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GENETICALLY MODIFIED FOOD AND INTERNATIONAL LAW — THE BIOSAFETY PROTOCOL AND REGULATIONS IN EUROPE*

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I. INTRODUCTION

Biotechnology has the potential to transform industry, including pharmaceuticals, and agriculture.[1] The Biosafety Protocol [hereinafter *Protocol*], adopted by over 130 states in Montreal, Canada, on January 30, 2000, defines modern biotechnology in the context of regulating the international trade of genetically modified organisms (GMOs). This regulation takes place through the application of "(a) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection."[2] The Protocol defines a living organism as "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and vi-

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1. In 1987, the National Academy of Sciences released its study regarding the potential of biotechnology. NAS, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES (1987). *See also* U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY (1991).

2. *Convention on Biological Diversity, Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity*, UNEP, Pt. Two, Annex to decision EM-I/3: Cartagena Protocol on Biosafety to the Convention on Biological Diversity, art. 3(i), U.N. Doc. UNEP/CBD/ExCOP/1/3 (2000) [hereinafter Biosafety Protocol].

roids."[3] It defines a living modified organism as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[4] Thus, a GMO or transgenic product is created by inserting foreign genes from one organism into another, thereby crossing species barriers. Thus, genes from viruses, bacteria and animals may be planted in grains, fruits and vegetables.

Genetic modification (GM) or manipulation in agriculture, undertaken by what is commonly known as genetic engineering, is aimed at increasing the quantity of world food supplies and improving their quality by enhancing beneficial traits, such as making crops resistant to insects or herbicides and reducing their dependence on pesticides. Two examples are insect-resistant corn and Roundup-Ready soybeans, which are impervious to Roundup herbicide, manufactured by the giant biotech firm Monsanto, the largest producer of GM seeds. Major substantive issues related to the creation and use of and trade in GMO products include the threat to biological diversity, economic considerations, intellectual property issues, ethical and religious concerns, risks to human and animal life or health, consumers' right to know, and food security.[5] The security interest, may be affected in several says, such as further consolidation of control over the methods of food production in the hands of a few large firms, excessive use of chemicals because of the increasing resistance of crops to herbicides, and reductions in crop diversity.[6]

While all these issues are important, in this paper I will focus the discussion primarily on 1) the attempts internationally to regulate the trade in GMOs by the adoption of the Biosafety Protocol, and 2) regulation of GMOs in Europe. The first section will briefly describe the controversy. The second section will discuss the regulatory practice in the United States. The third and fourth sections will describe and analyze the Biosafety protocol and GMOs' regulation in Europe, respectively, before the final concluding section.

II. THE CONTROVERSY

The use of biotechnology in agricultural practices has increased substantially in the United States and other major food exporting countries. These exporters are also the foremost proponents of the biotech-

3. *Id.* at art. 3(h).

4. *Id.* at art. 3(g).

5. *See* Center for International Environmental Law, *Implications of Proposals to Consider Trade in Genetically Modified Organisms (GMOs) at WTO—Draft Discussion Paper* 1-2 (Oct. 1999) (copy on file with the *Denver Journal of International Law and Policy*).

6. *See id.*

nology industry and operate as the so-called "Miami Group"[7]. To illustrate, 50 percent of soybean and one-third of corn crops in the United States in 1999 were grown from GM seed, and almost all canola oil in the US is made from genetically altered rape seeds.[8] Similarly, in Argentina, the world's largest soybean exporter, GM soybeans accounted for approximately 70 percent of the 1998-99 soybean crop.[9]

The controversy surrounds the genetically modified crops because of the potential long-term risks to human health and the environment caused by the release of GMOs into the environment. Proponents claim that GM foods are beneficial because of their higher nutrient value and because of their capacity to substantially increase food production to feed the world's growing population. On the other hand, critics argue that the potential risks cannot be dismissed. Among unanticipated outcomes, the new genes might jump to other crops or species, or even to people. For example, unexpected toxins or allergens may be introduced into crops through genetic engineering, thus causing unforeseen allergic reactions in humans. In 1996, scientists genetically engineered soybeans to incorporate a gene from Brazil nuts that enhanced the soybeans' protein content. Subsequent testing showed that the protein introduced could trigger allergic reactions similar to those caused by Brazil nuts.[10] A plant with genes resistant to insects or herbicides could spread that gene through pollination, thus creating "super weeds."[11] Recent laboratory studies have shown that the pollen of genetically altered corn can kill caterpillars of the monarch butterfly, that the lives of ladybirds are shortened when they are fed aphids living on GM crops, and that lacewings, natural predators of insect pests, are killed when they are fed corn borer worms raised on genetically altered corn plants.[12]

Consumer resistance to GM foods in Europe has been intense. United States exports to Europe of corn and soybeans, both genetically modified and conventional, have declined from nearly $3 billion in 1996,

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7. The Miami group, consisting of Argentina, Australia, Canada, Chile and Uruguay, was named after the city where the group first met to promote free trade in GMs

8. *See* Ruth Walker, *Safety Rules for Genes and Food*, CHRISTIAN SCI. MONITOR, Jan. 25, 2000, at 1. Andrew Pollack, *130 Nations Agree on Safety Rules for Biotech Food*, N.Y. TIMES, Jan. 30, 2000, at A1.

