Food Principles:
Regulating Genetically Modified Crops after the 2006 WTO Ruling

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In 2006, the World Trade Organization (WTO) ruled on a complaint by the United States concerning the European Union's regulation of genetically modified (GM) crops.[1] It ruled that the EU failed its WTO obligations by not lifting its moratorium on the approval of GM crops and delaying the approval of new crops. In addition, the WTO ruled against the marketing and import bans put in place by six EU member states.[2] Captured in the background to this ruling is the nature and breadth of the public debate about GM crops and biotechnology that has been raging since the late 1990s. Therefore, understanding this dispute and its impact on future GM crop regulation requires understanding the context of both the antecedents to the U.S.–EU dispute over trade in GM crops as well as the different approaches the United States and European Union have adopted in regulating genetically modified organisms (GMOs). Consequently, this paper begins with a discussion as to why the products of biotechnology have proven so controversial, followed by an outline of the U.S. and EU approaches to regulating such products. These regulations are then set in the broad context of WTO rules, which leads into a discussion and evaluation of the U.S.–EU dispute and the findings of the WTO.[3]

Background to the U.S.–EU Dispute over Trade in GM Crops

Since the mid-1990s, there has been rapid adoption of GM crops, where genetic modification refers to the technology of developing plants through the use of recombinant DNA techniques.[4] The key commercially available GM crops (corn, soybeans, canola,

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and cotton) are grown in a concentrated group of agricultural-exporting countries, including the United States, Argentina, and Brazil. In 2006, of the 246 million acres of GM crops planted worldwide, 83 percent was planted in these three countries, the most being planted in the United States at 54 percent of the total. Argentina and Brazil accounted for 18 percent and 11 percent, respectively.[5]

Even though there is as yet no reputable scientific evidence that existing, approved GM crops are unsafe for human consumption, the political and regulatory environment of many importing countries gives little confidence that trade in GM crops will simply be accepted as a fait accompli.[6] During the past decade, there has been widespread public discussion of GMOs—the debate having been most intense and most publicized in the European Union, where consumer surveys have consistently shown that the public typically has a very negative attitude toward GM foods. For example, a poll published by the European Commission in 2006 found that only 27 percent of EU citizens surveyed believe that the technology behind GMOs should be encouraged, the remainder finding it hard to see any clear benefits.[7] The overriding feeling of EU consumers is that they will see little benefit from GM foods but will bear great risks.

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The production and marketing of GM foods has raised issues about the ethics of biotechnology, food safety, and the environment. In the case of ethics, many observers do not accept the proposition that genetic engineering of crops is just a logical extension of traditional plant breeding, and therefore question the moral basis of interfering with the genetic structure of species through the introduction of genes from unrelated species.[8] Tied in with these ethical concerns is the argument by consumer advocates and NGOs that consumers have a "right to know" whether the foods they are purchasing and consuming are either genetically modified or contain genetically modified ingredients.[9]

From the standpoint of food safety, various regulatory efforts have not calmed concerns that the transfer of genes will also transfer allergenic risks to foods that never previously had that potential.[10] This issue received much media coverage in 2000 and 2001 following an announcement that taco shells marketed by Kraft Foods in the United States under the Taco Bell brand name were found to contain a variety of GM corn, StarLink, not yet approved for human consumption by the U.S. Environmental Protection Agency due to concerns over potential allergic reactions.[11] As well as allergenicity, there are also concerns that human pathogens will become resistant to antibiotics. In the process of transferring specific genes, genetic markers have often been used to show the successful uptake of the novel genetic material, but these markers may inadvertently

deactivate antibiotics intended for therapeutic use.[12]

Finally, there is an expectation that GM crops might be harmful to the environment. Three environmental impacts of GM crops have received widespread coverage: non-target species could be harmed by crops modified to produce their own pesticide; pollen drift from GM crops may contaminate non-GM versions of those crops; and crops that are modified to be resistant to certain herbicides may confer the same resistance on weedy relatives.[13]

