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# Agricultural Biotechnology Meets International Trade: The US-EU GMO Dispute

## Part I: Technology and Regulation

In 1996, US farm exports reached record levels: At \$60.4 billion, they totaled about 10 percent of the merchandise exported by the United States.<sup>1</sup> “One out of every three acres of America’s farms is dedicated to exports,” noted US Trade Representative (USTR) Charlene Barshefsky.<sup>2</sup> Around the same time, US farmers undertook the first commercial plantings of genetically modified (GM) crop varieties.<sup>3</sup> These crops were designed to be resistant to insect pests, herbicides (weed killers), and disease. Use of GM varieties—mainly of soybeans, corn, and cotton—skyrocketed in the United States. By 2000, about 54 percent of US soybean acreage and 25 percent of US corn acreage were planted with GM varieties. By 2004 approximately

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1. Figures from Economic Research Service, United States Department of Agriculture, *Foreign Agricultural Trade of the United States (FATUS) Export Aggregations*, [www.ers.usda.gov](http://www.ers.usda.gov).

2. Testimony of Ambassador Charlene Barshefsky, United States Trade Representative, before the Senate Committee on Agriculture, Nutrition and Forestry, 105th Cong., 1st sess., June 18, 1997. Barshefsky also noted that the US agricultural trade surplus was \$27 billion in 1996—the largest in history—making the agricultural sector the largest positive contributor to the US balance of trade.

3. The term *genetically modified* is not an entirely accurate descriptor. The process of genetic modification has taken place for thousands of years, via controlled breeding.

**Table 6.1 Total US crop acreage in biotechnology varieties, 1996–2004**  
(percent)

Crop	1996	1997	1998 <sup>a</sup>	1999	2000	2001	2002	2003	2004
Soy	7.4	17.0	44.2	55.8	54	68	75	81	85
Corn	n.a.	n.a.	n.a.	n.a.	25	26	34	40	45
Bt	1.4	7.6	19.1	25.9	18	18	22	25	27
Ht	3.0	4.3	18.4	n.a.	6	7	9	11	13
Stacked	n.a.	n.a.	n.a.	n.a.	1	1	2	4	5
Cotton	n.a.	n.a.	n.a.	n.a.	61	69	71	73	76
Bt	14.6	15.0	16.8	32.3	15	13	13	14	16
Ht	2.2	10.5	26.2	42.1	26	32	36	32	30
Stacked	n.a.	n.a.	n.a.	n.a.	20	24	22	27	30

n.a. = not available

a. 1998 estimates for corn and cotton include acreage and production with stacked varieties (with both Bt and Ht genes).

Note: Bt = insect-resistant. Ht = herbicide-tolerant. Stacked gene varieties include those containing biotechnology traits for both herbicide and insect resistance.

Sources: For 1996–99: Fernandez-Cornejo and McBride (2000, 13; 2002, iv, 10). For 2000–2004: National Agricultural Statistics Service (NASS), US Department of Agriculture, *Acreage*, June 30, 2000; June 29, 2001; June 28, 2002; June 30, 2003; June 30, 2004.

85 percent of US soybean acreage and 45 percent of US corn acreage were planted with genetically engineered varieties (see table 6.1). In addition, about 75 percent of the processed food sold in the United States contained ingredients derived from GM crops.<sup>4</sup> Canada and Argentina also adopted GM crops.<sup>5</sup>

After some public debate, GM foods were generally treated the same as non-GM foods by the US regulatory system. But not all countries were as quick to embrace agricultural biotechnology. The European Union developed a separate regulatory approach for GM products, including a different approach toward risk. Resistance to the technology grew in Europe, and many consumer groups, environmentalists, nongovernmental organizations (NGOs), and politicians rejected genetically modified organisms (GMOs). In the end, the European Union placed a de facto moratorium on the approval of new GM products, frustrating US exporters. As the use of GM technology increased in the United States, US corn sales to the European Union declined from 4 percent of total US corn exports before 1997 (generating about \$300 million) to less than 0.1 percent in 2004.<sup>6</sup>

4. Pew Initiative on Food and Biotechnology, “US vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food,” December 2005, 1.

5. Of the 120 million acres of GM crops planted worldwide in 2002, the United States grew 68 percent; Argentina, 22 percent; Canada, 6 percent; and China, 3 percent (see Pringle 2003, 2).

6. Pew Initiative on Food and Biotechnology (2005, 4).

Some US government officials and agribusiness industry representatives argued that the European Union's approach to agricultural biotechnology amounted to protectionism—that Europe had erected barriers to impede trade. Without scientific proof that GM crops caused harm to human health or the environment, how could Europe reject these products? Others noted that though European GM policies restricted trade, they did not amount to a simple case of protectionism. Instead, the European Union's de facto moratorium and more recent strict GM legislation resulted from consumers' lack of confidence in regulators, demands for choice, and suspicion of big business, as well as ethical and environmental considerations, growth of the green and consumer movements, and tensions related to internal EU politics.

The US government continued to pressure Europe to enact reliable regulations based on science and to resume the approval and import of GM crop varieties. US frustration culminated in a complaint against the European Union at the World Trade Organization (WTO), launched in May 2003. But in anticipation of such a complaint, both the European Union and the United States had worked to enshrine their approaches to GMOs in relevant international institutions. Debate had been ongoing for years at the Codex Alimentarius Commission (the international food standards body), at the WTO, and in negotiations for a Biosafety Protocol.

As these debates continued, some observers noted that the US-EU dispute had distracted the international community from a more important goal. It was poorer tropical countries that had the most to gain from engineered seeds, they argued. Resources should be directed not to transatlantic debate but to funding public agricultural research to develop GM crop varieties for the nations that needed them the most.

## A History of Innovation

Genetic modification was not the first new technology to transform the practice of agriculture. In the early part of the 20th century the important developments were mechanical. US farmers started adopting gasoline-powered tractors in 1910, replacing horses and mules. Later came other farm machinery such as self-propelled harvesters. The manufacture and use of farm machinery increased steadily in the United States until the 1960s, when they leveled off.<sup>7</sup>

Mechanical advances in agriculture were followed by chemical and biological innovations. Chemical engineering brought synthetic fertilizers, herbicides, and pesticides. For example, in 1974, Monsanto Company introduced Roundup, a broad-spectrum herbicide sprayed on fields before

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7. See National Agricultural Statistics Service (NASS), USDA, *Trends in US Agriculture*, at [www.usda.gov](http://www.usda.gov).

or after harvest to kill weeds, which would become the world's best-selling agricultural chemical of all time.<sup>8</sup> Meanwhile, plant-breeding techniques such as hybridization (breeding between two varieties of plants) were used to create heartier or healthier crops, making food production more efficient. Double-cross hybrid corn varieties designed to increase yields were introduced in the 1930s.<sup>9</sup> By 1960, hybrid corn accounted for 96 percent of US corn acreage.<sup>10</sup>

As a result of these mechanical, chemical, and plant-breeding technologies, agricultural output per acre and per worker increased dramatically in the developed world, and the real price of food dropped. Many countries achieved a 30-fold increase in crop production between the 1930s and 1960s (Bernauer 2003, 28). A number of the plant-breeding breakthroughs of the 1960s and 1970s also spread to some developing nations. The increase in food production caused by the introduction and diffusion of new wheat and rice varieties in Asia became known as the "green revolution."<sup>11</sup>

In addition to its impact on agriculture, plant hybridization also provided the foundation for modern genetics. In the mid-1800s, an Augustinian monk named Gregor Mendel traced the characteristics of successive generations of pea plants in his monastery's garden. By crossbreeding plants over seven years, Mendel proved the existence of paired units of heredity—now called genes—and established the statistical laws governing them, leading to his 1865 paper "Experiments in Plant Hybridization."

Scientists' understanding of genetics continued to grow at an increasing rate. In 1944, Oswald Avery identified deoxyribonucleic acid, or DNA, as the substance associated with the storage and transfer of genetic information. In 1953, James Watson and Francis Crick described the structure of a DNA molecule. By 1973, scientists had successfully transferred DNA from one organism to another. Out of this event grew a new technique—recombinant DNA technology—that would become the most important tool of genetic engineering. To create a recombinant DNA molecule, one gene or, most commonly, a set of a few genes is taken out of the DNA of one organism and inserted into the DNA of another.<sup>12</sup> The new genes,

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8. David Barboza, "Monsanto Struggles Even as It Dominates," *The New York Times*, May 31, 2003, C1.

9. In addition, Congress passed the Plant Patent Act in 1930, enabling the products of plant breeding to be patented.

10. National Agricultural Statistics Service, USDA, *Trends in US Agriculture*.

11. This "revolution" largely missed Africa. For example, between 1970 and 1983, new high-yield rice varieties spread to about 50 percent of Asia's rice lands but only 15 percent of sub-Saharan Africa (Paarlberg 2000, 24).

12. Enzymes are used to break the DNA strand, a vector is used to carry the new genes to the strand, and after the new segments are inserted, the strand is "stitched" back together.

which code for specific proteins, allow the expression of a desired trait in the recipient organism.

With the discovery of recombinant DNA techniques came new questions. Were there hazards associated with such research? Should recombinant DNA research be restricted or regulated? At first, some scientists were cautious. In 1974, the biologist Paul Berg along with 10 other genetic researchers published a letter in the journals *Science* and *Nature* asking scientists throughout the world to join them in “voluntarily deferring” certain types of experiments “until the potential hazards of such recombinant DNA molecules have been better evaluated or until adequate methods are developed for preventing their spread” (Berg et al. 1995, 512). In 1975 scientists from all over the world came together at a conference in Asimolar, California, to discuss the possible risks associated with recombinant DNA. Members of the public worried that use of this new technology could create dangerous “mutant” organisms that might escape the laboratory or harm researchers. For example, in 1976, the mayor of Cambridge, Massachusetts, urged Harvard University to halt the construction of a genetics lab out of fear that strains created by biologists might spread incurable disease. Lawmakers “better hurry up and pass laws to control what goes on—and what crawls out of—these laboratories,” Mayor Alfred Vellucci said.<sup>13</sup> Critics also wondered if researchers should be “tampering” with nature.

## Regulating Agricultural Biotechnology in the United States

Government oversight of biotechnology in the United States began in the mid-1970s when scientists asked the National Institutes of Health (NIH) to create a set of laboratory safety guidelines for biomedical research using recombinant organisms. In 1976 the NIH published guidelines for laboratories conducting federally funded experiments (the guidelines did not cover private industry, an omission that some observers protested). In the years that followed, the guidelines were revised and relaxed as more experiments and organisms were shifted to lower-risk categories (Office of Technology Assessment 1991, 173). As safety problems with recombinant DNA research in the lab failed to materialize, public concern declined. By the early 1990s, most recombinant DNA research in the United States was exempt from review and subject to minimal restrictions.

While the controversy over the hazards of recombinant DNA research waned, a debate began over how to regulate the uses of that research. By

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13. Vellucci, quoted in “Scientists Say Law Is Needed to Regulate Genetic Research,” *The Washington Post*, March 8, 1977, A6. The mayor was unsuccessful in persuading the Cambridge city council to pass an ordinance outlawing all research that combined genetic material of different species.

the early 1980s, it was becoming clear that genetic engineering would play a major role in agriculture. In 1982, scientists at Monsanto pioneered the modification of a plant cell's genetic structure.<sup>14</sup> New genetic information could be added to plant DNA to form new proteins, creating new traits. Genetically engineered crop plants designed to resist insects and herbicides were soon ready to be field-tested. The first such test, of genetically engineered tobacco, took place on a Wisconsin farm in 1986. Agracetus, the company conducting this first test, would not disclose the site's location because it feared protesters might sabotage the experiment.<sup>15</sup>

Some observers believe that early objections raised in the United States to genetic engineering were significant in the history of the US-EU GM dispute. According to Robert Paarlberg, a professor of political science at Wellesley College and an associate at the Weatherhead Center for International Affairs at Harvard University,

In the United States, we went through a period of public and open debate about genetic modification in the 1970s and the 1980s. Even here at Harvard, I remember when Harvard genetically engineered its own mouse for laboratory experiments; there were enormous anxieties about the consequences of doing this. Anti-GM activist groups were trying to stop the planting of test plots of genetically modified strawberries. The European Union didn't have the same type of early public debates about these technologies as the United States.<sup>16</sup>

At the same time, researchers and industry were looking to the government for guidance on the use of agricultural biotechnology. Some industry executives believed that government regulation was a key part of a strategy to gain public acceptance of GM technology. "We recognized early on that while developing lifesaving drugs might be greeted with fanfare, monkeying around with plants and food would be greeted with skepticism," said Earle Harbison Jr., Monsanto's president and chief operating officer from 1986 to 1993.<sup>17</sup> Two industry associations were created, the Industrial Biotechnology Association (in 1981) and the Association of Biotechnology Companies (in 1983), which by the end of the 1980s had hundreds of members; these groups would merge in 1994 to form the Biotechnology Industry Organization (Cantley 1995, 535). Congress also showed some initial interest in legislating restrictions on biotechnology.

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14. Monsanto's scientists genetically modified both petunia and tobacco cells to make the host plants and their offspring resistant to an antibiotic.

15. Keith Schneider, "Gene-Altered Tobacco Is Planted in Wisconsin," *The New York Times*, May 31, 1986, 9. Agracetus was jointly owned by the Cetus Corporation and W. R. Grace & Company.

16. Unless otherwise noted, all quotes from Robert Paarlberg come from a 2004 interview with the author.

17. Harbison, quoted in Kurt Eichenwald, "Redesigning Nature: Hard Lessons Learned; Biotechnology Food: From the Lab to a Debacle," *The New York Times*, January 25, 2001, A1.

In response to the growing calls for policy coordination, the Reagan administration established an interagency working group under the cabinet council of economic affairs and charged it with drafting an overall federal framework for regulating biotechnology. Some suggest that by convening a group under White House auspices, thereby ensuring that meetings would not be open to the public, the administration was able to avoid public oversight (Vogel 2001, 4). The working group first circulated a set of guidelines for comment in December 1984. In June 1986, with the approval of President Reagan, the *Coordinated Framework for Regulation of Biotechnology* was published in the *Federal Register*.<sup>18</sup> The Coordinated Framework remains the key US government document on biotechnology.

Under the Coordinated Framework, the administration decided that products of biotechnology would generally be regulated in the same way as products of other technologies, using existing health and safety laws; no new legislation was required.<sup>19</sup> “No new legislation was needed, because experts agreed with the National Academy of Sciences’ recommendations that there were enough provisions in existing laws to deal with agricultural biotechnology,” says Dr. Isi Siddiqui, former senior trade advisor to US Department of Agriculture (USDA) Secretary Dan Glickman. “So US agencies would adopt regulations pursuant to existing acts. These laws were the backbone of the Coordinated Framework.”<sup>20</sup>

Agencies that were responsible for regulatory oversight of certain products were now also responsible for evaluating the same kinds of products that were developed using genetic engineering. Thus, for agricultural biotechnology, the Environmental Protection Agency (EPA), the USDA’s Animal and Plant Health Inspection Service (APHIS), and the Food and Drug Administration (FDA) would have authority over different aspects of GM product regulation. The USDA would check that GM plant varieties were safe to grow; the FDA would check that GM food and plants were safe to eat (for both humans and animals); and the EPA would monitor GM crops that produced their own pesticides. The USDA was also tasked with issuing licenses for the field-testing of food crops before their

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18. “1986 Coordinated Framework for Regulation of Biotechnology,” *United States Federal Register* 51 (June 26, 1986): 23302–93.

19. The framework noted “upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately” (“1986 Coordinated Framework for Regulation of Biotechnology,” 23302).

20. Unless otherwise noted, all quotes from Isi Siddiqui come from a 2005 interview with the author. Siddiqui is now a vice president of science and regulatory affairs at CropLife America, which represents companies that produce, sell, and distribute almost all the crop protection and biotechnology products used by US farmers. In this interview, he was speaking in a personal capacity and not on behalf of CropLife America or its member companies.

commercial release.<sup>21</sup> Moreover, the framework established the Biotechnology Science Coordinating Committee, an interagency committee chaired by the National Science Foundation that was responsible for continuing policy coordination.

## The Business of Agricultural Biotechnology

The potential benefits of GM technology for agriculture created much excitement in industry, and interest increased when the Supreme Court extended patent protection to new types of plants in 1980. “Only after the Court guaranteed the protection of intellectual property rights did private corporations make the substantial investments necessary to develop commercially attractive transgenic crops,” notes Robert Paarlberg (2000, 24).

While traditional crossbreeding could be time-consuming—sometimes several generations of breeding were required before the desired plant emerged—genetic engineering techniques made possible faster and more precise development of new crop varieties. Genetic engineering also increased the range of available traits: Because genes could be introduced from unrelated species, new varieties might be created that traditional breeding methods never could have produced. For example, one popular strain of GM corn (Bt) includes genes from the soil bacteria *Bacillus thuringiensis*. Like the bacteria, Bt corn produces a toxin that kills some insects—notably the corn borer, which annually destroyed about 7 percent of the world’s corn crop.<sup>22</sup> Supporters of agricultural biotechnology saw many possibilities for higher crop yields, lower pesticide use, greater food security in the developing world, increased profits for farmers, and more nutritional food.