9. *See* Ben Christie, *Tweaked Beans Do Not Faze the Farmers of Argentina*, FIN. TIMES, Feb. 11, 2000, at 34.

10. *See* Peter N. Spotts, *The Brave New World of Biotechnology and Beyond*, CHRISTIAN SCI. MONITOR, Oct. 28, 1999, at 17.

11. *See* David Nicholson-Lord, *GM Foods: The Natural Result of Genetic Change*, INDEPENDENT (London), Oct. 12, 1999, features section; Andrew Pollack, *We Can Engineer Nature. But Should We?*, N.Y. TIMES, Feb. 6, 2000, at 16.

12. *See* Robert C. Cowen, *New Findings Say Genetically Altered Corn Can Poison the Soil*, CHRISTIAN SCI. MONITOR, Dec. 2, 1999, at 2; Paul Brown, *From Gung-ho to Acceptance of Legitimate Concerns*, GUARDIAN (London), Feb. 28, 2000, at 6.

when American farms began shipping biotechnology crops to Europe, to about $1 billion in 1999.[13] While European regulators have not approved any new GM seed strains for nearly two years, "[p]lanting, importing or selling genetically altered seeds or foods has virtually stopped, because farmers will not plant the seeds, consumers will not buy the foods, and stores decline to stock them."[14]

A major controversy was sparked when scientist Arpad Pusztai, at Rowett Research Institute in Aberdeen, Scotland, reported on British television that transgenic potatoes damaged the health of rats by stunting their growth and injuring their immune systems.[15] He was fired and silenced. Subsequently, however, the British medical journal, *The Lancet*, published a peer-reviewed paper co-authored by Pusztai in which he repeated the finding.[16] According to polls, only one percent of Britons think that there is any value in GM plants, and ingredients from these plants are called "Frankenstein food" by several British newspapers.[17] It is ironic that at a kitchen at Monsanto's Britain factory only GM-free meals are served.[18] Bowing to consumer concern, British Prime Minister Tony Blair wrote in late February 2000:

> There is no doubt that there is potential for harm, both in terms of human safety and in the diversity of our environment, from GM foods and crops. It's why the protection of the public and the environment is, and will remain the Government's over-riding priority.
>
> Testing [of GM food ingredients] has been tightened by this government even further. I can promise that no GM food will be put on the market here without going through the most rigorous safety assessments in the world.
>
> We also recognize the genuine fears over the impact of GM crops on

13. *See* David Barboza, *In the Heartland, Genetic Promises*, N.Y. TIMES, Mar. 17, 2000, at C6.

14. Donald G. McNeil, Jr., *Protests on New Genes and Seeds Grow More Passionate in Europe*, N.Y. TIMES, Mar. 14, 2000, at A1.

15. For a short report, *see* Joel Bleifuss, *No Small (Genetic) Potatoes; A British Researcher Raises Doubts About Genetically Engineered Food*, IN THESE TIMES, Jan. 10, 2000, at 2.

16. *See id.* *See also* Geoffrey Lean, *Exposed: Blair's Hypocrisy Over GM*, INDEPENDENT (London), Mar. 5, 2000, at 13 ("The [British] Government has also refused to repeat research by Dr. Arpad Pusztai, which suggested that eating GM potatoes damaged the health of rats, even though it was financed by the official bodies in the first place.")

17. *See* McNeil. Jr., *supra* note 14; Warren Hoge, *Britons Skirmish Over Genetically Modified Crops*, N.Y. TIMES, Aug. 23, 1999, at A3. "A new MORI poll says 79 percent of the British public think that genetically modified crop testing . . . should be stopped. Major food manufacturers, supermarkets and fast food chains have already announced the removal of all genetically modified ingredients from their products sold in Britain." *Id.*

18. *See* Michael Mccarthy, *GM Food Banned in Monsanto Canteen*, INDEPENDENT (London), Dec. 22, 1999, at 7.