Widespread unease among EU consumers about GMOs formed an essential background to the European Union placing a moratorium on GMO approvals in 1999. The roots of the moratorium lie in the Novartis Bt-176 corn case, which despite initial French approval in 1996, was rejected by Austria, Denmark, Sweden, the United Kingdom, and others, who argued that the marker gene contained in the corn could be harmful to human health.[14] Subsequently, Austria and Luxembourg lobbied for a temporary ban on the marketing approval on the grounds that there was new evidence antibiotic resistance could occur due to the marker gene contained in Bt-176 corn, and that one-fifth of the Austrian population had signed a petition against approval. Then in 1999, Denmark, France, Greece, Italy, and Luxembourg declared they would block future GM crop approvals, which by EU voting rules amounted to a moratorium.

The European Union's regulations have been described by some observers as protectionist. For example, trade lawyer Lawrence Kogan wrote in the *International Herald Tribune* in November 2004 that such policies are "arguably illegal from the perspective of international trade laws enforced by the World Trade Organization."[15] Whether these actions really violate WTO rules will be discussed later.

Regulation of GMOs in the United States and the European Union

The differences between U.S. and EU approaches to regulating GMOs are where conflict arises. On the one hand, the U.S. approach is based on a scientific, risk-based assessment that considers GM food "substantially equivalent" to regular foods, resting on the notion that zero risk in food safety regulation is not practical, given that conventional foods are already presumed to be safe. On the other hand, the EU approach to regulation of GMOs draws on the precautionary principle, resulting in both import bans and strict labeling requirements.[16]

U.S. Regulation

In the United States, the Food and Drug Administration (FDA) has taken the position under the Federal Food, Drug, and Cosmetic Act that recombinant DNA methods of plant development are not "material" information, which essentially means that existing GM foods do not differ in any substantial way from those developed through

traditional plant breeding methods—genetic modification simply extends traditional methods to the molecular level.[17] This principle of substantial equivalence establishes that the FDA would only require labeling of a GM food product if the GM version is substantially different from an existing product, has very different nutritional properties, or contains an allergen that would not normally be present. Aside from these, there is no explicit right-to-know labeling requirement.

The key to the U.S. approach to regulation of GMOs is the principle of minimal oversight of food products that are generally regarded as safe (GRAS). Conventional food products are considered GRAS, and this is the standard by which GM foods are being judged in the United States. The approach recognizes that zero tolerance for potentially hazardous ingredients in food would result in few foods ever being marketed. In addition, there are practical difficulties in conducting toxicological tests on whole foods as compared to pesticides and food additives. As a result, the concept of substantial equivalence has been developed as part of the process of evaluating the safety of GM foods. The objective of such an approach is not to establish absolute safety, but to consider whether a GM food is as safe as its conventional counterpart by finding differences between the types of food.[18]

EU Regulation

Between 1992 and 1998, the EU approved 18 GM plants and crops for commercial marketing, including four varieties of GM corn, four varieties of canola, one variety of soybeans, and one variety of tobacco. However, in 1999 the European Council formalized a moratorium on GMOs,[19] the provisions of which were for the EU to apply the precautionary principle to future approval of GMOs: that GMOs should not be placed on the market until it could be demonstrated that there is no adverse impact on human health and the environment, and that principles regarding traceability and labeling be applied.[20] This approach to regulating GMOs was subsequently approved by the European Parliament and European Council in 2003 under Directive 2001/18/EC.

This new regulatory system has major implications for the future approval of GMOs in the European Union. After a GMO undergoes a risk assessment by the European Food Safety Authority (EFSA), it must be approved by the European Commission and a qualified majority of EU member states. Once authorized, products are entered into a public register and subject to a post-market monitoring plan. The new authorization procedure abandons the concept of substantial equivalence by which GM foods have previously been placed on the market.

The rules for labeling GM foods in the European Union have been expanded significantly in the new legislation. Almost all foods that contain ingredients that have been derived from GM crops have to be labeled, irrespective of whether the relevant

recombinant DNA or proteins are still detectable. Importantly, while the new labeling rules apply to animal feed, they do not apply to meat, milk, and eggs from animals fed with GM feed. In addition, cheese and beer produced with GM-based enzymes are also exempt from labeling.