In the end, the GM plants that entered mass production in the United States were those whose traits led to commercial or production advantages that appealed to farmers (such as cheaper weed and insect control), as opposed to those whose traits directly benefited consumers (such as increased nutritional value). There were thus two main categories of genetically engineered crops: herbicide-tolerant (i.e., crops modified to resist the effects of common weed killers) and insect-resistant.

The companies involved in agricultural biotechnology included DuPont, W. R. Grace, Pioneer Hi-Bred, Ciba (which later became part of Novartis), and Dow/AgroSciences. For example, Ciba became the first

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21. The relevant laws were the Plant Pest Act, which regulates crops and microbes that might be plant pests; the Federal Insecticide, Fungicide, and Rodenticide Act, which requires EPA to regulate the sale and use of pesticides in the United States; the Toxic Substances Control Act; and the Food, Drug, and Cosmetic Act.

22. Jenny Luesby, “Patents Wars over High-Tech Seeds,” *The Financial Times*, March 22, 1996, 3. In 1995, the corn borer knocked out almost 30 percent of Canada’s corn harvest.

company to market and sell GM corn in the United States when it introduced its Bt corn—the Maximizer hybrid with Knockout corn borer control—in 1995.<sup>23</sup> In 1996, Pioneer Hi-Bred, the largest US seed company, was forecasting that transgenic products would account for one-third to one-half of its seed lines by 2000<sup>24</sup> (Pioneer Hi-Bred was acquired by DuPont in 1999). US companies were not alone in engaging with agricultural biotechnology: Switzerland’s Novartis and Britain’s Zeneca (which merged in 2000 to become Syngenta) sold seeds resistant to herbicides, as did Germany’s AgrEvo and France’s Rhône-Poulenc (which merged in 1999 to form Aventis).

But the company that became most identified with GM crops was American: St. Louis-based Monsanto. Founded by a chemist in 1901 to manufacture the artificial sweetener saccharin, Monsanto would become a big supplier of plastics, chemicals, and synthetic fabrics before developing the two herbicides, Lasso and Roundup, that turned it into the most profitable agricultural company in the world. Monsanto first became active in biotechnology in the early 1980s. Starting in 1992, Monsanto began to reinvent itself as a life sciences company. In 1996, it announced plans to spin off its chemical operations and dedicate itself fully to biotechnology. By 1999, Monsanto had invested more than \$8 billion to buy seed companies and close marketing agreements with some of its largest competitors, making a greater commitment to producing genetically modified crops than any other organization in the world (Specter 2000, 60).

In 1985, company scientists developed Monsanto’s first product that relied on genetic modification—a hormone called recombinant bovine somatotropin (rbST), which was designed to increase milk production in cows by 10 to 25 percent. Produced by genetically engineered bacteria, it was marketed under the name Posilac. The FDA approved its use in 1993, noting that there was no significant difference in milk from cows treated with the hormone and milk from untreated cows. The hormone bovine somatotropin (bST) occurs naturally in milk because cows produce it. Recombinant bST was “a safe and effective product when used as indicated on its approved label,” an FDA spokesman said.<sup>25</sup>

But rbST became the focus of what many describe as the first battle over biotech foods. Its introduction was accompanied by controversy as protests were voiced by consumers who were wary of potential health risks both to humans and cows. Concerns about cows ranged from increased udder in-

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23. Timeline at [www.syngenta.com](http://www.syngenta.com) (accessed in November 2004). Ciba and Sandoz merged in 1996 to become Novartis (one of the largest corporate mergers in history), and Novartis Agribusiness and Zeneca Agrochemicals merged in 2000 to become Syngenta.

24. Barnaby J. Feder, “Out of the Lab, a Revolution on the Farm,” *The New York Times*, March 3, 1996, section 3, 3.

25. Sharon Schmickle, “FDA Stands Behind BST After Canada Bans Growth Hormone,” *The Star Tribune* (Minneapolis), January 16, 1999, 14A.

fections to infertility. Mothers wrote op-ed pieces worrying about the safety of the milk they gave their children.<sup>26</sup> As a result, some questioned the wisdom of introducing rbST as the first major agricultural biotechnology product. "From the point of view of the many advances of the biotechnology industry, this was an unfortunate product to lead with, in the sense that the public doesn't perceive a benefit from it or feel it has control over whether it uses it," said Dr. C. Wayne Callaway, a spokesman for the Dairy Coalition, which represented milk producers and processors.<sup>27</sup>

Yet efforts by US consumer groups had little success in insisting that milk produced from cows treated with rbST should be so labeled. While companies could voluntarily label products as produced from cows that had not been treated with the hormone, they could not tout their milk as "bST free." Much of the consumer protest had subsided by 1996, though debate continued in California, Maine, Vermont, and some other dairy states. By the beginning of 1999, according to Monsanto, about 30 percent of US dairy cows, or around 2.7 million animals, were in herds supplemented with Posilac.<sup>28</sup> The product was not sold in Europe, however, where a moratorium was declared on rbST in 1990. Canada banned rbST in 1999 because of concerns about animal health.

Monsanto also developed GM crop varieties, including corn and soybeans that were engineered to tolerate the use of its Roundup herbicide. Farmers purchasing Monsanto's GM seeds agreed not to resell the seeds, not to retain them without planting them, and not to collect seeds from the plants they grew. They also agreed to crop inspections by company representatives. Farmers who bought Roundup Ready seeds also paid a per-acre licensing fee and committed to using Roundup pesticide. In explaining the need for its fees and restrictions, Monsanto representatives told farmers that Monsanto had spent \$500 million over the past 10 years just to develop Roundup-resistant crops.<sup>29</sup> Nor was Monsanto alone in the use of these technology fees; other companies followed the same practice. The adoption of Monsanto's pesticide- and herbicide-resistant corn, cotton, and soybeans in the United States increased from 14.5 million acres in 1997 to 46.5 million acres in 1998 to 68 million acres in 1999 (Leamon 2003, 14, exhibit 1).

Observers say that the quick embrace of GM crops was not hard to understand, given that they decreased the need for tillage and chemical

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26. See Trisha Flynn, "Mother Knows Best: Leave Milk to the Cows and the Consumer, Please," *Rocky Mountain News* (Denver), April 17, 1994, 4M.

27. Callaway, quoted in Kathleen Day, "Hormone Hubbub Hinders Program; Genetic Drugs Dealt Setback in Foods," *The Washington Post*, March 15, 1994, D1.

28. George Gunset, "Growth Hormone Controversy Shrinks Higher Milk Production; Hasn't Hurt Profits," *The Chicago Tribune*, January 2, 1999, 1.

29. Feder, "Out of the Lab, a Revolution on the Farm."

sprays. Because most US farmers growing Roundup Ready soybeans cut their chemical costs by 10 to 40 percent, they profited. “While the seed companies made money, American farmers were the biggest winners, capturing roughly half of the total economic benefit from the new technology,” notes Robert Paarlberg. “Patent-holders and seed companies gained only about a third of the added profits, while consumers got less than that” (2000, 24). Many farmers also believed that reducing their use of chemicals allowed them to deliver healthier crops. “Personally, I’d rather eat a bowl of cornflakes made from Bt corn than from regular corn,” said Nebraska corn farmer Rick Gruber.<sup>30</sup>

## Regulating Agricultural Biotechnology in Europe

As GM products were taking hold in the United States, Europe’s approach to regulating agricultural biotechnology was evolving. In 1983, the European Commission became concerned that Europe was falling behind the United States and Japan in biotechnology development. That year, the Commission submitted a report to the European Council making clear its objective to increase the competitiveness of Europe’s biotechnology industry (Patterson 2000, 320). In 1984, the Commission created a senior policy discussion group at the director-general (DG) level called the Biotechnology Steering Committee (BSC), chaired by DG XII (Science, Research, and Development). When it became clear that more technical discussions were needed, the committee established the Biotechnology Regulations Interservice Committee (BRIC) a year later.

The importance of the BSC faded and the BRIC became the main forum in the Commission for developing biotechnology regulation. The chair alternated between DG III (Industry) and XI (Environment).<sup>31</sup> The participating Commission directorates had different perspectives on GMOs. For example, DG XII (Science) argued that any regulation should be based on accumulated information about risks, not on unproven concerns. DG VI (Agriculture) and DG III (Industry) argued that existing regulations were adequate or could be adapted to address biotechnology products.<sup>32</sup>

In contrast, DG Environment viewed biotechnology more skeptically. It urged that Community-wide regulatory directives specifically for GMOs

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30. Gruber, quoted in Scott Kilman, “Seeds of Doubt: Once Quick Converts, Farmers Begin to Lose Faith in Biotech Crops—DuPont and Others, Mindful Of Their R&D Billions, Struggle to Hold Ground—Prospects for Labeling Law?” *The Wall Street Journal*, November 19, 1999, A1.

31. The secretariat for the committee was DG XII’s Concentration Unit for Biotechnology in Europe (CUBE) (Cantley 1995, 544).

32. This discussion of the positions of DG X11, DG IV, DG III, and DG XI on biotechnology is based on Patterson (2000, 327–28).

were necessary because “Microorganisms with novel properties could cause adverse effects in the environment if they survive and establish themselves, out-competing existing species or transferring their novel traits to other organisms.”<sup>33</sup> In taking this stand, it dissented from a 1986 Organization for Economic Cooperation and Development (OECD) report, which noted that “there is no scientific basis for specific legislation to regulate the use of recombinant organisms.”<sup>34</sup>

Up until this point, Commission communications on biotechnology were largely drafted by DG Science—the other DGs had seen “the mysteries of biotechnology as still playthings of DG XII and their scientific community,” according to one former DG Science employee (Cantley 1995, 535, 543). But it was DG Environment that took the lead in drafting the November 1986 Commission report, “A Community Framework for the Regulation of Biotechnology,” which laid out plans to introduce EC-wide regulatory proposals.<sup>35</sup> The report noted that some member states (including Denmark and Germany) had already moved to adopt national measures on biotechnology, thereby threatening the EC’s single market.<sup>36</sup>

In May 1988, the Commission released drafts for two new directives on GMOs, one on safety procedures for laboratories and the other on the planned release of GMOs into the environment.<sup>37</sup> DG Environment was the *chef de file* for the directive on planned release, which would also deal with the marketing of GM foods and crops. In fact, DG Environment drafted most of the language with very little input from the other directorates general (Patterson and Josling 2002, 9). “Unlike in the US, where EPA’s role had been limited, DG XI became the . . . responsible authority,” note University of California at Berkeley’s David Vogel and Diahanna

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33. European Commission, DG XI/A/2 Biotechnology, *The European Community and the Contained Use of Genetically Modified Micro-organisms* (Brussels, 1988); quoted in Patterson (2000, 327).

34. OECD, “Recombinant DNA Safety Considerations” (1986); quoted in Cantley (1995, 550).

35. According to the report, the Commission’s intention was to introduce proposals for Community regulation of biotechnology “with a view to providing a high and common level of human and environmental protection throughout the Community, and so as to prevent market fragmentation by separate unilateral actions by Member States.” The report added, “microorganisms are no respecters of national frontiers, and nothing short of Community-wide regulation can offer the necessary consumer and environmental protection.” European Commission, “A Community Framework for the Regulation of Biotechnology,” November 4, 1986, vii, viii, quoted in Cantley (1995, 553).

36. In June 1986, Denmark adopted the Gene Technology Act.

37. Two directives would emerge from this effort—Directive 90/219, on the contained use of GMOs (which focused on safety procedures for the laboratory), and Directive 90/220, on the deliberate release of GMOs into the environment, which also dealt with the marketing of GM foods. This case will focus on Directive 90/220.

Lynch (2001). As *chef de file*, DG Environment was also able to determine how the proposed directive was presented to the Council of Ministers. It was the Council of Environmental Ministers that received the proposal.

The Commission's draft directive on deliberate release followed the approaches of Germany and Denmark in creating special and distinct regulations for the approval and marketing of GMOs (Shaffer and Pollack 2004, 17). The United States did not support this approach. "By basing the Directive on the technique by which the organism is modified, the EC is regulating organisms produced by a given process," noted one government statement.

As expressed in the US Coordinated Framework for the regulation of biotechnology, the US generally regulates products rather than the process by which they are obtained. We are concerned whether differences in approaches and their implementation may lead to difficulties in our attempts to achieve international harmonization. It is important to understand that whether an organism is "unmodified" or "genetically modified" is, in itself, not a useful determinant of safety or risk.<sup>38</sup>

In August 1989, a number of companies involved in biotechnology expressed their concerns about the lack of overall coordination in the proposals to regulate biotechnology and argued the need for science-based regulations based on the safety of the product, not the process by which it was made, in a letter sent to EC President Delors and the commissioners. But the group—the Senior Advisory Group for Biotechnology (SAGB)—was not organized in time to affect the passage of the directives (see Patterson 2000, 334).<sup>39</sup>

In April 1990, the European Council adopted the Deliberate Release Directive (90/220) creating a complicated approval procedure for GM crops. The directive required an environmental risk assessment to be carried out before any GM crop or food could be cultivated or placed on the market. Individual member states were given a significant role in the process. Any individual or firm seeking to market or cultivate a GM product was required to submit a request (with the completed risk assessment) to the member state in which it would first be marketed. That country would approve or reject the application. If it was approved, and if no objections were raised by the European Commission or other member states, then the product could be marketed throughout the European Community.

However, if the request was rejected or faced any objections, then the application would be forwarded to the European Commission. The Commission's decision would be voted on by a regulatory committee of

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38. US Ambassador to the European Communities, "International Harmonization in the Biotechnology Field," July 7, 1989; quoted in Cantley (1995, 559).

39. The founding members of SAGB were Monsanto Europe, Hoechst AG, ICI PLC, the Ferruzzi Group, Rhône-Poulenc, Sandoz, and Unilever (Patterson 2000, 334).

member-state representatives. If a qualified majority of the committee supported the Commission's decision, it was approved.<sup>40</sup> If not, the decision would be forwarded to the Council of Ministers, where it could only be rejected by a unanimous vote. Failure to act by the Council in three months would result in the adoption of the Commission's decision. Finally, in a move that would become important later, Article 16 of the directive also allowed individual member-states to "provisionally restrict or prohibit the use and/or sale" of a GM product as a safeguard measure (on the approval process, see Shaffer and Pollack 2004, 19–20).

## European Food Scares and the Introduction of GM Crops

In 1996, the year GM crops went into commercial production in the United States, food safety became a burning issue in Europe. The European Commission banned all exports of British beef in response to the appearance of bovine spongiform encephalopathy (BSE), popularly known as mad cow disease. The deadly brain disease had spread through British herds from processed cattle feed containing the ground-up remains of already-infected animals (using animal parts in feed was outlawed in 1996). The condition was transmissible as new variant Creutzfeldt-Jakob disease (nvCJD) to humans who ate brain or spinal material from afflicted animals. After a long incubation period that could extend decades, the disease induced dementia and death. Britain was forced to slaughter hundreds of thousands of cattle, and most countries banned imports of British beef. And because UK government officials had initially assured consumers that eating beef from diseased animals posed no danger, the mad cow outbreak also magnified Europeans' distrust in governments' abilities to monitor food safety. Robert Paarlberg sums up the result: "The believabilities and credibility of the European regulatory system was undercut." Similarly thrown into doubt were modern methods of industrial farming and food processing. In the end, the BSE crisis was a multibillion-dollar catastrophe for Europe.

Other questions about food safety and industrial farming methods were raised in 1996 when the United States brought a WTO case against the European Union over its ban on hormone-treated beef. In the United States, hormones were widely used to speed growth and lean-meat production in beef cattle. In 1989, Europe had banned the use of such hormones, effectively closing its market to US beef. To justify their position, some European officials invoked the "precautionary principle," claiming that it entitled the European Union to prohibit or restrict products that were suspected, but

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40. A qualified majority is not a simple majority. Each member state is given a certain number of votes based on its population. As of November 2004, a qualified majority in the European Council is 232 votes out of a total of 321. A majority of the countries must also be in favor (see <http://europa.eu.int>).

not proved, to be hazardous. In addition, officials argued that European consumers had made clear their desire not to eat beef from cows raised with hormones. For its part, the United States argued that the European Union was protecting its beef market from foreign competition by invoking scientifically unsupported claims about the harmful effects of hormones. The case would be decided under the WTO's Agreement on Sanitary and Phytosanitary Standards (SPS), which mandated that measures taken by member countries to protect human, animal, or plant health or life must follow international standards or be based on science.