> our environment and wildlife. That is why no GM crops will be grown commercially in this country until we are satisfied there will be no unacceptable impact on the environment.
>
> We have insisted that products containing GM foods on shop shelves have to be labeled. And anyone eating in a restaurant has a legal right now to ask whether the food they serve contains GM ingredients. And we are leading the fight to have labeling extended in Europe.[19]

The Minister for the Cabinet Office in Britain, Mo Mowlam, had earlier said in December 1999 that in 2000, the government would announce new rules on labeling of additives and flavorings as well.[20] In Wales, there has been a movement toward declaring that region of Britain a GM-free zone.[21] Because of the backlash against GM crops, the biotechnology industry is unable to find enough British farmers willing to grow GM crops even for a trial period.[22]

The concern has now spread beyond Europe to many other countries. For example, the *Washington Post* reported in January 2000 that in Japan,

> [i]n the five months since the labeling requirement was announced, a major supermarket chain has started identifying its genetically modified products. The Asahi and Kirin Beer Companies said they will switch entirely to non-genetically modified ingredients. And Japanese soybean farmers, who do not use any genetically modified seeds, are enjoying a huge demand for their beans—even at three to four times the price of imported American ones.[23]

In Canada, McCain Foods, Ltd., a major potato producer and a leading supplier of French fries to Burger King, says that it will not use gene-altered potatoes.[24] Similar developments have occurred in several other countries, including Brazil,[25] Mexico[26] and South Korea.[27]

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19. Tony Blair, *The Key to GM is Its Potential, Both for Harm and Good*, INDEPENDENT (London), Feb. 27, 2000, at 28.

20. *See* Martha Linden, *Mowlam Promises Tougher GM Rules*, INDEPENDENT (London), Dec. 18, 1999, at 11.

21. Fran Abrams, *Wales Set to Throw GM Policy Into Chaos*, INDEPENDENT (London), Mar. 13, 2000, at 5.

22. *See* Paul Brown, *et al.*, *U-Turn By Blair on GM Food*, GUARDIAN (London), Feb. 28, 2000, at 1.

23. Kathryn Tolbert, *In Japan, It's Back to Nature; Consumers Add Non-Modified Products to Shopping Carts*, WASH. POST, Jan. 24, 2000, at A8. *See also* Takehiko Nomura, *Japanese Press For Labels on Their Tempered Tofu*, CHRISTIAN SCI. MONITOR, Aug. 25, 1999, at 7; Melody Petersen, *New Trade Threat for U.S. Farmers*, N.Y. TIMES, Aug. 29, 1999, §1, at 1.

24. *See* Barboza, *supra* note 13, at C6.

25. *See* Jack Epstein, *Brazilians Boil Over Ban on Altered Beans*, CHRISTIAN SCI.

A major controversial issue is whether genetically modified foods are "substantially equivalent" to their natural counterparts. The concept of "substantial equivalence" is the basis for US regulators not to treat such food differently from conventional food. Critics, however, argue that a GM food's being chemically similar to a conventional food "is not adequate evidence that it is safe for human consumption."[28] They contend that, while this "approach might seem plausible and attractively simple . . . it is misguided, and should be abandoned in favor of one that includes biological, toxicological and immunological tests rather than merely chemical ones."[29]

The concept of substantial equivalence has never been properly defined; the degree of difference between a natural food and its GM alternative before its "substance" ceases to be acceptably "equivalent" is not defined anywhere, nor has an exact definition been agreed by legislators. It is exactly this vagueness that makes the concept useful to industry but unacceptable to the consumer. Moreover, "the reliance by policymakers on the concept of substantial equivalence acts as a barrier to further research into the possible risks of eating GM foods."[30]

At an international conference on genetically modified crops in late February 2000, held in Edinburgh, Scotland, under sponsorship of the Organisation for Economic Co-operation and Development and funded by the British government, there was a clash of views on the safety of GM foods.[31] At the conference the assumption of "substantial equivalence," as employed by the US Food and Drug Administration (FDA) in testing GM foods and thus allowing speedy commercialization of GM crops throughout the United States, was challenged by an FDA scientist, Dr. Linda Kahl. In a memo, she said, "The process[es] of genetic engineering and traditional breeding are different, and according to the technical experts in the [FDA], they lead to different risks."[32]

The concern with potential risks of GM foods has spread to the United States, as well. Some food and beverage companies and several grocery chains have decided not to carry GM foods. To illustrate, Gerber and Heinz baby foods have announced that they will not use geneti-

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MONITOR, Aug. 25, 1999, at 1 (In June 1999, a federal judge banned sales of Monsanto's Roundup Ready soybean seeds until the government sets biosafety rules). Australia and Singapore have also begun regulating GMOs. *See Id.*

26. *See* Petersen, *supra* note 23, at 1.

27. *Id.*

28. Erik Millstone, Eric Brunner & Sue Mayer, *Beyond 'Substantial Equivalence,'* 401 NATURE 525 (Oct. 7, 1999).

29. *Id.*

30. *Id.*

31. *See* Michela Wrong, *Differences Widen on Use of Modified Foods*, FIN. TIMES (London), Feb. 29, 2000, at 14.