The Precautionary Principle

Importantly, the European Union's adoption of the precautionary principle in its GMO regulations has triggered a good deal of debate in the popular media.[21] Some critics of the principle have argued that it has become less of an approach for risk management and more of a tool for NGOs and other lobby groups to influence the regulatory process, undermining the role of science.[22] Others argue that it has the potential to stymie the regulatory process in the sense that any attempt to be "universally precautionary will be paralyzing, forbidding every imaginable step, including no step at all."[23]

Economists, including this author, view the precautionary principle as potentially providing guidance about how risk should be managed.[24] In the jargon of decision theory, society has to decide how to trade off the costs and benefits of a new technology across possible future states of the world, which requires knowing the size of the benefits and costs, the probabilities of occurrence, and the risks society will tolerate in each possible future state. If there is scientific uncertainty about a new technology that can only be resolved over time through learning, then the precautionary principle can be viewed in three ways. First, if preventive measures are not taken today, vulnerability to harm from a new technology may be increased so that there is a precautionary motive for risk-prevention. Second, if introduction of a new technology is an irreversible decision, any decision to adopt now reduces flexibility in the future. Third, due to a process of learning by doing, knowledge may improve through early observance of risk. The impact of great harm today from a new technology makes the prospect of greater harm in the future much worse, which would lead to an increase in preventative efforts today.[25]

Photo courtesy of Matt Reichel

Genetical modification of corn can potentially transfer allergenic risks.

Irrespective of the economic rigor of this analysis, a strong word of caution is necessary. For example, in 2002 some southern African countries threatened by famine rejected food aid from the United States due to health and environmental concerns about

GM crops. These countries chose to avoid undefined future risks about GM crops and instead accepted the certainty of widespread famine, starvation and death, leading some economists to comment, "It is unlikely that architects of the precautionary principle had this interpretation in mind."[26] Therefore, unless policy makers undertake in-depth cost-benefit analyses of any regulatory choice, blanket application of the precautionary principle may "sometimes provide us with dangerously misleading advice."[27]

The Position of GMO Regulations in the WTO

In order to understand the specifics of the recent WTO ruling, it is important to show broadly how WTO rules could affect the application of GMO regulations. Since GMO regulation has no direct trade component, the WTO would not get involved in regulations for testing and adoption of GMOs in specific countries. The WTO, and the General Agreement on Tariffs and Trade (GATT) before it, explicitly recognizes the right of countries to develop policies that protect human, plant, and animal health.[28] The WTO would, however, be involved in any potential conflict over GMO regulation insofar as there are rules over import restrictions contained in the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements of the WTO. [29]

The two main principles of the WTO that could impinge on the regulation of GMOs in world trade are non-discrimination (GATT Article I) and national treatment (GATT Article III). In other words, it would be WTO inconsistent to either ban imports of GM products from one WTO member and allow them from another or to impose additional restrictions on GM products once the product had been imported if such restrictions were not imposed on domestic producers of the GM product. It is unlikely that the European Union would either explicitly discriminate against U.S. exports of GM products or allow domestic production of a GM product without regulation, but it could impose regulations on the imported product. However, there might well be a claim of discrimination if the European Union, as a deliberate act of trade policy, were to ban imports of a GM product but allow imports of the conventional product. GATT Article III states that countries cannot discriminate between like goods on the basis of country of origin.[30] The key issue in any GMO dispute could be the definition of *like goods*; the question then is whether genetic modification or presence of GM ingredients constitutes sufficient grounds for differentiation from conventional products. Likeness of products has so far been judged on a case-by-case basis in the GATT/WTO, but this dispute clearly demonstrates the potential for conflict between the U.S. and EU approaches to regulating GM foods: by the argument of substantial equivalence the United States would consider import rules on GMOs that have been subject to rigorous pre-market approval to be discriminatory, whereas the European Union would not consider GMOs and their conventional counterparts to be like goods.