Interestingly, not every GM food introduced to Europe met resistance. In 1996, GM tomato puree was sold in the United Kingdom by Safeway and Sainsbury's supermarkets. Marketed by the UK-based Zeneca Group,<sup>41</sup> the puree was made with GM tomatoes designed to produce more pectin and less water, thereby reducing the need for heat treatment and concentration before canning. The production advantages were transferred to consumers in the form of cost savings (Bernauer 2003, 24).<sup>42</sup> Safeway and Sainsbury's did not try to hide the technology—in fact, a prominent label on each can informed shoppers that the puree was made from “genetically modified” tomatoes. The Safeway label explained, “This modification helps the farmer to harvest the crop at the best time, which in turn leads to a more usable, ripe fruit. Less energy is used in processing these tomatoes when compared to non-modified types.” Initial sales were brisk; by early 1998, more than 1.6 million cans of the puree had been sold.<sup>43</sup>

The European Union first approved a GM crop in May 1996: Roundup Ready soybeans, soon followed by Novartis's Bt corn. Using a gene that conferred resistance to its Roundup herbicide, Monsanto had developed the soybeans to yield larger harvests at lower costs. One of the first projects of Peter Scher, the new chief of staff at the Office of the USTR and later the special trade ambassador for agriculture, was to monitor the European approval process. “I stayed up all night trying to get a Portuguese minister to vote ‘yes,’” he remembers.<sup>44</sup> The Advisory Committee on Novel Foods and Processes within the British Ministry of Agriculture, Fisheries,

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41. Zeneca Group would later merge with the Swedish drug company Astra to become AstraZeneca.

42. Zeneca officials announced that the product would be 10 percent cheaper than conventional tomato puree. According to British news reports, a 170-gram can of the GM puree cost 29p, which would buy only 140 grams of the traditional product (“On Sale Now, the Puree Taste of the Future,” *Daily Mail*, February 5, 1996, 7).

43. Paul Durman, “Sales of Modified Tomato Puree a Success,” *The Times* (London), February 18, 1999. See also Alison Goddard, “A Puree Genius at His Work; Interview with Don Grierson,” *The Times Higher Education Supplement*, July 17, 1998, 16.

44. Unless otherwise noted, all quotes from Peter Scher are from a 2005 interview with the author. Scher served as USTR chief of staff from 1995 to 1996 and USTR special trade ambassador for agriculture from 1997 to 2000.

and Food noted that the flour and oil made from the soybeans contained no trace of the gene or the enzyme it produced and could be sold without special labeling. “The flours produced by ordinary soya and the genetically modified form are indistinguishable,” said Professor Derek Burke, the committee’s chairman.<sup>45</sup>

Within months, however, European consumer and environmental groups had taken a stand against Roundup Ready soybeans as “their main line of resistance against a coming wave of bioengineered crops,” according to the *New York Times*.<sup>46</sup> In the end, Greenpeace and Friends of the Earth—the two largest environmental interest groups in Europe—would make campaigning against GM foods one of their top priorities. Groups like Greenpeace believed that scientific understanding of the impact of GMOs on the environment and human health was inadequate. Once these organisms were released into the environment and the food chain, the organization argued, there was no way of recalling them. Critics also voiced continuing ethical concerns about the transfer of genetic material across different species and worried about decreasing biodiversity.

In November 1996 Greenpeace sent out a barge in an attempt to block the freighter *Ideal Progress*, which contained the first shipment of Roundup Ready soybeans, but the freighter successfully docked in Hamburg, Germany. In Germany, Unilever, Nestlé Deutschland A.G., and other packaged-food companies pledged not to use the Monsanto soybeans. While many companies, including Swiss-based Nestlé S.A.—the parent of Nestlé Deutschland—stressed their commitment to the new products and saw their acceptance as inevitable, they were worried about consumer response. “The soya bean has wide-ranging approval and in our assessment it is safe,” said Frank Vanoooyen, a spokesman for Unilever in the Netherlands. “But the fact remains we are a consumer-driven company, and therefore we leave the decision up to our operating companies on a country-by-country basis.”<sup>47</sup>

Controversy also grew over the approval of Novartis’s Bt corn. In April 1997, the European Parliament challenged the Commission’s decision to approve the corn, and called on the Commission not to implement that approval pending further investigation. “Most disturbingly for the European Union, whose internal market provides for the free movement of goods (including agricultural goods),” notes the European academic Thomas Bernauer, “some EU countries imposed unilateral restrictions or bans on GM products that had been cleared by the European Union” (2003, 45). In-

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45. Burke, quoted in Nigel Hawkes, “Superbean Leads Shops into Battle with Gene Scientists,” *The Times* (London) August 21 1996.

46. Youssef M. Ibrahim, “Genetic Soybeans Alarm Europeans,” *The New York Times*, November 7, 1996, D1.

47. Information about Nestlé and Vanoooyen, quoted in Ibrahim, “Genetic Soybeans Alarm Europeans,” D1.

deed, Austria, Italy, and Luxembourg banned the importation of the corn under the 90/220 safeguard clause.

It was in this environment that the European Parliament and Council turned to making rules for foods containing or produced from GM crops. On May 15, 1997, these rules came into force under the Novel Foods and Novel Food Ingredients Regulation 258/97, which supplemented but did not replace Directive 90/220. A “novel food” was defined as one that was hitherto unknown in Europe. The regulation created an approval process for such foods that was similar to the approval process of Directive 90/220.<sup>48</sup> It also mandated that foods containing or derived from GMOs be so labeled, but it failed to define a threshold percentage of GM ingredients a product could contain before triggering this requirement. In addition, the regulation did not apply to granted or pending approvals such as Bt corn or Roundup Ready soybeans (Bernauer 2003, 47). Dissatisfied, some countries started to introduce their own labeling regulations. In response, fearing that such unilateral actions could confuse consumers and distort the European Union’s single market, in September 1997 food safety representatives from the 15 member states unanimously passed additional regulations requiring labels for foods produced from the Bt corn and GM soybeans that were already on the market.<sup>49</sup>

Clearly, one of the challenges of introducing GM products in Europe was the mixed response to the technology. Some Europeans took note of the “astonishing multitude of reactions [among EU member states] to the challenges that biotechnology presented in terms both of public debates as well as regulation” (Torensen et al. 2002, 24). As the debates and regulations continued to evolve, US officials became increasingly concerned about their trade implications for US producers of GM crops. “During the Clinton administration there was a lot of White House interest in this,” remembers Peter Scher.

It was very serious when you looked at how much was being grown within the United States. The failure to approve these [GM] products could have a significant impact on US farm exports. Moreover, one of the most important accomplishments of the Uruguay Round Agreement, which established the WTO, was the adoption of the SPS agreement, the Agreement on Sanitary and Phytosanitary Standards, which required countries to adhere to sound scientific principles in making these types of regulatory determinations. Prior to this, there were few tools available to address these types of issues. We felt that if the EU could ignore

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48. Like Directive 90/220, the Novel Foods Regulation contained a safeguard clause that allowed member states to restrict or suspend the trade or use of a GM food. The regulation also established a simplified approval process for foods derived from, but not containing, GMOs, such as refined oils. These products could be placed on the market provided they were found “substantially equivalent” to existing conventional foods by the competent authority of a member state.

49. Neil Buckley, “EU Wants Labels for Genetically Modified Foodstuffs,” *The Financial Times*, August 4, 1997, 1.

sound science in their regulatory process, it would be a signal to other countries that it was OK to do the same.

US industry was not happy about the European regulatory process. In September 1997, 48 US food industry companies and trade associations wrote to Scher, expressing frustration at the slow pace of EU approval of each new GM variety. "The length of the process was one concern, but the politicization was the bigger problem," says Scher.

Companies that wanted to get approval for a new product had to go through a fairly lengthy process to provide data and other scientific information about these products. They played by the rules and they would meet the standards, but then you'd have European politicians saying, "No, we won't approve that." We weren't suggesting that the EU had to adopt the US regulatory regime. We just wanted a transparent and science-based regime that made sense.

Discussions with European officials about the GM approval process were sometimes challenging. "The problem when dealing with Europe is that there is not one person you can go to and bring your complaints," Scher observes.

Many in the Commission agreed with us, but then you had the member states. The frustrating response I would get from some of the agriculture ministers and trade ministers was, "Our consumers don't want these products," which I always found to be a fairly bogus argument. The issue wasn't whether consumers would buy them, it was whether we had the right to try and sell them. From a trade policy perspective, if we are going to get into a situation where politicians can use what they believe is consumer acceptance or lack of acceptance as a basis for stopping trade, how do you control that? Think if we said, "US consumers don't like German cars. Sorry. We are not going to let you sell them." You can't have a trading system based on that principle.

## The De Facto Moratorium

In the end, no food containing GMOs would be approved under the terms of Europe's 1997 Novel Foods Regulation.<sup>50</sup> Instead, the process ground to a halt in October 1998 when a number of member states led by France said they would block GM product approvals until safety and labeling rules were further tightened.<sup>51</sup> (Before 1998, 11 GM agricultural crops had been approved in the European Union.) In other words, the European Union effectively placed a moratorium on the approval of additional GM prod-

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50. Though no food containing GMOs was approved under the regulation, some foods that were derived from but no longer contained GMOs themselves were approved after being found "substantially equivalent" to existing foods in "their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein" (Article 3; quoted in Shaffer and Pollack 2004, 21).

51. Pew Initiative on Food and Biotechnology 2005, 10.

ucts. US trade officials were not completely surprised. "I think the moratorium had been building for years," Scher says. "Frankly, there was really an informal moratorium before the moratorium started." Though European Commission officials initially indicated that product approvals would resume, the process remained stalled.

In 1999, high-level discussions began between US government officials and the European Commission in an effort to resolve the growing trade dispute. "On one level it was helpful in terms of developing a dialogue between the US and the European Commission," remembers Scher. "But ultimately, the problem wasn't really the Commission. It was mostly the member states."

As negotiations continued, food scares featured prominently in the European media. In May 1999, following a TV report on contaminated animal feed in Belgium, European retailers began yanking from their shelves foods feared to have been tainted with dioxin. At the order of the Commission, Belgium destroyed huge quantities of chicken, dairy products, eggs, baked goods, and some beef products. Because Belgian government officials had reportedly known about the tainted feed, the dioxin crisis led to the resignations of Belgium's farm and health ministers, and ultimately toppled the incumbent Belgian government. The US response was to halt all EU poultry and pork imports, an action that some observers criticized as based more on fear than on fact. A *Journal of Commerce* editorial described the move as "ironic" in light of US diplomats' concurrent efforts to convince Europe that its fears about GM crops and growth hormones were rooted in emotion rather than science.<sup>52</sup>

In another incident, hundreds of people in Belgium and France, including children, reported feeling ill in June 1999 after drinking Coca-Cola products. In the company's largest-ever product recall, 17 million cases of Coke, Fanta, and Sprite were pulled off the shelves. Later, in 2001, English farms were hit by foot-and-mouth disease. The severe measures taken to quickly bring the outbreak under control included the slaughter of more than 4 million cattle, sheep, and pigs. Seventy countries imposed bans on importing UK animal products (Josling, Roberts, and Orden 2004, 89). These events also shaped opinions in Europe about the food regulatory system.

The European movement against GM food moved into full swing. In May 1999, Greenpeace launched its True Food campaign, which took aim at the release of GMOs into the environment. In a nationally publicized event in England, Greenpeace volunteers dressed in white decontamination suits entered a GM cornfield and attempted to cut down the crop and seal it in bags. In June, Prince Charles announced that he was barring new tenant farmers on his land from using GM products, pending further testing. "I happen to believe that this kind of genetic modification takes

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52. "Global Food Panic," editorial, *Journal of Commerce*, June 9, 1999, 7.

mankind into realms that belong to God, and to God alone," the Prince of Wales said (quoted in Specter 2000, 58). Green Party representatives in member-state parliaments also rejected GMOs. However, some observers argued that GM products could actually help the environment, pointing out that farmers who planted insect-resistant crops would reduce their pesticide use.

In Europe, the primary target for concerns about biotechnology was the Monsanto Company. For one thing, Monsanto chose to be aggressive in pushing GM foods in Europe. Convinced of the merits of its products and faced with competition from other companies, the company used what some called a "legal approach" in its efforts to win product approvals. Observers also noted that Monsanto's enormous investment in GM crops made it a target. Lord Peter Melchett, who led Greenpeace's efforts to stop the use of GMOs, declared, "Of all the companies in this business, Monsanto is the most committed to agricultural biotechnology. They are no worse than DuPont. But DuPont can survive without genetically modified organisms, and I don't think Monsanto can. So we have had an opportunity with them that we did not have with anyone else" (quoted in Specter 2000, 63).

To improve public perceptions of GM foods, Monsanto began a \$1.6 million advertising campaign in the United Kingdom and France (Vogel 2001, 9).<sup>53</sup> Monsanto invited European companies to participate in the campaign, but Zeneca, Novartis, and others declined. "Corporate-backed issue campaigns aren't the European way," noted the *Wall Street Journal*. In June 1998, a series of advertisements debuted in British newspapers. One ad featured hungry children in developing countries and stated, "While we'd never claim to have solved world hunger at a stroke, biotechnology provides one means to feed the world more effectively."<sup>54</sup> The company's public relations campaign did not have the desired effect; Monsanto continued to be a lightning rod in the biotechnology debate, and it admitted that it had acquired "bogeyman" status. "Greenpeace and so on are doing a much better job than we are," conceded Monsanto president Hendrik Verfaillie.<sup>55</sup>

More companies backed away from marketing GM foods. By July 1999, Sainsbury's had eliminated GM ingredients from its own store brands and both Sainsbury's and Safeway had withdrawn the GM tomato puree

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53. By March 1999, Monsanto had spent an estimated \$5 million on advertising and public relations activities related to GM foods in Europe (Nikki Tait and Vanessa Houlder, "Monsanto Admits Promotion of Modified Foods in Europe Has Backfired," *The Financial Times*, March 15, 1999, 18).

54. Scott Kilman and Helene Cooper, "Crop Blight: Monsanto Falls Flat Trying to Sell Europe on Bioengineered Food," *The Wall Street Journal*, May 11, 1999, A1.

55. Tait and Houlder, "Monsanto Admits Promotion of Modified Foods in Europe Has Backfired," 18.

that had initially sold so well (see Bernauer 2003, 24). Switzerland's Novartis also confirmed that it would stop using GM soy and corn in its Gerber brand baby food, not because it had any doubt about the safety of the genetically engineered crops but because buyers seemed to be wary of them (the company continued to sell GM seeds).

Concern about GM food was spreading to nations outside of Europe. Japan, South Korea, Australia, and New Zealand made plans to begin labeling some GM foods, including heavily imported products such as GM soybeans and GM corn, if intended for human consumption (Paarlberg 2000, 24). Many of these countries did not accept all of the GM varieties approved in the United States. In addition, some observers noted, the US approach to GMOs, in both government and industry, was evolving. In 1999, the EPA requested that farmers plant conventional crops around GM crops to act as a "buffer." And the USDA announced it was setting up an independent scientific review of its GM crop approval process in order to bolster public confidence and ensure consumer safety.<sup>56</sup> Also in 1999, Archer Daniels Midland Company, a major US grain processor, told farmers to begin efforts to segregate GM crops from conventional crops. Though "supportive of the science and safety" of GM crops, the company wanted to supply the growing number of overseas customers who were skeptical of such claims.<sup>57</sup>

Meanwhile, the EU Council began debating a new directive on the release of GMOs into the environment; it would replace Directive 90/220. In June 1999, the Environmental Council reached a political agreement, but some member states balked and demanded additional legislation. The Danish, Greek, French, Italian, and Luxembourgian delegations called for the labeling and traceability of GMOs and all GMO-derived products, declaring that "pending the adoption of such rules, in accordance with preventive and precautionary principles, they will take steps to have any new authorisations for growing and placing [GMOs] on the market suspended."<sup>58</sup>

During this time, the United States seriously considered bringing a case against Europe at the WTO. "We talked about it for a long time," says Scher, "but it didn't seem to make sense in 1999 and 2000." One issue was competing priorities. In 1999 the USTR was both negotiating a major market access agreement with China and preparing for the Seattle WTO ministerial. US officials were also concerned that filing a complaint at the WTO

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56. David Barboza, "Monsanto Faces Growing Skepticism on Two Fronts," *The New York Times*, August 5, 1999, C1.

57. Scott Kilman, "ADM Warns Grain Suppliers to Start Segregating Genetically Altered Crops," *The Wall Street Journal*, September 2, 1999, A2.

58. "Declaration by the Danish, Greek, French, Italian and Luxembourg Delegations Concerning the suspension of new GMO authorizations," 2194th Council Meeting, Environment, Luxembourg, June 24/25, 1999.

could have the unintended consequence of extending the existing European moratorium. “The dilemma was that if you go to the WTO, you could just end up stopping the clock,” Scher points out. “Going to the WTO takes a long time and the fear many officials had was that once we launched a complaint, it would just become an excuse for European officials to say, ‘Well let’s just hold off on everything until we hear what the WTO says.’”

Some also wondered what would be gained by bringing a case to the WTO. In its WTO case against Europe’s ban on beef raised with growth-promoting hormones, the United States had emerged the winner. But the beef ban remained in place, even after the United States imposed punitive tariffs on \$117 million of European food imports beginning in 1999. (WTO rules allow the unilateral imposition of trade sanctions only if the defendant refuses to comply after “losing” a case.) As former US ambassador to the European Union Richard Morningstar puts it,

As I saw it at the time, the biggest problem with a WTO GMO case was: What happens if we were to win the case? It could be very similar to the beef hormone case where we won, some form of sanctions was awarded, but then the ban continued. If we won this case, would the EU be willing to try and force member states to allow GMOs, or would they just simply take the political decision to accept sanctions? So there was a reluctance to bring the GMO case and a hope that maybe the issue could be resolved.<sup>59</sup>

Yet, as some analysts note, the United States significantly benefited from the beef hormone case. Though Europe did not lift its ban, the US victory sent a strong signal to other countries, discouraging them from following the EU policy.