32. *Quoted* in Jack O'Sullivan, *US "Covered Up Warnings from Its Scientists on Dangers of GM Foods,"* INDEPENDENT (London), Feb. 29, 2000, at 2.

cally altered corn or soy ingredients because of public concern about safety.[33] In January 2000, Frito-Lay, Inc., told the farmers who grow the corn used in its snack foods not to use genetically engineered seed for this year's planting.[34] Whole Foods Markets, a chain of 104 natural foods supermarkets, has committed itself to not using GM ingredients in its Whole Foods brand or private label products.[35] Over 30 farm groups across the country have warned their members that planting GM crops might be risky to their livelihoods because of the unpopularity of such crops with consumers, and because farmers could be vulnerable to "massive liability" from damage caused by the spread of biologically modified pollens.[36] A study by the American Corn Growers Association published in February, 2000, showed a sixteen percent drop in sowings of GM maize across the US Midwest.[37]

The battle against GM crops has, however, apparently led Monsanto to renounce the use of "terminator" genes in their plants, by which the next generation of seeds is rendered infertile, thus preventing farmers from saving seeds from year to year.[38] In mid-December 1999, several plaintiffs, five farmers in the US and one in France, filed a class-action lawsuit in US district court in Washington against Monsanto.[39] They alleged fraud and violations of US anti-trust laws, claiming that the defendant had: (1) defrauded them by telling them that GM

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33. *See* Alex Salkever, *Are These New Bio-Crops Safe?*, CHRISTIAN SCI. MONITOR, Aug. 5, 1999, at 3; Laurent Belsie, *New Genes Meet a Wary Market*, CHRISTIAN SCI. MONITOR, Dec. 8, 1999, at 1; *Eating Well: What Labels Don't Tell You (Yet)*, N.Y. TIMES, Feb. 9, 2000, at 5 [hereinafter *Eating Well*]. A leading brand of baby food, Earth's Best, a division of the Hain Food Group, also announced in January 2000 that it would not use GM ingredients. *See* Florence Fabricant, *Food Stuff*, N.Y. TIMES, Jan. 26, 2000, at F2. *See also* David Barboza, *Modified Foods Put Companies in a Quandry*, N.Y. Times, Jun. 4, 2000, sec. 1, at 1.

34. *See* Eating Well, *supra* note 33.

35. *Id.*

36. *See* William Claiborne, *Biotech Crops Spur Warning; 30 Farm Groups Say Consumer Backlash Could Cost Markets*, WASH. POST, Nov. 24, 1999, at A11.

37. *See* Michela Wrong, *Modified Crop Sowings to Fall*, FIN. TIMES (London), Feb. 23, 2000, at 6 (In late March 2000, the U.S. Department of Agriculture released a survey showing that "biotech corn planting could be down 24 percent from a year ago and soyabeans could be down 9 percent); David Barboza, *Farmers are Scaling Back Genetically Altered Crops*, N.Y TIMES, Apr. 1, 2000, at 5.

38. *See generally* James Erlichman, *GM Foods: Fighting for the Future of Our Food*, INDEPENDENT (London), Oct. 12, 1999, from Features section; John Vidal, *The Seeds of Wrath; Thousands Will Demonstrate Today at a Meeting of the Leading Economic Powers*, GUARDIAN (London), Weekend Page, June 19, 1999, at 10; *Ending a Genetic Food Fight*, Editorial, CHRISTIAN SCI. MONITOR, Sept. 28, 1999, at 20.

39. *See* John Schwartz, *6 Farmers in Class Action vs. Monsanto; Lawsuit Questions the Company's Testing of Genetically Modified Seeds*, WASH. POST, Dec. 15, 1999, at E1; Henry Miller, *The Unexpected Arm of the Bio-Police*, FIN. TIMES (London), Dec. 21, 1999, at 10; Scott Kilman, *Monsanto is Sued Over Genetically Altered Crops*, WALL. ST. J., Dec. 15, 1999, at A3.

seeds were safe and that the public would accept GM crops, because the company should have known that adequate standards of testing do not exist in any state and hence such safety could not be assured; and had (2) conspired to monopolize the world's market for GM agriculture by patenting genes and requiring that farmers "license" their seeds instead of buying them outright. Earlier, in May 1998, the Alliance for Bio-Integrity filed a lawsuit against the FDA seeking mandatory safety testing and labeling of all GM foods. The plaintiff alleged that current FDA policy, under which GM foods are authorized to be marketed without testing and labels, violates the Agency's statutory mandate to protect public health and to provide consumers with relevant information about the foods they eat.[40]

Finally, shareholders of several corporations have called for shareholder votes to halt the development and sale of GM food and crops until they are tested on a long-term basis and are shown to be safe to both humans and the environment.[41]

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40. Alliance for Bio-Integrity, *Landmark Lawsuit Challenges FDA Policy on Genetically Engineered Food*, Press Rel., (visited 3/27/00) <http://www.biointegrity.org> (copy on file with the *Denver Journal of International Law and Policy*). *See also* Alliance for Bio-Integrity, Statement of Steven M. Druker, *Lawsuit Uncovers Disagreement Within FDA Over Safety of Biotech Foods* (visited March 27, 2000) <http://www.biointegrity.org>:

> The FDA's records reveal it declared genetically engineered foods to be safe in the face of broad disagreement from its own experts—all the while claiming a broad scientific consensus supported its stance. Internal reports and memoranda disclose: (1) agency scientists repeatedly cautioned that foods produced through recombinant DNA technology entail different risks than do their conventionally produced counterparts and (2) that this input was consistently disregarded by the bureaucrats who crafted the agency's current policy, which treats bioengineered foods the same as natural ones.