The key is how these approaches could be evaluated in terms of the SPS and TBT agreements. The standard interpretation of the SPS Agreement is that an import ban on a GM product would have to meet the risk assessment criteria of the agreement, and scientific justification would have to be made if the risk exceeded international standards. The point of conflict might be where, for instance, the United States has approved a GM product under its regulatory system, whereas the European Union determines there is still a scientific reason not to approve that product for import. The 1997 WTO panel ruling on the European Union's prohibition on imports of hormone-treated beef offers some guidance as to how a ruling might be made under the SPS Agreement. The key rulings of the panel, subsequently upheld by the WTO's Appellate Body, were that the ban was not based on a risk assessment, violating Article 5.1 of the SPS Agreement, and that the EU had not provided scientific justification for a standard set above internationally recognized standards, which violated Article 3.3 of the SPS Agreement.[31]

Importantly, Article 5.7 of the SPS Agreement does allow WTO member states to take precautionary measures if scientific information is unavailable, but at the same time members have to seek additional information. The term *precautionary principle* is not used explicitly in the SPS Agreement, but the language in Article 5.7 clearly implies use of a "limited, provisional and facts-oriented precautionary approach."[32] In the hormone-treated beef case, the European Union argued that the broader precautionary principle had reached a level of international acceptance that it should be used in interpretation of the SPS Agreement. The Appellate Body subsequently ruled though that the precautionary principle could not override Articles 5.1 and 5.2 of the SPS Agreement.[33]

Finally, the European Union's use of mandatory labeling could be challenged under both the SPS and TBT Agreements. Although application of the TBT Agreement to food products has so far been very limited, it is likely that a case involving labeling of GMOs will provide a test of whether it is legitimate to label a product based on the process by which it was produced. Some observers argue that if GM labeling is designed to cover a range of issues not explicitly related to health concerns, then it could fall under the legal purview of the TBT Agreement and not the SPS Agreement.[34] Consequently, labeling of GM foods could be justified in terms of a consumer's right to know, so that a case brought under the TBT Agreement would revolve around the question of which label is the least trade-distorting form of labeling.

The WTO Ruling and the Regulatory Environment

In light of the preceding discussion, the WTO's Dispute Panel ruled on three aspects of the European Union's regulation of GM crops. First, the European Union had acted

inconsistently with its obligations under the SPS Agreement by applying a de facto moratorium on approvals on new GM crops between June 1999 and August 2003. Second, in the case of specific measures delaying the approval of 24 new GM crops, the European Union had breached its obligations under the SPS Agreement. Third, safeguard measures implemented by six EU member states against the import or marketing of specific GM crops were not based on any risk assessment as required by the SPS Agreement, and hence the European Union had acted inconsistently with its obligations under that Agreement. The latter ruling covering a total of nine GM crops is particularly important. In each case, the panel found that the safeguard measure was neither based on a risk assessment as required under Article 5.1 of the SPS Agreement, nor was it consistent with the requirements of Article 5.7 of the SPS Agreement for applying a precautionary approach.[35]

The panel recommended that the Dispute Settlement Body of the WTO request the European Union to bring the moratorium, the product-specific measures, and the safeguard measures into conformity with its obligations under the SPS Agreement.[36] It should also be noted that the WTO was extremely clear about what issues it did not examine: the safety of GM foods; the similarity of GM and conventional foods; and whether the EU's GMO approval process is consistent with its obligations under the WTO.

It would appear that the very specific focus of the complaint by the United States resulted in a somewhat narrow legal ruling by the WTO. In fact, when the complaint was originally filed, several observers argued that it might even be redundant, given the European Union's own actions at the time to implement its GMO approval process.[37] For example, in 2003, the European Commission announced that member states would vote on approval of Syngeta's Bt-11 sweet corn as a test case for lifting the moratorium. It also referred Austria, Belgium, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, and Spain to the European Court of Justice for failing to adopt and notify national legislation implementing Directive 2001/18/EC. Not surprisingly, part of the case the European Union presented focused on whether the panel could actually make a ruling on measures that no longer existed.[38]