Observers perceived no unified push within industry to bring a WTO GMO case at the time. Interested groups ranged from the processed-food industry to seed companies to agricultural companies. “There were different stakeholders in the US who had differing views as to what to do,” remembers Morningstar. “There were even different views within certain companies. For example, a government relations person in Washington would always take a maximalist view on the issue and would push the government to take action. A person at corporate headquarters might take a different view. And their representative in Europe might take a third view. I saw that in any number of instances.”

US-EU efforts to solve the conflict continued. In May 2000, European Commission President Prodi and President Clinton agreed to launch another bilateral effort to solve the GM trade dispute—the EU-US Biotechnology Consultative Forum. The forum, composed of 10 US experts and 10 EU experts, was charged to “consider the full range of issues of concern in biotechnology in the United States and the European Union, most of which

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59. Unless otherwise noted, all quotes from Richard Morningstar are from a 2004 interview with the author. Morningstar was US ambassador to the European Union from 1999 to September 2001.

relate to the use of modern biotechnology in food and agriculture” (EU-US Biotechnology Consultative Forum 2000, 4). Members included a Nobel Prize-winning agriculture scientist and representatives from biotech companies, environmental groups, agriculture associations, and academia.

In December, the forum issued its final report at the EU-US summit meeting. The report called for GM foods to be labeled and traced and urged a precautionary approach to protecting the environment and health. One of the recommendations read: “Consumers should have the right of informed choice regarding the selection of what they want to consume. Therefore, at the very least, the EU and US should establish content-based mandatory labeling requirements for finished products containing novel genetic material” (EU-US Biotechnology Consultative Forum 2000, 16). Some argued that this recommendation differed from FDA regulations, which required labeling of a GM product only if its nutritional value or other characteristics made it different from its conventional counterpart, but others disagreed, pointing to the term *content-based* (as opposed to *process-based*). In any case, according to many observers, the report would provide new ammunition to critics of biotechnology. One industry source noted that its “practical effect is to give license to those who want no risk at all.”<sup>60</sup> Critics of labeling all foods produced from GM crops objected to the expense of such a requirement. US officials estimated that the need to separate GM and conventional foods at every step of production could increase costs by 10 to 30 percent (Paarlberg 2000, 24).

## The Science

As debates over GM food gathered steam, scientists tended to agree that new risks to human health from currently marketed GM foods had not been found.<sup>61</sup> Some GM crops had been on the market for a number of years, and scientific evidence for any human health risks was negligible. As one historical overview noted, “Twenty-five years have elapsed without a single major accident caused by biotechnology” (Torresen et al. 2002, 22). While there were concerns about the potential for health problems in the future, such as the introduction of GM products that contained a human allergen, many NGOs chose not to make the human health risks of agricultural biotechnology the central component of their campaigns.<sup>62</sup>

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60. “Expert Panel Recommends Strict Regime for Biotechnology,” *Inside US Trade*, December 22, 2000.

61. These researchers included European scientists whose studies were published by the EU Directorate of Research, the Royal Society of London, and the French Academy of Sciences.

62. However, a new debate was growing about plants that were genetically modified to produce pharmaceuticals—some feared that traits from these plants could contaminate the food supply.

Some disagreement existed as to the long-term environmental risks of GM crops (Bernauer 2003, 27). In May 1999 John Losey, an entomologist at Cornell University, fed monarch butterflies milkweed dusted with pollen from Bt corn. Forty-four percent of the monarch larvae died, while the entire control group survived. The British journal *Nature* rejected the article documenting these results but carried a letter from the researchers (Losey, Raynor, and Carter 1999, 214). Some media reports of the findings were dramatic—a *Washington Post* headline read “Biotech vs. ‘Bambi’ of Insects? Gene-Altered Corn May Kill Monarchs.”<sup>63</sup> But Losey himself noted that his study was not conclusive. “We need to look at the big picture here,” he said. “Pollen from Bt corn could represent a serious risk to populations of monarchs and other butterflies, but we can’t predict how serious until we have a lot more data. And we can’t forget that Bt corn and other transgenic crops have a huge potential for reducing pesticide use [because farmers no longer have to spray in the old-fashioned way] and increasing yields.”<sup>64</sup> Subsequent studies conducted by independent research teams under field conditions (not in the laboratory) found that Bt corn pollen posed a “negligible” risk to monarch butterfly populations.<sup>65</sup>

Critics of GMOs also underscored the potential for GM crop traits to be inadvertently introduced to other plants, such as weeds. Others worried about GM crop traits mixing with conventional crops, a process that some called “biotech pollution.”<sup>66</sup> For example, in a front-page story in the *Wall Street Journal*, organic farmers in Europe and the US complained that their crops were being contaminated by GM varieties.<sup>67</sup>

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63. Rick Weiss, “Biotech vs. ‘Bambi’ of Insects? Gene-Altered Corn May Kill Monarchs,” *The Washington Post*, May 20, 1999, A3.

64. Clive Cookson, “Comment and Analysis—The Juggernaut and the Butterfly,” *The Financial Times*, May 22, 1999, 13.

65. For example, see Mark K. Sears, Richard L. Hellmich, Diane E. Stanley-Horn, Karen S. Oberhauser, John M. Pleasants, Heather R. Mattila, Blair D. Siegfried, and Galen P. Dively, “Impact of Bt Corn Pollen on Monarch Butterfly Populations: A Risk Assessment,” *Proceedings of the National Academy of Sciences*, 98, no. 21, Washington, DC, October 9, 2001, 11937-942. This 2-year study suggests that the impact of Bt corn pollen from current commercial hybrids on monarch butterfly populations is negligible.

66. Studies noted that the environmental effects of GM crops, such as gene transfer, were similar to those that existed for traditional agricultural crops. See G. J. Persley, The Doyle Foundation for The International Council for Science, “New Genetics, Food and Agriculture: Scientific Discoveries—Societal Dilemmas,” *The International Council for Science*, June 2003, 29, [www.icsu.org](http://www.icsu.org).

67. Scott Miller and Scott Kilman, “Out of the Lab: Biotech-Crop Battle Heats Up as Strains Mix with Others—Nations Seek Rules to Attempt to Keep Varieties Separate; Fears Hurt US Farmers—Mr. Ballarin’s Tainted Corn,” *The Wall Street Journal*, November 8, 2005, A1.

## Agricultural Biotechnology and International Institutions

### *Codex Alimentarius Commission*

Concerns about trade and GM foods spurred efforts to address agricultural biotechnology on the multilateral level. One organization that turned to the issue of GM foods was the Codex Alimentarius Commission. An international food standards body, Codex was established in 1962 by the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Its main goals were to protect the health of consumers, ensure fair practices in food trade, and coordinate food standards.

Codex moved into the spotlight when its standards and guidelines were recognized under the WTO's SPS agreement in 1994. Under the SPS agreement, WTO members had the right to take measures that protected health and life within their territories, but such measures could not be used to restrict international trade in arbitrary or unjustifiably discriminatory ways. The benchmarks for food safety standards, guidelines, and recommendations would be those established by Codex (see the SPS agreement in appendix 1C in chapter 1 and appendix 6B). While WTO members could set standards higher than the international Codex standard, they needed scientific evidence in order to do so. Codex's new role in world trade arguably made its deliberations subject to more political pressure.

Codex played an important role in the US-EU dispute over beef hormones. A scientific committee commissioned by Codex, the Joint FAO/WHO Expert Committee on Food Additives (JECFA),<sup>68</sup> concluded that residues of the growth-promoting hormones in meat did not create a safety hazard to humans as long as their use followed proper veterinary practice. In 1995, Codex representatives voted 33–29 to adopt standards on the hormones that were supported by the United States—though Europe lobbied hard to defeat them.<sup>69</sup> According to Lester Crawford, the former head of the FDA's Center for Veterinary Medicine and a US representative to Codex, the Codex vote “marginalized the Europeans for sure. They had staked a lot of political and Codex capital in their position. And once they lost that, then their side went into retreat and [the hormone case] was immediately referred to the WTO.”<sup>70</sup> In 1997, as noted above, the WTO ruled against Europe in the beef hormones case, declaring that

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68. JECFA is made up of independent scientists serving as individuals, not as representatives of their governments or other organizations.

69. The vote established maximum residue limits (MRLs) for the hormones in meat.

70. Crawford quoted in Chapter 1.

the European Union had not provided the scientific evidence necessary to impose rules stricter than the Codex standards.

Also in 1997, Codex failed to adopt a draft standard on rbST, the hormone produced by GM bacteria to increase milk production in cows. Setting a Codex standard for rbST was strongly opposed by Europe, and the issue was sent back to JECFA. After reevaluating the scientific data, JECFA concluded that milk produced by cows treated with rbST was safe for human consumption, but Codex remained divided over the hormone.<sup>71</sup> In 1999 and again in 2003, the EU perspective prevailed—unlike in the beef hormones case, where the US position won out—and the standard failed to be adopted; it remained parked at Step 8 of the eight-step Codex approval process. The United States reaffirmed its position that the establishment of a standard for veterinary drugs was a food safety issue and that maximum residue limits (MRLs) for rbST should be adopted.<sup>72</sup>

In 1999, Codex set up a task force to spend four years looking at GM foods. The stated goal of the Ad Hoc Task Force on Foods Derived from Biotechnology was to “develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced in foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices.”<sup>73</sup> European pressure led to the inclusion of “other legitimate factors” in addition to scientific evidence and risk analysis. The Codex task force, which was chaired by Japan, included not only scientists but also representatives from governments of Codex member countries, consumer and industry organizations, and international NGOs.

The group’s first meeting was contentious. While US members argued that the task force should consider only science when evaluating the safety of foods derived from biotechnology, European members believed that additional issues should be taken into account. “Essentially the entire meeting was spent discussing what the task force should look at and what it should not look at,” says a US Codex representative.

The task force acknowledged that there was a raft of other issues such as labeling, ethics, animal welfare, consumer right to know, environmental concerns—all of these things that we agreed are important. But [the United States] said those issues are not within the mandate of Codex and therefore Codex should stick strictly to

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71. JECFA also concluded that bST residue levels in milk were very low and that bST naturally found in milk is nontoxic. According to JECFA, no MRL was necessary when rbST was administered properly.

72. “Codex Holds Draft Maximum Residue Levels for BST at Step 8,” *Food Chemical News* 41, no. 21, July 12, 1999.

73. FAO press release 00/16, “Codex Alimentarius Commission Task Force Opens Session to Develop Standards and Guidelines on Biotech Foods,” March 14, 2000.

food safety. Everyone agrees what the safety questions are; it is all of these other issues that are much, much more difficult. In the end, the task force decided it would simply look at the science of evaluating the safety of foods derived through biotechnology.

It focused first on GM foods of plant origin (rather than animals or microorganisms). The scientific data were provided by the FAO and WHO, which set up independent expert consultations to offer advice on the safety and nutritional features of foods derived from biotechnology.

### ***The Biosafety Protocol***

Meanwhile, trade and GMOs were also being debated in negotiations under the auspices of the United Nations. Europe and some developing countries worked to include provisions on trade and biotechnology in the 1992 United Nations Convention on Biological Diversity. While these efforts were unsuccessful, language in the convention allowed participating governments to explore the need for a supplementary agreement on trade and GMOs that might harm biological diversity.

In the mid-1990s, European and other countries pushed to begin negotiations for such an agreement, later called the Biosafety Protocol (also known as the Cartagena Protocol).<sup>74</sup> Because the Senate had failed to ratify the Convention on Biological Diversity due to objections from a blocking minority, the United States could not formally participate in these talks. However, along with Canada, Australia, Uruguay, Argentina, and Chile—grain-producing nations known as the Miami Group—it blocked the first attempt to negotiate the Biosafety Protocol. In early 1999, the talks recommenced. The United States fought for language that would place the protocol under WTO authority, but the European Union joined many developing countries in thwarting this move. “When the protocol was negotiated, the United States and other members of the Miami Group worked hard to insert something called a savings clause into the protocol, which would have left the authority of the World Trade Organization unchallenged and intact,” says Robert Paarlberg. “There would have been reference to the continued authority of the WTO, but the US could not get that savings clause inserted.” As recalled by Calestous Juma, the former executive secretary of the Convention on Biological Diversity and now profes-

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74. See the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article I: “In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”

sor of the practice of international development at the John F. Kennedy School of Government, “Those countries that already had some biotechnology capacity lined up with the US but those that didn’t defined it as a threat and lined with the Europeans.”<sup>75</sup>

In the end, the United States came to support the Biosafety Protocol after ensuring that it would apply only to living modified organisms (LMOs), such as GM seeds for planting, and not GMO commodities used for processing and feed. In January 2000, more than 130 countries adopted the Biosafety Protocol, which would enter into force in September 2003. The European Union ratified it in 2002.

Unlike the WTO’s SPS agreement, the Biosafety Protocol explicitly addressed the precautionary principle, stating in Article 10 that a “lack of scientific certainty” could justify a country’s rejecting imports of LMOs.<sup>76</sup> “That is very different from the WTO standard,” explains Paarlberg. “The SPS agreement says that you need to have a science-based risk assessment to back up any restrictions on imports. You can block imports on a provisional basis while you are gathering more information, but you can’t block imports on a precautionary basis.”<sup>77</sup>

Some observers believe that by enshrining such language in the Biosafety Protocol, Europe was building an international case for its approach to GM foods. Codex debated the significance of the Biosafety Protocol, and some members suggested that it should adopt similar language. “It has definitely been a point of contention,” says a US Codex representative. For example, in 2001, the Codex Executive Committee issued a recommendation that Codex should ensure “coherence between Codex and texts arising from the Cartagena Protocol dealing with such matters as traceability, labeling and identification of Living Modified Organisms used as food.”<sup>78</sup>

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75. Unless otherwise noted, all quotes from Calestous Juma are from a 2005 interview with the author.

76. “Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects” (Biosafety Protocol, Article 10.6; similar language appears in Article 11.4). See also Annex III, which deals with risk assessment: “Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.”

77. Many in Europe claimed that Article 5.7 of the SPS agreement indirectly sanctioned the use of the precautionary principle by allowing members to take provisional measures to protect plant and animal health while they are conducting further scientific research.

78. “Codex Rejects EU Effort to Endorse Biotech Traceability, Labeling,” *Inside US Trade*, July 27, 2001. See also “EU to Seek International Backing for Biotech Regulations,” *Inside US Trade*, February 16, 2001.

The United States, with support from Argentina, Malaysia, and other countries, rejected the recommendation.

### ***The World Trade Organization***

Efforts to bring discussions about trade and biotechnology directly into the WTO were also under way. At the November 1999 WTO ministerial in Seattle, the United States and Canada sought to establish a biotechnology working party. Canadian officials noted that such a group was necessary to move the GMO debate out of nontrade arenas, such as the proposed Biosafety Protocol.<sup>79</sup> In a controversial move, EU Trade Commissioner Pascal Lamy initially agreed to the plan. European environmental groups and many member states were incredulous. “You didn’t just shoot yourself in the foot. You machine-gunned yourself in the foot,” Denmark’s trade minister told Lamy. The environment ministers of France, the United Kingdom, Italy, Denmark, and Belgium issued a joint statement calling the Biosafety Protocol negotiations the only “proper forum for deciding a multilateral approach to biotechnology issues” and claiming that the talks would be undermined by the creation of the WTO working group. Greenpeace also criticized Agriculture Commissioner Franz Fischler for the move, declaring, “He will have a lot of explaining [to do] to the millions of citizens across Europe and the rest of the world who demand the right to choose not to swallow genetically-modified food.” In response, the Commission released a statement noting that its priority remained the timely completion of the Biosafety Protocol and that no WTO working group would interfere with Europe’s power to reject GM seeds on safety grounds. Lamy admitted, “We have taken flak from all sides . . . the Member States, parliamentarians, unions, businessmen. But that is my job.”<sup>80</sup>

In the end, the Seattle ministerial collapsed and efforts to launch the working party did not move forward. According to sources speaking to *Inside US Trade*, Assistant USTR for Agricultural Affairs Jim Murphy told US agricultural and biotechnology groups that the United States had secured support for a WTO working group and had moved on to the question of how to formally propose this approach when the ministerial broke down.<sup>81</sup>

Around the same time, in September 1999, the European Commission formed a new directorate for health and consumer protection, which had

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79. “US, Ag Interests Split on How to Tackle Biotech in WTO Round,” *Inside US Trade*, September 24, 1999.

80. All quotations in the paragraph are from “EU/WTO: Seattle Delegates Grind Through Painful Agenda,” *European Report*, no. 2456, December 4, 1999.