Id. In October 2000, a federal judge upheld the Food and Drug Administration's policy on genetically modified food, dismissing the lawsuit, stating that the government did not have to follow procedures for public notice and comment or file an environmental impact statement because there has been no formal regulation announced by the agency. *See* Andrew Pollack, *Judge Upholds F.D.A. Policy on Genetically Altered Foods*, N.Y. Times, Oct. 4, 2000, at C18.

41. *See* Mary Dejevsky, *Big US Firms Face Investors' Revolt Over GM Foods*, INDEPENDENT (London), Feb. 15, 2000, at 13.

III. THE U.S. REGULATORY FRAMEWORK[42]

A. *Introduction*

The United States has no special laws that specifically apply to GM foods. The biotech approval process involves three departments: the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). However, biotech companies are only required to consult the FDA as they bring new biotech products to market, so long as the added genes do not substantially change the nature of the foods. Labeling is also not required. Environmental groups and consumer activists demand that extraordinary steps be taken to ensure the safety of GM food, since the technology is totally novel and is practically transforming our food supplies.

Unlike several states that apply process-oriented approaches, thereby implementing new biotechnology laws to regulate GMO releases,[43] the US regulates GMOs under already-existing statutes. For a decade since the mid-1970s, the National Institute of Health (NIH) was primarily responsible to ensure genetic engineering safety and hence established guidelines for research involving recombinant DNA in 1976.[44] Subsequently, in 1986, the Coordinated Framework for Regulation of Biotechnology was issued by the Office of Science Technology Policy,[45] prescribing jurisdiction over biotechnology regulation among several federal agencies. Under the Framework several general principles apply: (1) existing laws are to regulate biotechnology;[46] (2) the products of biotechnology and not the process are to be regulated;[47] (3) the safety of a biotechnology product is to be determined on a case-by-case basis;[48] and (4) a coordinated effort is to be undertaken between all the agencies involved in regulating biotechnology.[49]

The following discussion will address the roles of major agencies in-

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42. For a thorough review, *see* T. Morath, Office of U.S. Trade Representative, *U.S. Regulation of Products Derived from Biotechnology* (1998) [hereinafter Morath]. *See also* Terence P. Stewart & David S. Johanson, *Policy In Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243, 248-52 (1999); Judy J. Kim, *Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms*, 16 FORDHAM INT'L L. J. 1160 (1993).

43. *See* Kim, *supra* note 42, at 1169-77.

44. For a discussion of NIH's role, see id. at 1178-79.

45. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23, 302 (1986).

46. *Id.*

47. *Id.*

48. *Id.*

49. *Id.*

cluding the EPA, USDA and FDA in regulating biotechnology. The section will conclude with a case holding that a mandatory law may be unconstitutional.

B. The Environmental Protection Agency

The current procedure calls for the EPA to approve pesticides derived from biotechnology and bioengineered plants that contain Bacillus thuringiensis ("Bt"), which is toxic to certain maize pests.[50] Two statutes are applicable to regulating the release of GMOs—the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[51] and the Federal Food, Drug and Cosmetic Act (FFDCA).[52] Under the former, a manufacturer is required to register a pesticide, including plants with pesticidal qualities, with the EPA before selling it in the US market.[53] The EPA performs two main regulatory functions. First it establishes maximum tolerance levels for pesticide residues in foods. Second, before new microorganisms, which include intergeneric organisms derived through biotechnology, can be manufactured or imported, the EPA must be notified in accordance with the Toxic Substances Control Act.[54]

Because of the rising concern over the safety of biotech crops, the EPA responded to the Cornell laboratory study showing that GM pollen could kill monarch butterfly caterpillars by announcing new regulations to take effect in the spring of 2000. These new regulations, *inter alia,* ask farmers "to voluntarily protect butterflies by planting traditional corn around the edges of Bt corn fields. That would create a buffer to prevent toxic pollen from blowing into butterfly habitats."[55] It also required farmers to plant at least 20 percent of their crops as non-Bt corn. The purpose of this requirement is to slow the evolution of resistance to the Bt toxin, a natural insecticide available to organic farmers.[56]

C. The U.S. Department of Agriculture

The USDA's regulation of the release of GMOs is done under its

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50. *See* Morath, *supra* note 42, at 1; Novartis Seeds—Approval of a Pesticide Product Registration, 63 Fed. Reg. 43,935, 43,935 (1999).

51. 7 U.S.C. §§136-136y.

52. 21 U.S.C. §§301-395.

53. *See* Morath, *supra* note 42, at 1. According to a draft notice published August 9, 2000 (65 Fed. Reg. 48,701(2000)), the EPA is expected to issue a final rule classifying the agency's procedure of regulating genetically engineered plant pesticides while exempting from federal oversight traditional plant breeding. *EPA to Make Final "Core Components" of Regulation Covering Transgenic Plants*, 23 Int'l Env. Rep. (BNA), Curr. Rep., Aug. 16, 2000, at 644.