Despite the narrow context of its ruling, the panel's report, which runs to over 1,000 pages, does contain interesting implications for the debate over GMOs, and offers some insight into what might happen in any future complaint about the European Union's regulatory regime. In the context of safety, both the United States and the European Union clearly reflected their quite different views of biotechnology in their initial submissions to the WTO. On the one hand, the United States argued that there are several benefits to be derived from the products of biotechnology, including higher agricultural output; more nutritional food products; and less use of agricultural

chemicals, fertilizers, and water in the commercial agricultural sector. In addition, the United States stated that the safety of biotech products has been well-established by international institutions such as the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO), as well as independent scientists in the United States and Europe.[39] In contrast, the European Union noted that research has identified a number of potentially harmful human and environmental effects from both GM products and the process of genetic modification, including allergenicity, antibiotic resistance, and irreversible environmental effects.[40]

Importantly, even though the panel concluded that some concerns about the safety of GMOs were likely unwarranted, they were very clear that the EU has the right to consider the possibility of such risks prior to giving approval to new GM crops, also noting that this right was not being questioned by any of the complaining parties.[41] In addition, in a statement much trumpeted by the NGO Friends of the Earth, the panel noted that while the European Union had subjected GMO approvals to undue delay, this did not mean there would never be circumstances when such delay would be justifiable.[42] The panel concluded that "if new scientific evidence comes to light which conflicts with available scientific evidence . . . it might, depending on the circumstances, be justified to suspend all approvals pending an appropriate assessment of the new evidence."[43] This statement clearly indicates that it would not be WTO-illegal for a country to suspend its GMO approval process in the face of new scientific evidence as regards safety; however, it is also clear from the Panel Report that this does not constitute recognition by the WTO of the precautionary principle. As the panel noted, "it is clear that application of a prudent and precautionary approach is, and must be, subject to reasonable limits, lest the precautionary approach swallow the discipline" of the SPS Agreement.[44]

In their submissions to the WTO, both the European Union and the United States clearly stated their differing views on the precautionary principle. In defending its approach to GMO regulation, the European Union argued that application of WTO rules should be interpreted with reference to the relevant rules of international law outside of the WTO, appealing to the Vienna Convention on the Law on Treaties. In particular, the EU argued that the precautionary principle is now a general principle of international law existing in at least 19 different versions in various domestic regulatory settings or international agreements, including the 2000 Cartagena Protocol on Biosafety (hereinafter, Biosafety Protocol).[45] In contrast, the United States stated that neither the precautionary principle nor the Biosafety Protocol could be used as a defense by the European Union.[46] Specifically, the United States argued that the precautionary

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principle has no status in international law, noting that it has no agreed-upon definition. The United States has also claimed that the precautionary principle is an "approach" rather than a principle of international law, attesting that Article 5.7 of the SPS Agreement already allows the EU to follow a precautionary approach to regulating GMOs. The United States also disagreed with the notion that the Biosafety Protocol is a rule of international law, asserting that it does not apply to U.S.–EU relations within the WTO as the United States is not a signatory to the Biosafety Protocol.[47]

In its report, the Dispute Panel is very clear about the relevance of both the Biosafety Protocol and the precautionary principle to the current dispute. With regard to the former, as the United States is not a signatory and hence not a party to the Biosafety Protocol, the panel was not required to take it into account in making its ruling.[48] With regard to the latter—the precautionary principle—the panel followed the ruling of the Apellate Body in the hormone-treated beef case, arguing that the legal status of the precautionary principle is still unsettled, and that it did not have to take a position on whether the principle is a recognized principle of international law. Specifically, the panel noted that, "there has, to date, been no authoritative decision by an international court or tribunal which recognizes that the precautionary principle as a principle of general or customary international law,"[49] concluding that, "since the legal status of the precautionary principle remains unsettled, like the Appellate Body before us, we consider that prudence suggests that we not attempt to resolve this complex issue, particularly if it is not necessary to do so. Our analysis…makes clear that for the purposes of disposing of the legal claims before us, we need not take a position on whether or not the precautionary principle is a recognized principle of general or customary international law." [50] In other words, the panel stuck with the precedent set in the hormone-treated beef case that the precautionary principle does not override Articles 5.1 and 5.2 of the SPS Agreement. Faced with making a final ruling on the precautionary principle, the WTO chose to punt.