81. “US Seeks Biotech Deal in WTO, to Announce Group at Summit with EU,” *Inside US Trade*, December 10, 1999.

a special responsibility for food safety. The directorate's first commissioner, David Byrne, had served as Ireland's attorney general and as one of the negotiators for the 1998 Good Friday Agreement that provided a framework for resolving hostilities in Northern Ireland. In his new role, Byrne attended the WTO ministerial in Seattle. During his time there, Byrne spoke to many US officials and left the ministerial with strong feelings about the need to clarify the European Union's position on the precautionary principle. As he remembers,

Seattle was a very valuable few days for me because it was the very beginning of my time in the Commission. What struck me when talking to US government officials was the major concern about the application of the precautionary principle. I came back to Europe and spoke to my colleague [Environment] Commissioner Margot Wallström. I told her there was an enormous amount of confusion and distrust in the United States related to the precautionary principle and we should do something about it. And we did.<sup>82</sup>

Returning to Europe, Byrne and Wallström coauthored a communication on the precautionary principle in February 2000, setting out the circumstances under which it should be applied. The paper was welcomed by some in the United States, where the Commission's interpretation of the precautionary principle was viewed as more acceptable than that of some of the member states. As Richard Morningstar puts it,

At the Commission, it was pretty clear that the precautionary principle could only be invoked when a specific risk was identified, that the action taken had to be proportional, time sensitive, and could only be invoked if there was some reasonable scientific evidence to support taking action—even if it was in the minority. Many member states believed the precautionary principle created an absolute right to ban a product just if there was concern.

Byrne also believed that the precautionary principle needed to be discussed at Codex. "It was my ambition to commence a debate in Codex about the precautionary principle and when it should be applied," he says. "That would feed into the SPS agreement and in turn would affect the operation of the WTO. And I have to say that I found it very much an uphill battle to get any discussion in relation to this issue. . . . I couldn't get the US to agree." In the Committee on General Principles, Codex members debated the role of the precautionary principle in risk analysis. For example, European countries hoped to insert a footnote to language outlining a country's ability to take interim health measures that referred directly to the precautionary principle, but the United States and Latin American

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82. Unless otherwise noted, all quotes from David Byrne are from a 2005 interview with the author.

83. "Codex Rejects EU Effort to Endorse Biotech Traceability, Labeling," *Inside US Trade*, July 27, 2001.

countries objected.<sup>83</sup> (At Codex, Europe was represented by the member states.) Industry groups resisted the inclusion of any language referring to the precautionary principle, arguing that such a move by Codex could ultimately erode the protections offered by the SPS agreement at the WTO. These debates would continue for years to come.

## StarLink

In the fall of 2000 GM corn hit the front pages in the United States and disrupted agricultural markets when a type of GM corn called StarLink turned up in laboratory tests of taco shells bought at grocery stores. StarLink was developed by Aventis CropScience of France to resist corn borer insects by producing a protein that acted as an insecticide. In 1998 the EPA had approved the corn for animal feed and industrial use but not for human consumption, concerned that the protein resembled some that were known human allergens. After environmentalists led by Greenpeace and Friends of the Earth demonstrated that segregation had broken down—the corn was found in more than 300 products—Aventis, working with the USDA, took aggressive steps to track down the StarLink corn and compensate its owners for any loss in value. Estimates of the damages to Aventis ran to half a billion dollars. The Centers for Disease Control was unable to confirm a single allergic reaction to the StarLink protein.

This incident highlighted two growing concerns about the challenge of keeping GM crops separate from conventional crops. First, there was the risk that bioengineered plants might accidentally pass on their modified traits through cross-pollination. Experts said that StarLink—which was planted on less than 0.02 percent of corn cropland in 2000—was most likely bred inadvertently into seed corn through the drift of pollen from other cornfields. Second, the grain-processing infrastructure was not designed to keep grains segregated. “The US system developed over 100 years to handle massive quantities of grain which are basically interchangeable in their suitability for all end uses,” said James Bair of the North American Millers Association, a trade group then representing 45 US milling companies. “That system is fantastic in its ability to do that. But it’s not very nimble when it comes to satisfying special needs.”<sup>84</sup> As a result, some observers say, a key lesson of the StarLink incident was to not grant “split approvals”—allowing GM products to be used in animal feed but not in food market channels.

The StarLink corn debacle also intensified negative attitudes toward GM foods in major foreign markets. US corn exports to Japan, the United

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84. Bair, quoted in Anthony Shadid, “Biotechnology: Against the Altered Grain—Some North American Crops Grown from Bioengineered Seeds Face Bans in Certain Lucrative Export Markets,” *The Boston Globe*, May 2, 2001, C4.

States' biggest corn export market, declined by 11 percent in the months after Japanese tests found traces of StarLink in US shipments.<sup>85</sup> As it stood, while 16 GM corn varieties were approved in the United States, only 10 were allowed in Japan (and just 4 in the European Union). Because Japan imported billions of dollars worth of farm goods, exporters were concerned. Monsanto announced the recall of hundreds of tons of GM canola seed from Canadian farmers because the shipments might have contained genetic material not approved for consumption in Japan.<sup>86</sup> Some US grain processors began discouraging US farmers from growing GM crops. In a radio advertisement aired in Iowa and Illinois, Archer-Daniels-Midland warned farmers they would buy only crops "that have full feed and food approval world-wide."<sup>87</sup> US-based companies as well began to back away from using GM ingredients. Frito-Lay and McDonald's made moves to offer GM-free foods, and H. J. Heinz announced it would eliminate GM ingredients from its baby food products.

Around the same time, Monsanto developed the first genetically engineered variety of wheat designed for sale to farmers, expecting to bring it to market a few years later. Half of all American wheat was exported, accounting for \$3.7 billion in sales in 1999. As news about the Roundup Ready wheat spread, buyers in Japan, Europe, and Egypt said that their consumers would not accept it. A letter from a spokesman for the Japan Flour Millers Association noted that "Japanese consumers are highly suspicious and skeptical about safety of 'genetically modified' farm products. . . . I strongly doubt that any bakery and noodle products made of 'modified' wheat or even conventional wheat that may contain 'modified' wheat will be accepted in the Japanese market." The US wheat industry was responsive to these concerns. "We may in the future have a biotech wheat that the world does want," said Darrell Hanavan, chairman of a joint wheat industry committee on biotechnology. "But we need to proceed now under the assumption that some markets won't want it anytime soon. And the challenge will be to make sure that buyers and their customers get exactly what they want." Phil Isaak, a board member of US Wheat Associates, which promoted American wheat exports for growers, added: "Unless we get worldwide public approval of it, we have to take the position of resisting release for commercialization."<sup>88</sup> Monsanto agreed to hold its plans to release the GM wheat commercially.

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85. Satoko Adachi and Edmond Lococo, "Japan Likely to Return to US Corn; Exports Dropped 11% after Traces of StarLink Found," Bloomberg News, April 22, 2001.

86. Shadid, "Biotechnology." C4.

87. Quoted in Scott Kilman, "Some Grain Companies Dissuade Farmers from Using Biotech Seed," *The Wall Street Journal*, November 20, 2000, B4.

88. All quotations in the paragraph are from Marc Kaufman, "Gene-Spliced Wheat Stirs Global Fears; Buyers Spurn Grain Before It's Planted," *The Washington Post*, February 27, 2001, A1.

Canada, which then exported about 85 percent of its wheat, was also concerned; Algeria, which purchased more than 40 percent of Canada's durum wheat, had recently banned all GM foods. The Canadian Wheat Board, the marketing organization that controlled about 95 percent of Canada's wheat production, lobbied the Canadian government to make market acceptance a factor when deciding whether a GM product should receive regulatory approval. Monsanto opposed the idea—"That would give everyone outside Canada a say in how Canada runs its business," said spokeswoman Trish Jordan.<sup>89</sup>

## New Developments in Europe

In Europe, Commissioner Byrne was working to find a solution to the biotech food challenge. Observers spoke highly of his efforts to manage the US-EU GM dispute and the debates within Europe over food safety. As Ray Goldberg, professor emeritus of agriculture and business at Harvard Business School, reflects,

The globalization of the food system requires a common understanding of standards, a common definition of terms, and common understanding of science. For the long-run mutual benefit of all nations, we have to find that common ground. Commissioner Byrne was a unique person in his ability to create consensus with his background in Ireland and his work to bring different religious groups together. He was the right kind of person for the job.<sup>90</sup>

Richard Morningstar, the former US ambassador to the European Union, agrees that the Commission and David Byrne were trying to find workable answers: "I do think that the Commission was doing their best to try and come to a solution. I think that David Byrne definitely tried his best. He had his own politics to deal with."

In March 2001, the European Parliament and the Council adopted a new directive on the deliberate release of GMOs into the environment—Directive 2001/18/EC—that would supersede Directive 220/90. Under the new legislation, approvals for GM crops would be limited to 10 years (with the possibility for renewal) and environmental monitoring for field trials and commercial cultivation would increase. Approvals and field trials would also be subject to increased transparency, such as public registration of trial sites (Bernauer 2003, 47). For its implementation, all 15

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89. Information about Canadian wheat trade and Jordan quoted in Scott Morrison and Nikki Tait, "Commodities and Agriculture: Concern in Canada over Biotech Wheat: Growers Fear Loss of Exports to Countries That Have Banned GM Food," *The Financial Times*, April 27, 2001, 42.

90. Unless otherwise noted, all quotes from Ray Goldberg come from a 2004 interview with the author.

member states had to create national legislation adopting the directive by October 17, 2002. Twelve of the 15 states would fail to meet this deadline.

Directive 2001/18/EC contained calls for new legislation on labeling and traceability as well. Labeling rules would set a threshold above which consumers would have to be informed of the presence of GM products in food. Traceability rules would require shippers of bulk products to detail what GMO materials could be present and to track and document these materials through any processing and manufacturing steps from farm to fork," as some advocates put it. The European Commission proposed the new rules in July 2001, and debate over the details ensued.

One issue to be determined was what percentage of GM material could be present in a product before it had to be labeled "produced from GMOs." Environmental campaigners hoped to set the threshold at 0.1 percent, while some agricultural ministers were demanding 0.5 percent. A low threshold was particularly important to Germany, where elections were approaching and fears about GM food ran high. "I wanted 1 percent—that was my proposal," remembers David Byrne. "I was advised that 0.5 percent would be difficult to achieve and was impractical." After negotiations with Byrne, EU farm ministers agreed on a level of 0.9 percent for labeling of all food and animal feed containing EU-approved GM material in November 2002. Below this threshold, no label would be required. "I was asked later, 'What is the difference between 1 percent and 0.9 percent?'" Byrne recalls. "I said, 'Mathematically, 0.1; scientifically, none; but politically, all the difference in the world.'"

Many in the United States worried that the labeling and traceability proposals would prove costly, unworkably bureaucratic, and restrictive—and thus harmful to trade. "Potentially, these new regulations would be more disruptive to international trade than the moratorium on new approvals or the Cartagena Biosafety Protocol, because they set in place requirements that would be very difficult for exporters to satisfy," says Robert Paarlberg. And a more fundamental objection was raised to the very idea of labeling GM products. As one senior House Republican aide explains, "The Europeans say consumers need to know what they are buying. But if there is no substantive difference in a product from conventional products and you put a label on it that says 'This contains X,' you are basically saying something could be wrong with it. It is tantamount to putting a skull and crossbones on it, especially in Europe."

Codex also debated the labeling of biotech foods, but was unable to come to any agreement. The United States argued that labeling was appropriate only if there was a significant difference between a GM food and its conventional counterpart; the European Union argued that all foods derived from biotechnology should be labeled. "There is just no compromise between those two positions," says a US Codex representative. "We've been beating our heads on that for years with very little progress." In fact,

discussions on biotech labeling had been under way since 1992. “Codex has been criticized in the past for being too slow in the new trade environment—that we have to develop standards more quickly,” the Codex representative adds. “The poster child for that criticism is biotech labeling.” And the lack of progress could have serious consequences: “Frankly, part of our concern is that if Codex can’t find a way to get over these impasses, it will lose its credibility in the WTO sense. That would be a real tragedy. Codex should be able to develop standards that everyone agrees on, but if we’ve been arguing biotech labeling for 12 years, we are just not doing our job.”

Despite the US lack of enthusiasm for the European legislative proposals, former commissioner Byrne notes the growing recognition that the European approach toward GM food was not motivated by protectionism. US officials “might not agree with [the imposition of labeling and traceability rules], but they understand it was not motivated by trade protectionism,” he says. “They accept that now—they didn’t in 1999 when I was in Seattle. . . . I worked hard on that.” Trade requires consumer confidence, he argues.

A number of US participants agree that protectionism was not the central motivation for the European Union’s de facto moratorium. “When I first got involved in the summer of 1999, [the EU moratorium] was really looked at principally as a trade protectionist issue,” says Richard Morningstar. “Most of those involved in the US, including myself, didn’t appreciate at the time that the issue went far beyond protection and was in fact much more of a political/consumer issue.” Some, including Peter Scher, say that this element distinguished the GM dispute from the beef hormone case: “I think there is some protectionist element to the beef hormone dispute,” he declares. “I don’t believe there is a protectionist element to the GM dispute. I really don’t. I don’t believe it has to do with Europe trying to protect its industry. I think it had to do with the inability or unwillingness of European officials to take politics out of their regulatory decisions.”

As the debate continued, David Byrne was working to create a coordinated food safety system in Europe. The new agency would be known as the European Food Safety Authority (EFSA), and its primary function would be to conduct risk assessments of new food products. While the development of EFSA drew much interest, some noted that its approach to risk would be fundamentally different than that of the US FDA. At the FDA, regulators both assessed the risks of a given product and created the regulations to manage that risk, as guided by applicable statutes. Proponents of this arrangement argued that it ensured a regulatory body that would make rules based on sound science, independent of politics.

EFSA, in contrast, would leave risk management to the Commission and the ministers. Europeans generally argued that a functional separa-

tion between risk assessment and risk management was necessary. Byrne describes that position:

Some people say we must rely on good science and that scientists take decisions that are purported to be purely scientific. But how often is this the case? If they are independent and are also effectively the lawmakers because they are regulating what will happen in relation to all citizens, they are not answerable to anybody. As a lawyer, I have a problem with that. And from a political science point of view, and a democratic accountability point of view, I have a problem with that. I believe that if you have a function in lawmaking, you must be answerable and accountable to the people.

EFSA was established in 2002; as planned, it came into operation in 2003.

## Expanding Resistance

In October 2002 Zambia turned away 26,000 tons of US food aid, invoking the precautionary principle and claiming that the shipments contained potentially unsafe GM corn. Though the country was facing a famine, Zambia's agriculture minister argued that the corn could pollute the country's seed stock and hurt its export markets.<sup>91</sup> According to observers, while food safety and environmental issues related to GM foods dominated discussions in Europe, many developing countries were more worried about exports. In particular, Robert Paarlberg emphasizes, EU export markets were crucial to many African countries. "The European Union imports more agricultural commodities from developing countries than the United States, Canada, Argentina, Japan, and Australia combined," he points out. "So whatever Europe does, Africa likes to follow because African exports are frequently targeted to the European market."

As a result of Zambia's rejection of US food aid, transatlantic tensions increased. "Fairly or unfairly, there was a lot of bad publicity for the EU when the famous Zambia situation happened," says Richard Morningstar. "That [incident] really rubbed people the wrong way in the United States. I think that contributed to the frustration." While some in the United States believed that European officials had encouraged African countries to reject GM foods, others blamed European NGOs.

China also imposed restrictions on varieties of GM crops and required lengthy safety tests and labeling rules before such foods could be imported. Though some hoped that China's entry into the WTO would increase imports of US agricultural products, the sale of US soybeans to

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91. Neil King Jr., "US Ponders Next Course in EU Food Fight—Trade Suit Is Possible in Biotech-Crop Battle for Big Markets in Asia and Elsewhere," *The Wall Street Journal*, December 2, 2002, A4. The leaders of Lesotho, Swaziland, Zimbabwe, Mozambique, and Malawi also initially rejected GM US food aid; but later, after consultations with the WHO, they retracted their bans or accepted milled GM maize (a form that could not be planted).

China dropped by 23 percent from January to September 2002 compared to the same period in 2001.<sup>92</sup> Beijing also prohibited biotechnology companies such as Monsanto and Syngenta from investing in China to develop GM corn, soybeans, and rice seeds. While China justified such moves by stressing its concerns about access to EU agricultural markets, some in the US biotech industry believed that the real motivations were protectionist—China wanted to shield its domestic soybean producers, and also to build its own GM capacity.

At the same time, other countries—including India, Colombia, Honduras, and the Philippines—were adopting GM crops. In Brazil, one of the world’s largest growers of soybeans, many farmers were planting them illegally, a development that took on added significance in light of Brazil’s role as the main source of non-GM produce for Europe.<sup>93</sup> To further increase acceptance of agricultural biotechnology in developing countries, GM crops would have to be developed that directly benefited them. Some research was being undertaken at the international level through the Consultative Group on International Agricultural Research (CGIAR), an alliance of international agricultural centers whose aim is to mobilize science to benefit the poor. Emmy Simmons, who formerly was assistant administrator for economic growth, agriculture, and trade at the US Agency for International Development (USAID), explains: “Within that system, there is research going on to engineer new varieties of crops that are drought resistant or drought tolerant, can overcome aluminum toxicity, or have specific characteristics in terms of nutrient content, for example”<sup>94</sup>—all traits highly important to developing countries.