54. 15 U.S.C. §2603(d).

55. Carol Kaesuk Yoon, *E.P.A. Announces New Rules on Genetically Altered Corn,* N.Y. TIMES, Jan. 17, 2000, at A13.

56. *See id.*

Animal Plant and Health Inspection Service (APHIS), insofar as the GMOs are genetically engineered microorganisms derived from plant pests.[57] Those developing a new GMO plant must submit a petition to APHIS showing that, based upon field trials, the plant is safe and poses no risks as a plant pest.[58] APHIS's task is to conduct an environmental assessment to determine the GMO's possible effects on human health and the environment.[59]

APHIS will issue a "determination of non-regulated status" if it finds that the GMO is not a plant pest.[60] Then, the GMO may be released into the environment, that is, planted. From 1992 to 1998 APHIS provided non-regulated status to 36 genetically modified plants.[61]

In March 2000, the Department of Agriculture proposed strict rules prohibiting the use of GM ingredients in products carrying the organic label. The new rules, which could take effect by the end of 2000, address concerns about the use of three processes, genetic engineering, sewage sludge, and irradiation, in the production of food products that are labeled "organic." [62] This revision of the 1995 USDA rules would have established a nationwide certification program for organic foods. Presently, in order for raw products to be considered one hundred percent organic, "they must be grown or manufactured without added hormones, pesticides or synthetic fertilizers."[63]

D. The Food and Drug Administration

The Federal Food, Drug, and Cosmetic Act authorizes the FDA to ensure the safety of most foods, which includes foods derived through biotechnology.[64] It requires that new additives in food be demonstrated safe through standard scientific testing prior to their marketing.[65] However, biotech companies producing GM foods need not obtain ap-

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57. *See* Morath, *supra* note 42, at 1 (APHIS' authority is under Federal Plant Pest Act (7 U.S.C. §§150aa-150jj) and the Plant Quarantine Act (7 U.S.C. §§151-167)).

58. *See* Morath, *supra* note 42, at 5.

59. *See id.* at 4.

60. *See id.* at 1.

61. Animal and Plant Health Inspection Service, U.S.D.A., *Crop Lines No Longer Regulated by USDA*, (visited March 27, 2000) <http:// www.aphis.usda.dov/biotech/not reg.html>, *cited in* Stewart & Johanson, *supra* note 42, at 250 n.38.

62. *See New Rules on Organic Foods*, N.Y. TIMES, Mar. 9, 2000, at A28.

63. *Id. See also Strict Rules to Limit Genetic Engineering on Organic Foods,* N.Y. TIMES, Mar. 5, 2000, at 1 ("The [new rules] indicate an about-face in the agency's attitude on organic farming and represent one of several steps it is taking to help small and medium-sized farmers, who have received comparatively little attention from the agency for decades.")

64. 21 U.S.C. §§301-395.

65. *See id.* §321.

proval from the FDA to introduce such foods into the US market, and no prior testing is required, as the FDA considers them sufficiently similar to conventional foods, and they are thus "generally recognized as safe." Hence, the FDA does not regulate GMOs differently than their conventional counterparts. However, companies do usually consult the FDA before marketing their products, and the FDA has issued guidelines to assist the companies in this regard.[66] If it is discovered through consultations that a new product raises health concerns, the FDA may require under the FFDCA that a pre-market review be performed.[67] Those introducing the food product into the market are under a legal obligation to ensure that the food is safe.[68] Thus the responsibility for ensuring food safety is on the producer, who could be criminally liable for introducing an unsafe food into the marketplace.[69] The FDA could also stop the food's distribution if it is proven unsafe.

Since the US considers GM foods to be substantially equivalent to those produced through traditional breeding methods,[70] no labeling is required for GM foods. There could be exceptions, however, when a GM food product has a significantly different nutritional content or if it might pose a health risk.[71] One example would be where a GM food product contained a protein derived from a peanut, in which event the FDA might require labeling to warn consumers who are allergic to peanuts that the product contains such proteins.[72]

On the subject of GMO food safety, however, in late 1999, the FDA decided to hold public meetings. At the first, hearing held in November 1999, both proponents and opponents were vocal in advocating their respective positions,[73] the former claiming that the FDA had done an exemplary job in approving GM food and crops in the US as safe, and the latter arguing that the release of GMOs into the environment poses risks that are "potentially irreversible, untraceable and uncontrollable."[74] Also in November, Rep. Dennis Kucinich and several co-sponsors introduced a bill in the U.S. House, the "Genetically Engineered Food Right to Know Act," specifically citing as one of its threshold findings that "Federal agencies have failed to uphold Congressional intent by allowing genetically engineered foods to be marketed, sold and otherwise

66. *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,984.

67. *Id.* at 22,987-22,989.