While the panel made no ruling as to whether the European Union's actual GMO approval procedures are consistent with their WTO obligations, there is considerable discussion in the document of the legal status of these regulations. Importantly, this discussion does give some clue to how the WTO might proceed in any future dispute where the plaintiffs actually file a complaint concerning the European Union's GMO approval process claiming that it distorts international trade. Specifically, the panel concluded that the European Union's current approach to regulating GM crops, as contained in Directive 2001/18, constitutes a set of measures which may affect international trade as determined by the SPS Agreement.[51] The implication of this is that the EU's GMO approval process could subsequently be found in violation of WTO rules if it can be shown that it does not meet the risk assessment criteria of the SPS Agreement.

In addition, the panel examined the GM food labeling requirements of the European Union's Directive 2001/18. Here it concluded that insofar as these labeling requirements relate to the purpose of protecting human health and the environment from the unanticipated effects of GMOs, they consider that the European Union's rules on GM food labeling fall within the scope of the SPS Agreement.[52] However, further discussion of the European Union's labeling provisions recognizes the notion that labeling may be required in order to ensure that consumers who have a preference for non-GM foods are not "misled" into purchasing GM foods. In this case, such a measure should not be considered an SPS measure designed to protect consumers from the potential risks of GMOs. The implication of this would seem to support what was noted earlier—the European Union might be able to defend its GM food labeling requirements outside of the SPS Agreement on the grounds of consumers' right to know.

Conclusions

What is the likely impact of the WTO ruling on the regulatory environment for GM crops? As noted earlier, the ruling in some sense was quite narrow, focusing on the European Union's moratorium on approval of new GM crops, and also on the product-specific and safeguard measures. While it is moot whether the moratorium had already been lifted at the time the United States filed its complaint, it is certainly the case that in its ruling on the safeguards implemented by six EU member states, the Panel clearly asserted that they were put in place without the necessary risk assessment required by the SPS Agreement. In addition, in its analysis of the European Union's regulatory regime, the Panel was also quite clear that it is covered by the SPS Agreement, and therefore might have an effect on international trade. Even though much of the Panel's discussion is both legalistic and even arcane, it would be reasonable to conclude that in any future dispute, the WTO will carefully examine whether the European Union's or any other country's GMO regulations are consistent with their obligations under the SPS Agreement. In addition, the Panel's unwillingness to regard the precautionary principle as part of accepted international law suggests that like the hormone-treated beef case, this will not be a defense for implementing a trade-distorting regulation of GMOs.

From a narrow legal standpoint, the overall conclusion of this paper would be that little has changed with the WTO ruling, other than reasserting the primacy of the SPS Agreement and clarifying how a WTO Dispute Panel might rule in the future. In addition, from the standpoint of international trade in GM crops, while the ruling on import bans by six EU member states is important in principle, in practice we are unlikely to see a significant increase in exports of GM crops to the European Union in the near future, except perhaps those that are used in animal feed. This follows from the likelihood that a majority of consumers in the European Union will continue to

remain unconvinced of the benefits to them of the current generation of GM crops, and that consumers will be able to avoid purchasing and hence eating foods containing GM crops given current EU labeling requirements. WA

Notes

1. Even though Argentina and Canada also filed their own legally distinct complaints with the WTO, in this paper, the U.S. complaint is treated as being broadly representative of all three plaintiffs.

2. World Trade Organization, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293R (Geneva: World Trade Organization, 2006).

3. Ian Sheldon, "Regulation of Biotechnology: Will We Ever 'Freely' Trade GMOs?" *European Review of Agricultural Economics* 29 (2002): 155–176; Ian Sheldon, "Europe's Regulation of Agricultural Biotechnology: Precaution or Trade Distortion?" *Journal of Agricultural and Food Industrial Organization* 2 (2004).

4. In both the scientific and popular media, plants derived in this way are typically referred to either as GM crops or GMOs, while the products that contain GM crops/GMOs are usually referred to as either GM or biotech foods.