But funding for such research was limited, especially in comparison with the billions of dollars invested each year by private industry. In 2004, CGIAR spent \$425 million on its research agenda (CGIAR 2004). About 7 percent of that research was dedicated to exploring the solutions that new technologies had to offer, and only about 3 percent of that fraction was dedicated to exploring GMOs (CGIAR 2004–05). USAID had an earmark from Congress to support agricultural biotechnology research, but it amounted to just \$25 million annually. Some have argued that research on behalf of farmers in poor countries should be undertaken by biotechnology companies, but a source in academia strongly disagrees: “That is not a job that should be left to private companies. They would have to invest

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92. Joseph Kahn, “The Science and Politics of Super Rice,” *The New York Times*, October 22, 2002, C1.

93. Edward Alden, Tobias Buck, and Guy de Jonquières, “The Washington-Led Challenge to the European Union Moratorium Will Take Trade Disputes into Untested Areas, Further Straining the Legitimacy of the World Trade Organisation,” *The Financial Times*, May 14, 2003, 21.

94. Unless otherwise noted, all quotes from Emmy Simmons are from a 2005 interview with the author.

millions of dollars in a trait that won't provide adequate return on that investment. That is what the publicly funded international agricultural research centers should be doing."

## Part II: A Case at the WTO

The key question became: Would the Bush administration file a case against the European Union at the WTO over the GM moratorium? Pressure was growing from US farm organizations, the food industry, and biotechnology companies to take the issue to the WTO. A senior House Republican aide notes, "We were continuing to see numbers such as \$300 million in annual losses for corn exports because of a lack of approvals. The problem had been brewing for a couple of years and people were urging the administration to finally bring a case."

In a November 2002 letter, 25 US farm organizations urged USTR Robert Zoellick to "end US patience" and bring the case.<sup>95</sup> "We've been very patient with the Europeans, but their use of this ban as a trade barrier sets a precedent for countries around the world," said Mary Kay Thatcher, director of public policy at the American Farm Bureau Federation. "We rely on export markets for one-third of our crops; this is a nightmare."<sup>96</sup> Key groups that advocated taking action included the National Corn Growers Association, American Soybean Association, the American Farm Bureau, the US Biotechnology Industry Organization, and the National Grain and Feed Association.

The Senate was also exerting more pressure. In a December 19 letter, seven farm-state senators—including Max Baucus (D-MT), the outgoing Senate Finance chairman; his replacement, Chuck Grassley (R-IA); and Tom Harkin (D-IA)—urged President Bush to file a case "without delay." "Despite repeated assurance from European officials that the moratorium would be lifted," they argued, "there is no indication that this will happen in the foreseeable future. Indeed, the situation continues to worsen." The writers also criticized Europe's proposed traceability and labeling rules.<sup>97</sup> House Speaker Dennis Hastert (R-IL), who represented a major corn and soybean producing area, also pressed the Bush administration to challenge the European Union at the WTO, as did Representative Frank Wolf (R-VA), the chairman of the House Agriculture Committee, and Majority Whip Roy Blunt (R-MO).

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95. The letter is quoted in King, "US Ponders Next Course in EU Food Fight," A4.

96. Thatcher, quoted in Elizabeth Becker with David Barboza, "Battle over Biotechnology Intensifies Trade War," *The New York Times*, May 29, 2003, C1.

97. The letter is reprinted in a State Department press release, "Senators Urge WTO Dispute Case Against EU Biotech Policy," December 20, 2002; the other senators who signed it were Kit Bond (R-MO), Pat Roberts (R-KS), Chuck Hagel (R-NE), and Thad Cochran (R-MS).

In December, participants in interagency meetings debated whether to bring a case but reached no consensus. Discussion apparently centered on the possible benefits of bringing a case even if officials believed it would not lead to an earlier lifting of the moratorium. The State Department advocated giving European member-states one more chance to move forward on approvals. In response, the European Commission decided to allow sales of cottonseed oil derived from GM seeds, but not containing GM material. US officials said the decision was a positive signal, but fell short of addressing the issue of the moratorium.<sup>98</sup> The European Commission also wrote a letter assuring almost 200 members of Congress that approvals could start as early as the middle of 2003.<sup>99</sup>

USTR Robert Zoellick was in favor of moving forward with a case, as was US Agriculture Secretary Ann Veneman, but not all Bush administration officials were persuaded. Some worried that a backlash in Europe over the case would complicate US diplomacy on Iraq. In addition, other US-EU trade tensions were on the rise. The WTO had ruled against the United States in the foreign sales corporation/extraterritorial income (FSC/ETI) dispute concerning tax provisions seen as benefiting US companies. In March 2003, EU Trade Commissioner Pascal Lamy announced a draft list of more than 1,800 US products whose export value exceeded \$4 billion that could be subject to retaliatory tariffs unless the United States complied with the WTO ruling.

The GMO issue went up to the cabinet level several times before a decision was made. In the end, the administration decided to bring the case. On May 13, 2003, Zoellick and Veneman announced that the United States was moving forward in requesting WTO consultations with the European Union, backed by Argentina, Canada, and Egypt as co-complainants.<sup>100</sup> "Biotech food helps nourish the world's hungry population, offers tremendous opportunities for better health and nutrition and protects the environment by reducing soil erosion and pesticide use," said Zoellick. "We've waited patiently for five years for the EU to follow the WTO rules and the recommendations of the European Commission, so as to respect safety findings based on careful science."<sup>101</sup> If Europe did not lift its moratorium on the approval of GM commodities by the time the consultation

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98. "Administration Mulls WTO Biotech Case Against EU, Reaches No Decision," *Inside US Trade*, January 3, 2003. Approval of the cottonseed oil was allowed under the EU's 1997 Novel Food Law.

99. "EC Moves to Defuse Possible US WTO Biotech Challenge," *Inside US Trade*, April 18, 2003.

100. Australia, Chile, Colombia, El Salvador, Honduras, Mexico, New Zealand, Peru, and Uruguay expressed support for the US case by joining it as third parties.

101. USTR and USDA press release, "US and Cooperating Countries File WTO Case Against EU Moratorium on Biotech Foods and Crops EU's Illegal, Non-Science Based Moratorium Harmful to Agriculture and the Developing World," May 13, 2003.

period expired, Zoellick said, the United States would request the formation of a WTO panel.<sup>102</sup>

In a speech delivered at the Coast Guard Academy, President Bush added that the EU moratorium impeded the fight against famine. Genetic engineering of crops provided a way to feed more people, especially in Africa, Bush said. "Yet, our partners in Europe are impeding this effort. They have blocked all new bio-crops because of unfounded, unscientific fears. This has caused many African nations to avoid investing in biotechnologies, for fear their products will be shut out of European markets. European governments should join—not hinder—the great cause of ending hunger in Africa."<sup>103</sup> Lamy responded that such accusations were "unacceptable" and "should not be used in this kind of debate" (quoted in Pew Initiative on Food and Biotechnology 2005, 31).

Some observers were surprised at the US move. By May 2003 the EFSA was close to being operational, and EU Health and Safety Commissioner David Byrne expected the moratorium against approving new GMOs to be lifted sometime in the autumn (Goldberg and Hogan 2003, 2). In addition, the new European labeling and traceability rules were close to being adopted. At a time when new laws and institutions were being developed to try to solve the problem, bringing a WTO case appeared to make little sense.

Another argument—that bringing such a contentious case to the WTO would open the organization to further attacks, potentially undermining its authority—fell on skeptical ears. "Trade policy can be funny," says Peter Scher. "Every time a case is brought that someone doesn't like, whoever is on the defending end of it says, 'This is going to bring down the WTO!' The fact is that the WTO was able to handle the beef hormones case and they are handling the GMO case."

Others saw significance in the timing of the US action, pointing out that the Cartagena Biosafety Protocol was scheduled to come into force in September 2003. "The filing of the case was just before the protocol came into force," says Calestous Juma, former executive secretary of the Convention on Biological Diversity. "The US was saying, 'We really want this settled legally as opposed to sorted out politically by the influence of the protocol.'"

Europe warned that taking the dispute to a higher level could create an even stronger backlash against GM foods and thereby frustrate the US objective of opening EU markets. A 2002 European public opinion study had shown that majorities in most EU countries rejected GM foods as

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102. "US To Push WTO Case Unless EU Biotech Moratorium Lifted," *Inside US Trade*, May 16, 2003.

103. President George W. Bush's commencement address at the Coast Guard Academy, May 21, 2003, [www.whitehouse.gov](http://www.whitehouse.gov).

“risky” and “not useful” for society.<sup>104</sup> But some, including Robert Paarlberg, suspect that the European Commission may not have been completely against the idea of a WTO case. He explains:

The European Commission doesn't like encountering defiance from member governments—they want their authority established and they want to get beyond the dysfunctional approval process. One way to do that is to sponsor a new set of regulations on tracing and labeling, which they've done, and to create a higher bar for regulatory approvals, which they've done. But still there is resistance from member governments. So the Commission might not have been altogether opposed to some external pressure from the United States in the form of a WTO case. Indeed, when the WTO case was brought, it didn't take more than about a year for some approvals to be granted.

In addition, a ruling against the European Union might benefit European officials by enabling them to blame unpopular policies on outside pressures.

Initially, it was announced that the United States would be joined by Argentina, Canada, and Egypt as co-complainants in the case. Egypt was in a difficult position, however, since the European Union was its largest export market (and one of its biggest markets for fresh fruits and vegetables). Senate Finance Chairman Grassley sent a letter to Foreign Minister Ahmed Maher, warning that Egypt's failure to join the United States in the WTO case could hurt its chances of reaching a free trade agreement (FTA) with the United States. Grassley said that while he was supportive of a possible US-Egypt FTA, “one of the criteria that ought to be used to determine with whom the United States negotiates future FTAs is whether a country shares the same vision of the global trading system as does the United States. I certainly would like to be able to include Egypt in that camp.”<sup>105</sup> In the end, Egypt decided that it would not support the US complaint at the WTO. Following that withdrawal, US interest in negotiating an FTA with Egypt cooled dramatically. According to one US trade official, Egypt's decision raised doubts about its willingness to live up to other commitments. “Negotiations require being able to follow through on what you said you would do,” he said.<sup>106</sup>

In July 2003, Codex adopted the first-ever international guidelines for evaluating the consumer safety of biotech foods, guidelines developed by its task force.<sup>107</sup> Codex Commission Secretary Alan Randall noted,

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104. Pew Initiative on Food and Biotechnology 2005, 6.

105. Grassley, quoted in “US Announces Panel on EU GMO Moratorium, as Grassley Warns Egypt,” *Inside US Trade*, June 20, 2003.

106. “US Interest in FTA Cools After Egypt Fails to Join GMO Complaint,” *Inside US Trade*, July 4, 2003.

107. The Codex Commission published the guidelines in three documents: *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, and *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant DNA Microorganisms*.

“Consumers can be assured that foods assessed by these methods are fit to eat.”<sup>108</sup> Some analysts pointed out that the adoption of the guidelines strengthened the US position. “If a country was applying more rigorous requirements than the Codex guidelines, the United States would be in a fairly good position to take a trade case against them at the WTO,” says a US Codex representative.

## Arguments at the WTO

After the US-EU WTO consultations on the GM case failed to resolve the dispute, the United States, Canada, and Argentina requested a panel in August 2003. Before the end of the month, the WTO Dispute Settlement Body established a panel on the European Union’s “Measures Affecting the Approval and Marketing of Biotech Products”; its members were named in March 2004.<sup>109</sup> The panel heard arguments from the parties and also met with a group of experts to answer scientific and technical questions on GMOs.

In its arguments to the panel, the United States held that the European Union was in violation of the SPS agreement. As noted above, this agreement applies to measures taken by WTO members for the protection of human, animal, or plant life or health that affect international trade (for a definition of SPS measures, see Annex A.1 in appendix 1C in chapter 1). Members are obligated either to follow international standards or to ensure that any SPS measures designed to result in higher levels of protection are supported by risk assessments based on available scientific evidence.

First, the United States argued that Europe’s biotech approval regime was “unquestionably” an SPS measure because both Directive 2001/18 and Directive 90/220 state that one of their objectives is “to protect human health and the environment” when placing GMO products on the market or deliberately releasing them into the environment, and Regulation 258/97 states that foods “must not present a danger for the consumer.” The United States alleged that the European Union’s failure to approve any new GM products since 1998 constituted a general moratorium. Though adopted “in a nontransparent way, without official publication,” this moratorium clearly existed, affected international trade, and was an SPS mea-

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108. FAO/WHO press release, “Codex Alimentarius Commission Adopts More Than 50 New Food Standards; New Guidelines on Genetically Modified and Irradiated Food,” July 9, 2003.

109. WTO Director-General Supachai Panitchpakdi selected the panelists. The chair was Christian Haerberli, deputy head of the GATT/WTO division in the Swiss Federal Office for Foreign and Economic Affairs, and he was joined by Mohan Kumar, India’s deputy high commissioner in the Diplomatic Mission in Sri Lanka, and Akio Shimizu, a law professor at Waseda University in Tokyo, Japan. (See “ASA Takes Lead in Pushing for New WTO GMO Case Against EU,” *Inside US Trade*, March 12, 2004).

sure. Similarly, the United States argued that the SPS agreement also covered the European Communities' "product-specific moratoria"—namely, its failure to consider 27 pending applications of biotech products for approval.<sup>110</sup>

### ***Undue Delay***

The United States made clear that it was not asking the panel to judge whether Europe's legislation on novel foods and their deliberate release was WTO-consistent—it had no objection to Europe's maintaining a biotech approval system. Instead, the United States' central argument was that the European Communities' general and product-specific moratoria violated WTO rules because the SPS agreement required regulatory authorities to follow their procedures without "undue delay." As the USTR observed in its submission, "It is hard to think of a situation that involves 'undue delay' more than a complete moratorium on approvals."<sup>111</sup>

More specifically, the United States contended that the EC approval process for biotech products was subject to the requirements of SPS Article 8 and Annex C. Article 8 obligates members to "observe the provisions of Annex C in the operation of control, inspection, and approval procedures," and Annex C, paragraph 1(a) obliges WTO members to ensure "with respect to any procedure to check and ensure the fulfillment of sanitary or phytosanitary measures, that such procedures are undertaken and completed without undue delay."

The United States also argued that in adopting a moratorium, the European Union had failed to notify other WTO members of changes to its biotech approval process, as called for in Article 7 and Annex B.1 (see appendix 1C in chapter 1 and appendix 6B). In addition, the United States noted that the general moratorium was inconsistent with certain procedural obligations for SPS measures, such as communicating the processing period of an application, promptly examining the documentation to check for its completeness, and explaining any delays, as described in Annex C.1(b). In short, the United States maintained that having established a biotech approval regime, the European Communities were "obligated to apply those procedures fairly and transparently, and without undue delay."<sup>112</sup>

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110. "European Communities—Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291, 292, and 293), First Submission of the United States," April 21, 2004, 31, 33, 49.

111. "European Communities—Measures Affecting the Approval and Marketing of Biotech Products," first US submission, 1.

112. "European Communities—Measures Affecting the Approval and Marketing of Biotech Products," first US submission, 1.

## *Unscientific Criteria*

In addition, the United States argued that there was no scientific basis for the moratorium on biotech approvals. “In fact, many of the products caught up in the EC moratorium have been positively assessed by the EC’s own scientific committees,” its submission noted.<sup>113</sup> The United States claimed that the European Union’s general moratorium was not based on sufficient scientific principles, as required by Article 2.2, or a scientific risk assessment, as required by Article 5.1 and defined by Annex A.4. As a result, in setting its level of protection against risk, Europe had applied arbitrary or unjustifiable distinctions that led to discrimination or disguised restriction in international trade, violating Article 5.5.

The United States made the same arguments regarding product-specific moratoria, contending that the European Union had violated the SPS by imposing “undue delay,” by failing to publish the moratoria, by applying its approval procedures in a nontransparent manner, by failing to base the product-specific moratoria on risk assessments and scientific principles, and by applying arbitrary or unjustifiable distinctions in its levels of protection that resulted in trade discrimination.<sup>114</sup>

The United States also challenged nine measures enacted by six EC member states (Austria, Italy, France, Germany, Greece, and Luxembourg) that prohibited the importation or marketing of certain biotech products that had been approved under Directive 90/220 and Regulation 258/97, claiming that the measures were not based on risk assessments and scientific principles and that the arbitrary or unjustifiable distinctions in their levels of protection against risk resulted in trade discrimination.<sup>115</sup>

## *The EU Response*

The European Union rejected the US assertion that a moratorium on approvals existed, either as a general practice or in a product-specific form. Its first written submission declared that “the European Communities has not adopted any ‘moratorium’ on the approval of GMOs and nor has it suspended the application of its GMO legislation. . . . The Complainants’ assertions about a ‘moratorium,’ or a ‘suspension of procedures’ or any ‘failure to consider applications’ are all in reality complaints about delay.” The European Union also maintained that applications for specific products

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113. “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first US submission, 1.

