, G/SPS/GEN/265, October 7, 2001, at 2.
[88]. WTO, Australia - Measures Affecting Importation of Salmon (WT/DS18/R), Report of the Panel, Jun. 12, 1998 at Paras. 8.10-8.19.
[89] See, WTO, Australia - Measures Affecting Importation of Salmon (WT/DS18/AB/R), Report of the Appellate Body, Oct. 20, 1998
[90] Id.
[91] Id. at Para. 4.52.
[92] The Australian Final Report had concluded that there were extensive gaps in data relating to disease spread in fish. The Final Report therefore extrapolated data from studies demonstrating that other products for human consumption, such as meat and poultry, have been known to have spread diseases to live animals. Australia thus

concluded that given both the difficulty of proving the spread of aquatic animal diseases through salmon meat and the very short history of aquatic animal medicine, it would be prudent to presume that it was only a matter of time and attention until there was definitive proof of the spread of aquatic animal disease via product for human consumption, rather than assume it was unlikely. WTO, Australia - Measures Affecting Importation of Salmon (WT/DS18/R), Report of the Panel, Jun. 12, 1998, at Paras. 2.27-2.30.

[93]Id. at Para. 4.42.

[94] Id. at Para. 4.43.

[95] Id. at Para 9.1.

[96] WTO, Australia - Measures Affecting Importation of Salmon (WT/DS18/AB/R), Report of the Appellate Body, Oct. 20, 1998, at Para. 13.

[97] Id. at Para. 137.

[98] Id. at Para. 129

[99] Id. at Para. 127. According to a Geneva-based trade official, the Appellate Body move suggests that WTO Members must have conduct a risk assessment before adopting trade-restrictive measures. See, "WTO Salmon Ruling Clarifies Conditions For Banning Food Imports, Experts Say," BNA Daily Report for Executives, Oct. 28, 1998.

[100] AWTO Salmon Ruling Clarifies Conditions For Banning Food Imports, Experts Say,@ BNA Daily Report for Executives, Oct. 28, 1998.

[101] Department of Agriculture, Fisheries & Forestry - Australia, AQPM 1999/69, Importation Uncooked Salmonid Product, October 20, 1999.

[102] WTO, "Australia B Measures Affecting Importation Of Salmon - Recourse To Article 21.5 By Canada -Report Of The Panel," WT/DS18/RW, February 18, 2000.

[103] See WTO, "State of Play of WTO Disputes," at www.wto.org; on file with Public Citizen

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[105] WTO, Australia B Measures Affecting Importation Of Salmon - Recourse To Article 21.5 By Canada B (WT/DS18/RW), Report Of The Panel, February 18, 2000.

[106] WTO, Australia B Measures Affecting Importation Of Salmon - Recourse To Article 21.5 By Canada B (WT/DS18/RW), Report Of The Panel, February 18, 2000, at paragraphs 7.42, 7.58, 7.71. The panel established a three-pronged test for a risk assessment and found that Australia's 1999 risk assessment met each part.

[107] WTO, Australia B Measures Affecting Importation Of Salmon - Recourse To Article 21.5 By Canada B (WT/DS18/RW), Report Of The Panel, February 18, 2000, at paragraphs 7.145

[108] Australia Department of Foreign Affairs and Trade, Text of Bilateral Settlement Between Australia and Canada, on file with *Public Citizen*.

[109] Faith Thompson Campbbell, "The Science of Risk Assessment for Phytosanitary Regulation and the Impact of Changing Trade Regulations," *BioScience*, Vol. 51, Iss. 2, Feb. 1, 2001.

[110] Keizi Kiritani, "Invasive Pests and Plant Quarantine in Japan," National Institute of Agro-Environmental Sciences, 1999 at 7.