5. Clive James, "Global Status of Commercialized Biotech/GM Crops: 2006," *ISAAA Brief*, no. 35, 2006.

6. Many studies have now been published establishing the safety of GM foods, such as GM Science Review Panel, *GM Science Review* (London: GM Science Review Secretariat, 2003).

7. "Europeans and Biotechnology in 2005: Patterns and Trends," *Eurobarometer* 64 (2006): 1–85.

8. Paul Thompson, *Food and Agricultural Biotechnology: Incorporating Ethical Considerations* (Ottawa: Canadian Biotechnology Advisory Committee, 2002).

9. C. Ford Runge and Lee-Ann Jackson, "Negative Labeling of Genetically Modified Organisms (GMOs): The Experience of rBST," *AgBioForum* 3 (2000): 310–314.

10. For example, the World Health Organization/Food and Agriculture Organization lays out a decision-tree process for the assessment of the potential allergenic effects of GM foods. World Health Organization and Food and Agriculture Organization, *Safety Aspects of Genetically Modified Foods of Plant Origin* (Rome: World Health Organization/Food and Agriculture Organization, 2000)

11. For a good discussion of the timeline of events in the StarLink case, see Ragnar Löfstedt, Baruch Fischhoff, and Ilya R. Fischhoff, "Precautionary Principles: General Definitions and Specific Applications to Genetically Modified Organisms," *Journal of Policy Analysis and Management* 21 (2002): 381–407.

12. The National Academies of Science has noted that there is no definitive evidence that such marker genes harm humans, but given public concerns, they did recommend that developers remove such genes before crops go into commercial use, and utilize different types of markers in developing new transgenic varieties. National Academies of Science, *Transgenic Plants and World Agriculture* (Washington DC: National Academy Press, 2000).

13. Media reporting of a study by Cornell University scientist John Losey that Monarch butterflies were adversely affected by Bt corn pollen did much to galvanize the anti-biotechnology movement in the United States. "In Bt Football, It's Cornell vs. Cornell," *Scientist*, 11 October 1999.

14. Tamara K. Hervey, "Regulation of genetically modified products in a multi-level system of governance: Science or citizens?" *Review of European Community and Environmental Law* 10 (2001): 321–333.

15. Lawrence A. Kogan, "Trade Protectionism: Ducking the Truth about Europe's GMO Policy," *International Herald Tribune*, 27 November 2004.

16. Sheldon, "Regulation of Biotechnology." The regulatory systems in place in Argentina and Canada are very similar to that of the United States, while Japan, South Korea, and other European countries have regulatory systems similar to that in the EU.

17. Food and Drug Administration, "Statement of Policy: Foods Derived from New Plant Varieties," *Federal Register* (57 FR 22984), 29 May 1992.

18. This regulatory approach is consistent with recommendations for assessing the safety of GMOs

made by international institutions such as the Organisation for Economic Co-operation and Development and the World Health Organization.

19. This moratorium was encoded in an amendment to European Council Directive 90/220/EEC, which covered the deliberate release of GMOs by requiring notification of the release to the relevant competent authority in the member state where the GMO would first be marketed.

20. The precautionary principle, which governs the EU's approach to environmental policy, is enshrined in Article 174 of the EC Treaty (European Commission, February, 2000). Article 174 states, "Community policy on the environment . . . shall be based on the precautionary principle and on the principles that preventive action should be taken."

21. Löfstedt, Fischhoff, and Fischhoff, "Precautionary Principles."

22. Henry I. Miller and Gregory Conko, "Why Regulators' 'Precautionary Principle' Is Doing More Harm than Good," *Policy Review* 107 (2001): 25–39.

23. Cass R. Sunstein, "Beyond the Precautionary Principle," *Public Law and Legal Theory*, working paper 38 (Chicago: University of Chicago Law School, January 2003).

24. See, for example, Christian Gollier, "Should We Beware of the Precautionary Principle?" *Economic Policy* 33 (2001): 303–327; Giancarlo Moschini, "Agricultural Biotechnology and Trade: The Unresolved Issues," Iowa Ag Review 9 (2003): 8–10.