114. “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first US submission, 49.

115. “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first US submission, 56.

had reached various stages depending on when additional information was required. Even if a repeated pattern in the treatment of applications was found, the European Union argued that such a pattern constituted not a challengeable measure under the WTO but a “practice”—and according to prior case law, a practice is not actionable under the WTO.<sup>116</sup>

The United States argued that it had provided overwhelming evidence that the European Communities had adopted and maintained a general moratorium. Among that evidence were comments from European officials that acknowledged its existence. For example, in a June 2000 speech Commissioner Byrne said the reluctance of member states to approve new biotech products “has resulted in a complete standstill in the current authorisations and a de facto moratorium on the commercial release of GMOs.” The United States also highlighted the July 2000 remarks, made by Environment Commissioner Margot Wallström, that the moratorium was “illegal and not justified.”<sup>117</sup> But the European Union argued that none of these statements proved the existence of a moratorium. Prior cases had shown that “casual statement of any of the numerous representatives” of a sovereign state did not demonstrate that state’s legal position.<sup>118</sup>

The European Union also rejected the charge that the import bans maintained by six of its member states on GMO products approved by the European Union violated the SPS agreement, pointing out that Article 5.7 permits “provisional” measures while more information is gathered. (“In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information.”) The article also obligates members to obtain “additional information necessary for a more objective assessment of risk . . . within a reasonable period of time”—a requirement that member states failed to meet, according to the United States.

Perhaps most importantly, the European Union argued that most of the objectives of its GMO approval system addressed risks that fell outside the scope of the SPS agreement. Basing its arguments on Article I and the definition of an SPS measure in Annex A.1, the European Union declared that the “SPS Agreement was not intended by its drafters to apply to all products and all risks in all circumstances—it has a limited and defined

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116. European Communities—Measures Affecting the Approval and Marketing of Biotech Products (DS/291, DS/292, DS/293): First Written Submission by the European Communities,” May 17, 2004, 118, 168.

117. “Biotechnology: Building Consumer Acceptance,” speech by David Byrne, European Commissioner for Health and Consumer Protection, European Business Summit, June 10, 2000, and “EU Moves to Break Gene Crop Deadlock,” Reuters, July 13, 2000; both quoted in “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first US submission, 18.

118. “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first EC submission, 165.

scope of application,” adding, “It is clear that the SPS Agreement was not drafted with products having the particular characteristics of GMOs in mind.”<sup>119</sup> It argued that the three main characteristics of the GM products that were the subject of the proceedings—herbicide tolerance, insecticidal properties, and antibiotic resistance—entailed a total of 13 related risks and that only 3 of these were completely covered by the SPS agreement, which addressed measures intended to protect human, animal, or plant life or health. For example, the European Union claimed that the agreement does not cover certain measures taken to protect the environment, such as those that address the risks that handling GMOs might pose to soil biogeochemistry.<sup>120</sup> The United States countered that environmental protection fell within the SPS agreement.

Another EU argument was that the other elements of its regulatory regime could be reviewed under the Agreement on Technical Barriers to Trade (TBT).<sup>121</sup> The United States did not make any claims that the European Union’s system violated the TBT rules, though it “reserved the right to do so.”<sup>122</sup> The European Union also argued that GATT Article XX could also be used to justify its regulatory procedures.<sup>123</sup>

The European Union asserted that the issues raised by GMOs went far beyond the risks envisaged and regulated by the SPS agreement: “Indeed they deserve their own agreement, and so a specific agreement has been negotiated outside the WTO context and subsequent to the conclusion of the WTO Agreement. It is the Biosafety Protocol which lays down the most pertinent provisions to any consideration of problems related to

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119. “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first EC submission, 122, 120.

120. “WTO Panel Close to Completing Fact Finding in GMO Case,” *Inside US Trade*, March 4, 2005.

121. The WTO’s TBT agreement sets out rules for regulations, standards, and testing and certification procedures not covered in the SPS agreement. Josling, Roberts, and Orden note, “In the implementation of the TBT agreement, the appropriate use of labels for agricultural and food products to signal quality attributes has been one of the most contentious issues” (2004, 54).

122. “EU GMO Defense Seeks to Circumvent Possible WTO Negative Ruling,” *Inside US Trade*, May 28, 2004. In its submission to the WTO, the United States noted, “The United States submits that the measures subject to this dispute are within the scope of the SPS Agreement. Should the EC in its First Submission argue otherwise, the United States reserves the right to explain, in the alternative, the manner in which the EC measures are inconsistent with the Agreement on Technical Barriers to Trade” (see “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first US submission, note 156 at 29).

123. Article XX of the GATT allows members to take measures “necessary to protect human, animal or plant life or health” so long as those measures are not applied in a way that creates “arbitrary or unjustifiable discrimination between countries.”

GMOs.”<sup>124</sup> In its very first decision, the WTO’s Appellate Body concluded that “the General Agreement is not to be read in clinical isolation from public international law,” and the European Union submitted that as a result, the norms reflected in the Biosafety Protocol on the precautionary principle and on risk assessment must be taken into account when interpreting and applying WTO rules.<sup>125</sup> It was thus not the role of the WTO agreement to trump the other relevant rules of international law that permitted—or even required—a prudent and precautionary approach.<sup>126</sup>

But the United States argued that other sources of international law could be pertinent to the dispute only if those sources would assist the panel in “clarifying the existing provisions of the [covered] agreements in accordance with customary rules of interpretation of public international law,” as Article 3.2 of the Dispute Settlement Understanding stipulates. And according to the United States, the European Union had not identified how the Biosafety Protocol or a precautionary principle would be relevant to interpreting any particular provision of the WTO agreement.<sup>127</sup>

## The European Union’s Labeling and Traceability Regulations

Meanwhile, the European Union was still working on regulations for labeling and tracking biotech crops. In September 2003, the European Council of Ministers and the Parliament passed Regulations 1830/2003 and 1829/2003. As described above, under the new regulations, which were to take effect in April 2004, products with more than 0.9 percent EU-approved GM content would have to be labeled “This product is produced from GMOs.” Animal feed would also have to be labeled. In addition, a paper trail would track the history and content of GM foods at all stages of production. The regulations also streamlined the approval process for GM products. Industry continued to argue that the new labeling and traceability regulations would be extremely difficult and expensive to implement, further impeding trade, but a number of NGOs showed support. “This vote is a slap in the face of the US administration, which

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124. “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first EC submission, 121.

125. Appellate Body Report, US—Gasoline, p. 621. See generally Cameron and Gray (2001), as cited in “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first EC submission, 139.

126. “European Communities—Measures Affecting the Approval and Marketing of Biotech Products,” first EC submission, 4.

127. “European Communities—Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291, 292, and 293): Executive Summary of the Rebuttal Submission of the United States,” July 29, 2004, 3.

thought that by bullying, . . . Europe, and eventually others, would swallow its GMO policy,” declared Greenpeace’s Eric Gall<sup>128</sup> The European Commission also referred Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, and Spain to the European Court of Justice for failing to adopt and promulgate national legislation implementing Directive 2001/18/EC.

Former commissioner David Byrne notes that the adoption of the new labeling and traceability framework—pending even as the WTO case on the moratorium was brought—made the US action even more puzzling. “Yes,” he says, “the United States may at last get a technical win at the WTO, but we brought the legislation within a very short time of that. So even if they do succeed in getting a positive outcome, I can’t see it is going to be of any great advantage. What will the panel say? [Perhaps it will say to Europe,] yes, you should have harmonized, you should have authorized these applications, you were still bringing through legislation—you should have done it more quickly.” But what is going to be the practical outcome of that?

The United States did not accept Europe’s new legislation as “lifting the moratorium” and pushed on with its case. Groups like the American Soybean Association (ASA) hoped that the United States would challenge the European Union’s labeling and traceability regulations in a separate case at the WTO. In November 2003, ASA and 21 other agriculture-based organizations sent a letter to the USTR requesting that such a case be brought.<sup>129</sup> These groups were particularly concerned that the EU regulations on biotechnology imports would become a model for other countries. Commissioner Byrne countered that the United States should allow the legislation time to work instead of immediately challenging it as a WTO violation.<sup>130</sup> But US industry representatives were not optimistic as the signatories to the Biosafety Protocol worked out the details of the agreement’s implementation in February 2004. “Although the treaty underlying the Biosafety Protocol has a noble goal of protecting the world’s biodiversity, the European Union and anti-biotech activists hijacked the process to serve their own political ends of further restricting trade in biotech products,” lamented ASA President Ron Heck.<sup>131</sup>

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128. Gall, quoted in Peter Ford, “Europe to Allow GM foods, with ‘Farm-to-Fork’ Labels,” *The Christian Science Monitor*, July 3, 2003, 7.

129. The letter is available at the Web site of ASA, [www.soygrowers.com](http://www.soygrowers.com), and reprinted in *Inside US Trade*. Also see “Agriculture Groups Seek New WTO Action Against EU on GMO Rules,” *Inside US Trade*, November 28, 2003.

130. “Byrne Expresses Confidence EU Will Soon Approve Two GMOs,” *Inside US Trade*, March 26, 2004.

131. Farm Press Editorial Staff, “Soybean Group Disappointed in Trade Restrictions,” *Insight*, March 2, 2004.

Observers noted that a US challenge against the new EU labeling and traceability regulations at the WTO would be difficult to mount. Georgetown University's John Jackson argued that to mount an effective case, the United States would need to show that GM foods are "like products," comparable with other conventional foods. (Article III:4 of the GATT 1994 states that imported products are due "treatment no less favourable than that accorded to like products of national origin.")<sup>132</sup> According to the *Financial Times*, the argument before the WTO would involve "almost theological complexity."<sup>133</sup> In the ongoing WTO case, the European Union had argued that the only product "like" a given imported GM product was the same GM product cultivated or processed domestically.<sup>134</sup> Indeed, some have contended that the fundamental difference between the US and EU perspectives is that the United States treats GM products as substantially equivalent to or "like" conventional products, while the European Union does not.<sup>135</sup>

In May 2004, the European Commission gave the green light for the Swiss company Syngenta to sell its canned GM sweet corn in supermarkets across the European Union—the first approval of a new GM food for sale since 1998.<sup>136</sup> The sweet corn, from the maize line Bt-11, would be clearly labeled as a GM product, in line with the new EU legislation.<sup>137</sup> Commissioner Byrne said the corn had been "subject to the most rigorous pre-marketing assessment in the world. It has been scientifically assessed

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132. See GATT Article III:4: "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product."

133. Quote and Jackson's argument described in Alden, Buck, and de Jonquières, "The Washington-Led Challenge to the European Union Moratorium," 21.

134. "European Communities—Measures Affecting the Approval and Marketing of Biotech Products," first EC submission, 160.

135. The WTO generally prohibits discrimination among products based on production processes—how the product is made. In some cases, such as edible oil made from soybeans, GM-derived and non-GM-derived products cannot be distinguished because the oil contains no genetically modified DNA or protein; therefore, some say, there seem little grounds for arguing that the two oils are not like products.

136. "EU Commission Authorizes Import of Canned GM Sweet Corn under New Strict Labelling Conditions: Consumers Can Choose," press release 82/04, European Union—Delegation of the European Commission to the United States, Washington, DC, May 19, 2004, [www.eurunion.org](http://www.eurunion.org).

137. The Commission's decision came after agriculture ministers failed to agree on how to proceed with the authorization in April.

as being as safe as any conventional maize. Food safety is therefore not an issue, it is a question of consumer choice.”<sup>138</sup>

In light of the corn approval, EU Trade Commissioner Pascal Lamy argued that the current WTO case was unnecessary and that the United States was “trying to dynamite the door that is already open.” But a US spokesman in Brussels maintained that this approval did not mark “an end of the biotech moratorium.”<sup>139</sup> “We are not seeing this as a major move,” said a US official. “The approval of a single product will not affect our WTO challenge. . . . [It] is not evidence that applications are moving routinely through the approval process in an objective, predictable manner based on science and EU law, rather than political factors.”<sup>140</sup> The US Biotechnology Industry Organization agreed: “In our view, the moratorium is not over until a decision is reached on the more than 30 applications that have been pending for six years, and until a new application is acted on in a timely manner, meaning 12 months or less.”<sup>141</sup> But Commissioner Byrne said that since the European Union was no longer delaying the application of its own laws, “that part of the [WTO] complaint seems to me to be very difficult to make.”<sup>142</sup>

However, some frustration was building within Europe over the new process for approving GMOs. Once EFSA ruled that a GM product was safe, the Commission would make a decision and then ask a regulatory committee, composed of member states’ authorities, to approve it. But disagreement among member states prevented the committee from reaching a qualified majority. As a result, the Commission had to forward proposals to the Council of Ministers, where discussions consistently ended in stalemate, forcing the Commission to make the final decision.<sup>143</sup> Markos Kyprianou, who became commissioner for health and consumer protection in November 2004, was reportedly “chafing” over ongoing logjams in the committees and concerned that the approval process pushed all the responsibility onto the Commission, making it appear unbalanced.<sup>144</sup>

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138. “EU Commission Authorizes Import of Canned GM Sweet Corn,” EU press release.

139. Lamy and US spokesman, quoted in Tobias Buck and Raphael Minder, “US Keeps Pressure up on Biofoods,” *The Financial Times*, May 20, 2004, 10.

140. US official quoted in Anthony Brown, “Protests After Europe Ends GM Food Freeze,” *The Times* (London), May 20, 2004, 18.

141. US Biotechnology Industry Organization, quoted in Kara Sissell, “EU Approves Syngenta’s GM Corn,” *Chemical Week*, May 26, 2004–June 2, 2004, 36.

142. Byrne, quoted in Paul Geitner, “EU Ends Six-Year Biotech Moratorium with Approval of Sweet Corn Imports,” Associated Press, May 19, 2004.

143. “Trying to Sow the Seeds of Certainty over GM Crops,” *European Voice*, March 10, 2005.

144. “GMO Issue Moving Back Up Commission Agenda,” *Agra Europe*, February 25, 2005; “Trying to Sow the Seeds of Certainty over GM Crops.”

## New Initiatives

As the case at the WTO continued, new agricultural biotechnology policy initiatives were developing in Europe. One of the European Union's objectives was to become the most competitive and sustainable knowledge-based economy by 2010, and some European leaders worried that it was lagging behind the United States in agricultural biotechnology research. In March 2003, the European Council called for a forum of stakeholders to develop a strategic agenda for plant genomics research. In June 2004, European Research Commissioner Philippe Busquin released the first results of the effort, a document titled *Plants for the Future: A 2025 Vision for European Plant Biotechnology*; it was prepared by a variety of interested parties, including researchers, industry, farmers, regulatory bodies, consumer and environmental groups, and policymakers.

The vision paper noted that the agro-food industry was the European Union's leading industrial sector, with more than €600 billion in annual turnover. "The future competitiveness of Europe's agricultural and food processing industries will depend on plant genomics, biotechnology and their smart application," its executive summary concluded. "These areas are developing rapidly around the world, and Europe risks losing the competitive edge it once possessed as the mantle of innovation passes to the United States. . . . If Europe is not to fall behind its major global competitors in this crucial area of innovation and future prosperity, the legitimate concerns of both critics and advocates need to be addressed" (European Communities 2004, 2, 8). As the European strategic research agenda continued to develop, some believed that the collaborative effort would provide a foundation for new attitudes in Europe about GMOs.

New public initiatives were also in the works to bring the benefits of GM technology to poorer countries. In 2005, scientists from the publicly funded International Rice Genome Sequencing Project (IRGSP) announced that they had completed a genetic map of the rice plant; their paper describing the genome was published in the journal *Nature* in August.<sup>145</sup> The data, available anywhere in the world at no cost, would be a key tool for researchers working on improved strains of rice, the researchers said. Across the developing world, 3 billion people relied on rice as the staple of their daily diet, but many went hungry. "This is really a project that can lead to important discoveries and findings that can help the condition of the poor. The poorest of the poor are the ones that depend on rice the most," said project participant Rod Wing, a scientist at the University of Arizona. Supported by the Rockefeller Foundation, the IRGSP was a collaborative undertaking, led by scientists in Japan and involving others in China, Taiwan, Thailand, Korea, the United States, Canada, France, India, Brazil, the Philippines, and the United Kingdom. Monsanto and Syngenta

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145. International Rice Genome Sequencing Project, "The Map-Based Sequence of the Rice Genome," *Nature* 436, August 11, 2005, 793–800.

contributed genetic information to the project that sped up its completion by at least a year.<sup>146</sup>

## The Preliminary WTO Decision

The WTO panel's decision on the GM case was scheduled to be circulated in March 2005, but the report's release was delayed until June, then October, and then until December.<sup>147</sup> Some believed that the postponement was intended to prevent a controversial decision from disrupting the lead-up to the December 2005 WTO ministerial in Hong Kong. At the ministerial, a petition calling on the WTO to honor the right of governments to "protect their citizens and the environment from GMO food and farming" was presented to WTO Deputy Director-General Alejandro Jara; it was signed by more than 740 organizations in 100 countries.<sup>148</sup> Analysts saw little progress in Hong Kong toward the successful completion of the Doha Round of trade talks, and they mainly blamed ongoing disagreements over agriculture. Europe—and especially France—needed to make further concessions to open its agriculture markets in order to save the Doha Round, some argued.