[111] Faith Thompson Campbbell, "The Science of Risk Assessment for Phytosanitary Regulation and the Impact of Changing Trade Regulations," *BioScience*, Vol. 51, Iss. 2, Feb. 1, 2001.
[112] Japan's Ministry of Agriculture, Forestry and Fisheries, "Report on Agricultural, Forestry and Fisheries Trades in 2002," March 2002, at 20.
[113] World Trade Organization, Request for the Establishment of a Panel by the United States, May 8, 2002, WT/DS245/2.
[114] World Trade Organization, Request for Consultations by the United States, Mar. 6, 2002, WT/DS245/1.
[115] USDA, "World Trade Situation and Policy Updates," *World Horticultural Trade & U.S. Export Opportunities*, Jun. 2002, at 19.
[116] U.S. Department of Agriculture, "Fire Blight Control, Nature's Way," *Agricultural Research*, Jan. 1998, at 14.
[117] Michael Ellis, Ohio State University Extension, "Fire Blight of Apples, Crabapples and Pears," Extension *Factsheet*, HYG-3002-94. **DATE???**
[116] According to the Department of Agriculture, The favored anti-biotic treatment streptomycin to fight flaring Fire Blight introduced in the 1950s became significantly less reliable by the 1990s.
[118] Daniel Pruzin, "U.S. Initiates WTO Case Against Japan Over Fire Blight Import Curbs on Apples," *BNA International Trade Reporter*, Vol. 19, No. 10, Mar. 7, 2002; there is some evidence that Japan may have had outbreaks of Fire Blight in the past, but no definitive evidence that there is a sustained Fire Blight presence in Japan.
[119] Faith Thompson Campbbell, "The Science of Risk Assessment for Phytosanitary Regulation and the Impact of Changing Trade Regulations," *BioScience*, Vol. 51, Iss. 2, Feb. 1, 2001.
[120] Office of U.S. Trade Representative, *2001 National Trade Estimate Report on Foreign Trade Barriers*, Mar 30, 2001, at 253; *20021 National Trade Estimate Report on Foreign Trade Barriers*, DATE FR INTRO, at 224.
[121] Office of the U..S. Trade Representative, "WTO Consultations Regarding Japanese Measures Affecting the importation of Apples," Fed. Reg. Vol. 67, No. 62, Apr. 1, 2002.
[122] Office of the U..S. Trade Representative, "WTO Consultations Regarding Japanese Measures Affecting the importation of Apples," Fed. Reg. Vol. 67, No. 62, Apr. 1, 2002.
[123] Inter-American Institute for Cooperation on Agriculture, "XXIV Meeting of the WTO Committee on Sanitary and Phytosanitary Measures," *Access IICA-SPS News Report*, Bulletin No. 9, Jul. 2002, at 3.
[124] Japan Fair Trade Center, U.S. law firm of Willkie Farr & Gallagher, "Japan Blocks U.S. Request for WTO Panel Regarding Japan's Importation of Apples," *Washington Monitor: A Weekly Review of U.S. Trade Policy Developments Affecting Japan*, vol.6 iss. 21, May 24, 2002 at 6.
[125] World Trade Organization, Constitution of the Panel Established at the Request of the United States, "Japan – Measures Affecting the Importation of Apples," Jul. 17, 2002, WT/DS245/3.
[126] WTO, Japan – Measures Affecting the Importation of Apples, (WT/DS245), "Executive Summary of the First Written Submission of the United States of America," Sep. 11, 2002, at Para. 12.

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[128] WTO, Japan – Measures Affecting the Importation of Apples, (WT/DS245), "Executive Summary of the First Written Submission of the United States of America," Sep. 11, 2002, at Paras. 16-28.
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[132] Office of U.S. Trade Representative, *2001 National Trade Estimate Report on Foreign Trade Barriers*, Mar 30, 2001, at 253.
[133] Natural Resources Management, Victoria, Submission to Biosecurity Australia for the Draft Import Risk Analysis on the Importation of Apples (*Malus X Domestica* Borkh.) from New Zealand, Dec. 2000, at 3.
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