25. In the jargon of economics, there is an increase in society's aversion to risk, resulting in more caution—see Gollier, "Should We Beware." For an interesting perspective on this see Sunstein, "Beyond the Precautionary Principle."

26. Calum G. Turvey and Eliza M. Mojduszka, "The Precautionary Principle and the Law of Unintended Consequences," *Food Policy* 30 (2005): 145–161. It should be noted that a compromise was eventually reached with the governments of Malawi, Mozambique, and Zimbabwe whereby the United States sent milled corn to these countries. Sunstein also alludes to the potential unintended consequences of applying the precautionary principle.

27. Gollier, "Should We Beware."

28. The relevant section of GATT Article XX reads, "Nothing in this Agreement shall be construed to prevent the adoption or enforcement of by any contracting party of measures . . . necessary to protect human, animal or plant life or health."

29. The SPS Agreement, agreed on at the end of the Uruguay Round of GATT in 1994, focuses on regulations that are used explicitly to protect human, animal, and plant health, the objective being to ensure that such regulations are science-based and do not distort trade. The TBT Agreement, originating in the Tokyo Round of GATT and subsequently modified in the Uruguay Round, covers technical regulations that focus on non-safety related attributes of all products, such as the characteristics of how a product was produced. The objective of this agreement is to ensure that technical regulations designed to meet some legitimate objective be applied in a manner that is least disruptive to international trade. It should be noted, however, that the TBT Agreement does not require scientific justification for a specific technical regulation, and the list of legitimate objectives for such regulations is rather open-ended.

30. Kym Anderson and Chantal Nielsen, "GMOs, the SPS Agreement and the WTO," in *The Economics of Quarantine and the SPS Agreement*, ed. Kym Anderson, Cheryl McRae, and David Wilson (Australia: Center for Economic Studies and Bio-security, 2001).

31. Donna Roberts, "Preliminary Assessment of the Effects of the WTO Agreement on Sanitary and Phytosanitary Trade Regulations," *Journal of International Economic Law* 1 (1998): 377–405.

32. Lawrence A. Kogan, "World Trade Organization Biotech Decision Clarifies Central Role of Science in Evaluating Health and Environmental Risks for Regulation Purposes," *Global Trade and Customs Journal* 2 (2007): 149–155. Specifically, Article 5.7 states, "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the 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 full text of the SPS Agreement can be found at http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm.

33. World Trade Organization Appellate Body, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (Geneva: World Trade Organization, 1998).
34. Dirk Heumueller and Timothy Josling. "Trade Restrictions on Genetically Engineered Foods: The Application of the TBT Agreement," (papa, 5th International Conference on the Economics of Biotechnology, *International Consortium on Agricultural Biotechnology Research*, Ravello, Italy, 2001).
35. Kogan, "World Trade Organization."
36. World Trade Organization, *European Communities*, 1067–1087.
37. Moschini, "Agricultural biotechnology."
38. World Trade Organization, *European Communities*, 142.
39. Ibid., 27–28.
40. Ibid., 66.
41. Ibid., 1068.
42. Friends of the Earth, "Looking Behind the U.S. Spin: WTO Ruling Does not Prevent Countries from Restricting or Banning GMOs," Friends of the Earth International, Briefing Paper, February 2006.
43. World Trade Organization, *European Communities*, 673.
44. Ibid., 671.
45. Ibid., 98–99. The Cartagena Protocol on Biosafety was finalized and adopted in Montreal by 133 governments on 29 January 2000, and has subsequently been ratified by the required 50 signatories.
46. Ibid., 100–101.
47. Specifically, as a matter of law, a later and more specific agreement (the Biosafety Protocol) would have legal precedence over an earlier and more general agreement (the SPS Agreement). However, this principle only applies if all parties to both legal agreements are identical (Article 31(3) of the Vienna Convention).
48. World Trade Organization, *European Communities*, 336.
49. Ibid., 339.
50. Ibid., 341.
51. Ibid., 427.
52. Ibid., 417.