After the ministerial, the WTO announced that it needed yet more time to complete the panel report because of the "large number of issues to be addressed" in the case. The panel chairman also cited human resource issues, noting that "since much more time and effort was required for this case than originally planned for, some of the Secretariat staff is no longer available to the panel."<sup>149</sup> The final report's release was rescheduled for March 2006, making the GM case the longest panel process in WTO history.

In the lead-up to the report's release, the *Financial Times*'s Raphael Minder noted the WTO decision was "likely to have more political resonance than actual impact on European food and agriculture sectors."<sup>150</sup> Some

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146. Justin Gillis, "Secrets of Rice for All to Read; First Genetic Map of Major Food Crop Is Major Step Toward Reducing Hunger," *The Washington Post*, August 11, 2005, A1.

147. See WTO, "European Communities—Measures Affecting the Approval and Marketing of Biotech Products, Communication from the Chairman of the Panel," WT/DS291/27, November 2, 2004, and WTO, "European Communities—Measures Affecting the Approval and Marketing of Biotech Products, Communication from the Chairman of the Panel," WT/DS291/28, June 15, 2005.

148. Petition, quoted in "Civil Disobedience Called to Oppose GMOs At WTO," *All Africa*, December 21, 2005.

149. WTO, "European Communities—Measures Affecting the Approval and Marketing of Biotech Products, Communication from the Chairman of the Panel," WT/DS291/30, December 21, 2005.

150. Raphael Minder, "GM Foods Verdict Unlikely to Alter EU Rules," *The Financial Times*, January 5, 2006, 7.

observers agreed. "If the United States wins the case, it will be a win in terms of trade law, but not necessarily in terms of trade itself," says Robert Paarlberg.<sup>151</sup> The ruling would not change the wariness of European consumers toward GM foods, many argued. As Michael Taylor (2003) put it, "The United States cannot successfully litigate its way to public acceptance of biotechnology." The European Commission announced that the ruling would not force changes to EU approval procedures. "Only products recognized as safe will be allowed and the WTO report will not influence the decision-making process in the EU," the Commission noted. "Any idea that there is going to be a flood of GMOs is simply not the case."<sup>152</sup>

In February 2006, the WTO released its confidential preliminary decision to the parties—at 1,050 pages, the panel report was the longest in the WTO's history. Many interpreted the preliminary decision as a win for the United States and the agricultural biotechnology industry. Some NGOs criticized the "secretive" nature of the decision, and posted parts of the panel's confidential report on the Internet.

The WTO panel found that between June 1999 and August 2003, the European Commission had indeed "applied a general de facto moratorium on approvals of biotech products," which "resulted in a failure to complete individual approval procedures without undue delay"—and was therefore in violation of Article 8 and Annex C(1)(a) of the SPS agreement. In terms of product-specific approvals, the panel found "undue delay in the completion of the approval procedure with respect to 24 of the 27 relevant products." Finally, the safeguard measures taken by Austria, Belgium, France, Germany, Italy, and Luxembourg were found to be inconsistent with Articles 5.1 and 5.7 of the SPS agreement. However, the panel noted that it did not examine "whether biotech products in general are safe or not" or "whether the biotech products at issue in this dispute are 'like' their conventional counterparts." It also did not express a view as to whether "an amended de facto moratorium continues to exist or whether a new general de facto moratorium has since been imposed." The panel offered no findings under GATT Article XI or the TBT agreement. Finally, the panel did not find that the European Commission had violated all of the SPS articles that it was accused of violating.<sup>153</sup>

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151. Comments from Robert Paarlberg from a January 2006 interview.

152. European Commission, quoted in Minder, "GM Foods Verdict Unlikely to Alter EU rules," 7.

153. For example, the panel said the United States had not established that the European Commission acted inconsistently with its obligations under SPS Annex C(1)(b), Annex B(1) and Article 7, Article 5.5, Article 2.2 or Article 2.3 by applying a general de facto moratorium between June 1999 and August 2003 (see paragraph 8.14). The "Conclusions and Recommendations" section of the panel's interim report (pg. 1029–50) were posted on the Web site of the Institute for Agriculture and Trade Policy, [www.iatp.org](http://www.iatp.org). See paragraphs 8.3, 8.6, 8.7, 8.9, 8.10, 8.16.

Response to the WTO's preliminary decision was mixed. Some US officials celebrated the decision, saying it would speed approvals of GM products in the European Union and discourage other countries from adopting measures blocking GM imports. The panel's findings "will encourage the process of approvals and adoption within the European Union," summarized US agriculture negotiator Richard Crowder.<sup>154</sup> "This is a good, clear signal to the world that Europe was wrong," said Leon Corzine, chairman of the National Corn Grower's Association.<sup>155</sup> Observers also noted that the decision highlighted the importance of honoring global trade agreements. But a spokesperson for the European Union said the WTO report "is largely of historical interest" since the European Union had changed its approval process in 2004 and cleared nine products for import.<sup>156</sup> US trade officials countered that some applications filed in the 1990s still had not been approved.

NGOs sharply criticized the decision. "The WTO has bluntly ruled that European safeguards should be sacrificed to benefit biotech corporations," said Friends of the Earth Europe's Adrian Bebb.<sup>157</sup> The Institute for Agriculture and Trade Policy, a US nonprofit, called the decision "a major step back for the democratic rights of national and local governments to set their own environmental and human health regulations when there is scientific uncertainty."<sup>158</sup> NGOs also accused the WTO of challenging the authority of the Cartagena Protocol on Biosafety. Some observers said that the decision could harden European opposition to GMOs—and be bad publicity for the WTO. Robert Paarlberg notes that resentment over the case "could weaken the authority of the WTO across the board in Europe and further reduce the chances for a satisfying outcome in the Doha Round."

Observers also wondered if the WTO decision would exacerbate continuing internal conflicts between the European Commission and the member states. Though the European Union had passed new labeling and traceability directives, many member states continued to impose their own moratoria on the approval of new GMOs. But the Council of Envi-

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154. "US, EU Split on Significance of WTO Panel on EU GMO Ban," *Inside US Trade*, February 10, 2006.

155. Andrew Pollack, "World Trade Agency Rules for US in Biotech Dispute," *The New York Times*, February 8, 2006.

156. Paul Meller, "Europe Defends Stance on Genetically Altered Foods," *The New York Times*, February 8, 2006.

157. Paul Geitner and Andrew Pollack, "A Line in the Sand Over WTO's Modified-Food Ruling," *The International Herald Tribune*, February 9, 2006.

158. Institute for Agriculture and Trade Policy, press release, "WTO Ruling on Genetically Engineered Crops Would Override International, National and Local Protections: Preliminary Ruling Favors US Biotech Companies Over Precautionary Regulation," February 7, 2006, 1.

ronmental Ministers rejected proposals from the Commission calling on Germany, Austria, Luxembourg, France, and Greece to lift their bans on approved GM products.<sup>159</sup> In addition, as noted above, the European Commission brought a case against some member countries at the European Court of Justice for failing to implement the new directives.<sup>160</sup> These moves were taking place after the defeat of the proposed EU constitution in the 2005 Dutch and French referendums, at a time when the authority of the Commission in Europe was weakened and thus more easily questioned.

Finally, some argued that the dispute had slowed the development of GM technology in Europe and the United States, risking economic competitiveness. Without better management and increased access to biotechnology, leadership would move to other players. "Europe and the United States should learn to manage new technologies collectively, not to suppress them," noted Calestous Juma. "Failure to do so will shift technological leadership to other regions, such as China, that have made significant strides in using new technologies for economic growth."<sup>161</sup>

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159. "EU Member States Clash with Commission over GMOs, Could Signal Changes," *Inside US Trade*, July 8, 2005.

160. "US, EU to Face Off at WTO Early This Year over GMOs, Aircraft," *Inside US Trade*, January 6, 2006.

161. Calestous Juma, "'Satan's Drink' and a Sorry History of Global Food Fights," *The Financial Times*, February 9, 2006.

## Case Analysis

A central issue in the trading system is how to deal with divergent regulatory approaches and rules. On the one hand, regulatory uniformity facilitates free trade; on the other hand, regulatory diversity accommodates different national preferences, conditions and beliefs. In this case, we see that the very different approaches to GMOs adopted by the United States and the European Union have resulted in conflicts at the WTO, the Codex Alimentarius Commission and in negotiations for a UN Protocol on Biosafety. The case allows us to explore the origins of these differences and to consider whether they can be reconciled through the WTO dispute settlement system; in particular, it sheds light on the question of whether litigation is likely to help or hinder negotiation.

The case outlines the very different treatment accorded to GMOs in the two systems, the disputes generated by the dissimilarity, and the nature of the institutional barriers to achieving negotiated agreements to resolve these disputes. In the United States, initially there was no special legislative treatment of GM products, which were thus subject to the same health and safety procedures as other goods. At its essence, the US view, like that expressed in the WTO's SPS agreement, is that regulations should be based on science and on risk analysis. The net result is that the US system has allowed many GM products to be introduced into the market.

In the European Union, by contrast, these products were subject to special rules and directives influenced by the Environmental Directorate-General of the European Commission. By seeking compelling evidence that a GM product is safe before it is introduced, the European approach puts far more emphasis on taking precautions. The net result is that for long periods of time, few or no GM products have been approved for sale in the European Union. In addition, the European Union has insisted that if they are introduced, products must meet very strict labeling and traceability requirements.

What explains these different approaches? Why is it that in the United States GMOs are presumed innocent until science proves them guilty, while in the European Union they seem to be guilty until science proves them innocent? Is it that Americans are by nature more willing to accept new products and technologies? Do the two political and regulatory systems weight the different actors differently? Producers and biotech firms seem to be more powerful in the United States; consumer and environmental groups play a major role in the European Union. Have different national experiences with food regulation shaped these stances? Mad cow disease and other food scares have certainly reduced public confidence in food regulation in the European Union; Americans, who have had fewer scares, appear to be more trusting. Many observers add that culturally, Europeans have a different attitude toward food than do Americans.

Article 3.7 of the WTO Dispute Settlement Understanding (DSU) states, “Before bringing a case, a Member shall exercise its judgment as to whether action under these procedures would be fruitful.” Whatever the reasons for these differences in regulatory systems, are they likely to be reconciled through litigation in the WTO dispute settlement system? American farmers and biotech producers have clearly been very frustrated with the European approach, and bringing a case allows the Office of the USTR to voice their concerns—but would a US victory be effective in changing EU policies, or is it likely to simply harden attitudes on both sides of the Atlantic and make compromise more difficult? On the one hand, Americans favoring a case suggest that victory could strengthen the hand of those Europeans who argue in favor of more liberal treatment. They also feel that the United States must insist on enforcing its WTO rights and discourage other countries from following the EU policy example. On the other hand, Europeans against such a case see it as unnecessary, since approvals are being granted again, even if not as quickly as Americans might like; potentially counterproductive, since it could appear that US pressure rather than credible evidence that the products are safe is the reason for their approval; or ineffective and likely to result in more trade friction if the United States feels compelled to retaliate.

The arguments introduced by each side in the WTO dispute reflect their fundamental differences. The United States stresses in particular the role given to science in the SPS agreement. Specifically, Article 2.2 makes clear that such measures must be based on scientific principles and may not be maintained without sufficient scientific evidence. The Europeans, however, find support for a precautionary principle in Article 5.7, which says that if members have insufficient relevant scientific evidence, they may provisionally adopt protective measures “on the basis of available pertinent information.”

The conflict between these two trade superpowers has important implications for other nations. As the old saying goes, “When the elephants fight, the grass gets trampled.” What approach should other nations adopt? Many developing countries are attracted to the promise that biotechnology offers for improving farm productivity, saving on pesticides, and providing healthier foods. At the same time, many are wary about its possible impact on health and the environment and, as the Zambian example in the case makes clear, they are concerned that the use of GM products could prevent their exports from being accepted in the European Union. Egypt’s experience in being forced to withdraw its support for the US case at the WTO exemplifies the tensions this issue introduces not only in the WTO but also in the international forums concerned with food safety.

Are the two systems ultimately reconcilable? One approach might envisage GM and non-GM products coexisting, distinguished by agreed-on labels, and consumers ultimately being allowed to choose between them.

But there are problems with such an approach. First, as the case brings out, informed choice requires both labeling and traceability, and the devil lies in the details. Such requirements could be so demanding, and meeting them so costly, that in practice they could operate as a ban. Second, there are technical problems in actually segregating GM and non-GM crops and distribution systems, as the example of Starlink in the case demonstrates. And third, what if in some countries, regulators still believe it necessary to maintain bans on GM products until there is scientific evidence that the products are safe? Should the trading rules be used to try to force countries to import such products? If so, what would such pressure mean for the long-run legitimacy of the rules?

## Appendix 6A

### Timeline of Key Events in the GM Crop Dispute

Date	Event
1973	Scientists transfer DNA from one cell to another.
1975	Asilomar conference on recombinant DNA is held.
1976	US National Institutes of Health (NIH) publishes guidelines for biomedical research using recombinant organisms for labs conducting federally funded experiments.
1980	The US Supreme Court extends patent protection to new types of plants including seeds, tissue cultures, and genes.
1981	Industrial Biotechnology Association created (United States).
1982	Scientists at Monsanto pioneer the modification of a plant cell's genetic structure.
1983	Association of Biotechnology Companies created (United States). The organization later merged with the Industrial Biotechnology Association in 1994 to form the Biotechnology Industry Organization.
1984	European Commission forms the Biotechnology Steering Committee, which establishes the Biotechnology Regulations Interservice Committee a year later.
1986	DG XI (Environment) takes the lead in drafting the European Commission report "A Community Framework for the Regulation of Biotechnology." United States publishes the Coordinated Framework for Regulation of Biotechnology. First US outdoor field test of a GM crop plant.
1988	European Commission proposes directives on GMOs with leadership from DG XI (Environment).

*(timeline continues next page)*

## Timeline of Key Events *(continued)*

Date	Event
1990	European Council adopts Directives 90/219 and 90/220 on the contained use and deliberate release of GMOs.
1993	The FDA approves rbST.
1996	GM crop varieties are introduced for commercial production in the United States.  British BSE (“mad cow”) crisis leads to slaughter of cattle and public distrust of food safety.
1996–97	The European Commission approves Monsanto’s Roundup-Ready soybeans and Novartis’s GM corn; Austria, Italy, and Luxembourg invoke safeguard clause and ban the corn.
1997	The European Council and Parliament adopt the Novel Foods regulation that provides for labeling of some foods with GM ingredients.
October 1998	De facto moratorium on approval of new GM varieties starts.
1999	By 1999, Monsanto had invested more than \$8 billion to buy seed companies and close marketing agreements in its commitment to produce GM crops.  Denmark, France, Greece, Italy, and Luxembourg say they will refuse to approve new GM products until rules on traceability and labeling are in place.  Prince Charles bans new tenant farmers on his land from using GM products.  Codex establishes Ad Hoc Task Force on Foods Derived from Biotechnology.  Some companies begin to back away from GM ingredients.
January 2000	One hundred thirty countries adopt the Cartagena Protocol on Biosafety.

<b>Date</b>	<b>Event</b>
April 2000	European Food Safety Authority (EFSA) is created.
September 2000	StarLink corn—a GM variety approved only for animal consumption in the United States—is found in taco shells.
March 2001	European Council and Parliament adopt Directive 2001/18 on deliberate release of GMOs, replacing Directive 90/220, to be implemented in October 2002.
January 2002	EFSA becomes operational.
June 2002	European Union ratifies the Biosafety Protocol.
October 2002	Directive 2001/18 enters into force.
May 2003	United States launches a WTO complaint over EU regulation of GMOs.
July 2003	The European Commission refers 11 member states to the European Court of Justice for failing to adopt national legislation implementing Directive 2001/18.
September 2003	Council and European Parliament adopt Regulation 1830/2003 on Traceability and Labeling of GMOs and Regulation 1829/2003 on Genetically Modified Food and Feed.
April 2004	Regulations 1829/2003 and 1830/2003 enter into force.
May 2004	European Commission approves the marketing of canned Bt-11 sweet corn for 10 years, the first GM approval since October 1998.
July 2005	The European Council of Environment Ministers rejects the Commission's proposal to lift Austria, France, Germany, Greece, and Luxembourg's bans on authorized GMOs.
February 2006	The WTO panel announces its preliminary decision.

## **Appendix 6B**

### **Excerpts from Annexes B and C of the Agreement on the Application of Sanitary and Phytosanitary Measures**

*For the body of the agreement and Annex A, see appendix 1C in chapter 1.*

#### *Annex B*

##### *Transparency of Sanitary and Phytosanitary Regulations Publication of Regulations*

1. Members shall ensure that all sanitary and phytosanitary regulations<sup>1</sup> which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

#### *Annex C*

##### *Control, Inspection and Approval Procedures<sup>2</sup>*

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

- (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
- (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained[.]

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1. Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

2. Control, inspection and approval procedures include, inter alia, procedures for sampling, testing and certification.