68. *Id.* at 22,988.

69. *Id.*

70. *See id.* at 22,991.

71. *Id.*

72. *Id.*

73. *See generally* David Barboza, *2 Sides Square Off on Genetically Altered Food*, N.Y. TIMES, Nov. 19, 1999, at A30.

74. *Id.*

used without labeling that reveals material facts to the public."[75] Sen. Barbara Boxer introduced the Senate version in February 2000,[76] and Rep. Kucinich introduced a new House bill, the "Genetically Engineered Food Safety Act."[77] This new piece of legislation refers to the failure of federal agencies to uphold congressional intent of the Food Additives Amendment of 1958 by allowing genetically engineered foods to be marketed, sold and otherwise used without requiring pre-market safety testing addressing their unique characteristics.[78]

In some states, such as Colorado and Oregon, citizens' initiatives for state laws on the subject of mandatory labeling have been undertaken.

On May 3, 2000, the FDA announced that it would strengthen its policies regarding GM foods and would develop guidelines for companies that want to label such foods.[79] Biotech companies will henceforth be required to give a four-month advance notice to the FDA before marketing new GM food, providing the agency and the public with the research finding ensuring the new food's safety.[80] Food producers could now voluntarily label food as free of gene-altered ingredients.[81]

In the Fall of 2000, the FDA confirmed the presence of unapproved genetically engineered corn in some grocery taco shells and announced plans to begin testing other corn-based products as well for contamination.[82] Aventis CropScience, S.A., the developer of the corn, known as StarLink, which was approved in 1998 for use as animal feed but not for human consumption because of concerns that it might cause allergic reactions, agreed to voluntarily cancel its marketing license "at the strong urging" of the EPA, according to the agency.[83] Kraft Foods was

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75. H.R. 3377, 106th Congress, 1st Session, Nov. 16, 1999, Sec. 2, para. (3).

76. S. 2080, 106th Congress, 2d Session, Feb. 22, 2000.

77. H.R. 3883, 106th Congress, 2d Session, Mar. 9, 2000.

78. *Id.*, Sec. 2, para. 7.

79. *See* Proposed Collection and Comment Request at 65 FED. REG. 25491, May 2, 2000. *See also* Melody Petersen, *U.S. to Keep Closer Watch on Genetically Altered Crops,* N.Y. Times, May 4, 2000, at A23, col. 5.

80. *See* John Dillin, *White House Enters the Biotech Food Fight,* Christian Science Monitor, May 5, 2000, at 1; Rick Weiss, *U.S. to Add Oversight on Biotech Food,* Wash. Post, May 3, 2000, at A1.

81. *See* Weiss, *supra,* note 75; Andrew Kimbrell, *The F.D.A. Chickens Out,* N.Y. Times, May 8, 2000, at A23, col. 2.

82. *See generally* Nikki Tait, Taco shell recall puts biotech product testing under strain: Consumers reacted calmly to evidence of an unapproved corn but the episode raises important questions, Fin. Times (London), Oct. 11, 2000, at 14. *See also* Marc Kaufman, FDA Will Widen Probe of Biotech Corn Misuse, Wash. Post, Oct. 3, 2000, at 813.

83. *See* Andrew Pollack, Aventis Gives Up License to Sell Biotech Corn, N.Y. Times, Oct. 13, 2000, at C5; Firm Agrees to Withdraw Biotech Corn; EPA Had Sought Removal

prompted to recall over 2.5 million boxes of shells sold under the "Taco Bell" brand.[84]

E. A Vermont Case Holds That a Mandatory Labeling Law May Be Unconstitutional

In Vermont a group of trade associations challenged the state's 1994 law mandating the labeling of milk and milk products from cattle treated with recombinant bovine somatotropin (r-BST) a drug produced through recombinant DNA technology to increase cows' milk production.[85] The purpose of the law was to protect the interest of consumers who have a "right to know" about the foods they consume.[86] The FDA had determined that milk obtained from cows treated with r-BST posed no threats to human health. The challenge to the law was based on the rationale that the right of those dairy producers "not to speak," i.e., not to label, is protected under the First Amendment. The district court held that Vermont had a substantial interest in informing consumers of the use of r-BST in dairy products sold in the state.[87] On appeal, the Second Circuit overturned the lower court, stating that the "dairy manufacturers' constitutional right not to speak is a serious one" and that Vermont's law "requires them to speak when they would rather not."[88] It further said that, in a commercial context, "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement,"[89] and since Vermont had demonstrated "no cognizable harms," it held that the statute would likely be found unconstitutional and remanded the case for injunction.[90]

IV. THE BIOSAFETY PROTOCOL

A. Events Leading Up To The Biosafety Protocol

After five years of informal discussions and negotiations, representatives from over 130 states met in Montreal, Canada, from February 24 to 29, 2000, and finalized the Cartagena Protocol on Biosafety to the

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from Market After Latest Discovery in Taco Shells, Wash. Post, Oct. 13, 2000, at A13.

84. *See* Andrew Pollack, Kraft Recalls Taco Shells With Bioengineered Corn, N.Y. Times, Sept. 23, 2000, at C1; Barnaby J. Feder, Companies Act to Keep Bioengineered Corn Out of Food, N.Y. Times, Sept. 27, 2000, at C2; Marc Kaufman, Biotech Corn Fuels a Recall; Unapproved Variety Used in Taco Shells, Wash. Post, Sept. 23, 2000, at A1.

85. International Dairy Foods Ass'n v. Amestoy, 898 F.Supp. 246 (D. Vt. 1995).

86. *Id.* at 248-49.

87. *Id.* at 253-54.

88. International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71-72 (2d Cir. 1996).

89. *Id.* at 74.

90. *Id.*

Convention on Biological Diversity.[91] The Protocol is aimed at protecting the environment from the potential risks caused by the transboundary transfer of living modified organisms (LMOs), including GMOs, created by modern biotechnology. The Biological Diversity Convention[92] and Agenda 21,[93] an Action Plan calling for sustained economic growth through international cooperation, both adopted at the United Nations Conference on Environment and Development (UNCED) (the "Earth Summit") in Rio de Janeiro in June 1992, address safety issues concerning GMOs.

Although there are several related articles in the Biological Diversity Convention, which call for the signatories to either share technologies or provide remuneration as reparations to a developing country for genetic materials taken out of such country,[94] the one specifically applicable to safety issues is article 19.[95] The debate around article 19 centered on whether biotechnology as a process should be regulated. The US objected to the proposed regulation of biotechnology, contending that as a process it was not a threat to biological diversity. Article 19(4), as a compromise, obligates each party:

> directly or by requiring any natural or legal person under its jurisdiction . . . [to] provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.[96]

In addition, Article 19(3) calls upon the parties to consider the need for and modalities of a protocol setting out appropriate procedures. In particular, advanced informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.[97]

Regarding the introduction of living modified organisms, the Convention obligates each party, as far as possible and appropriate to,

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91. Biosafety Protocol, *supra* note 2.

92. Convention on Biological Diversity, *opened for signature* June 5, 1992, *reprinted in* 31 I.L.M. 818 (1992) [hereinafter Biological Diversity Convention].

93. *See* Report of the United Nations Conference on Environment and Development, U.N. Doc. A/CONF. 151/26/Rev.1, at 12 (1993).

94. *See,* Biological Diversity Convention, *supra* note 92, arts. 16, 20, 21.

95. *See id.* art. 19 (paragraphs (1) and (2) address the participation of the developing countries in biotechnological research and access to such countries "on a fair and equitable basis" to the "benefits arising from biotechnologies based upon genetic resources provided by" them. These, however, will not be discussed here.

96. *See id.* art. 19(4).

97. *See id.* art. 19(3).

> [e]stablish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.[98]

The United States, however, did not sign the Convention, contending that the text was "seriously flawed in a number of important aspects."[99] The US found "particularly unsatisfactory the text's treatment of . . . technology transfer and bio-technology."[100]

Chapter 16 of Agenda 21 entitled "Environmentally Sound Management of Biotechnology," states that Agenda 21's goal is to foster international principles for the environmental management of biotechnology and to promote sustainable applications of biotechnology.[101] Among other chapters, chapter 14 provides for the sharing of research and plant genetic resources among nations.[102] Chapter 15 aims at improving the conservation of biological diversity and supporting the Biodiversity Treaty.[103] Finally, Chapter 19 addresses the issue of risk management of toxic chemicals and may also apply to certain biopesticides and other hazardous products of biotechnology.[104]

It was pursuant to the Article 19(3) mandate of the Biodiversity Convention that the discussions on the drafting of a Protocol had begun. Thus, although between July 1996 and February 1999 the ad hoc working group on biosafety, established by the parties to the Convention, had held six meetings,[105] a final consensus on all points had not been reached on the draft at the earlier session of the parties, which met in Cartagena, Colombia, from February 22-24, 1999. Since the Cartagena session had been convened before the negotiations on the draft text of the Protocol could be concluded,[106] it ended in an impasse. Several groups presented proposals at the session, including the European Un-

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98. *Id.* art. 8(g).

99. Declaration of the United States of America, attached to the Nairobi Final Act, *reprinted in* 31 I.L.M. 842, 848, para. 3 (1993).

100. *Id.* para. 4.

101. *See* Agenda 21, UN Doc. A/CONF.151/26/Rev.1 (Vol. I), ch. 16, at 218 (1993). The final program areas in biotechnology include establishing enabling mechanisms for the development of and the environmentally sound application of biotechnology. *Id.*

102. *Id.* ch. 14.57(d), at 195: "To take appropriate measures for the fair and equitable sharing of benefits and results of research and development in plant breeding between sources and users of plant genetic resources."

103. *Id.* ch. 15, at 210.

104. *Id.* ch. 19, at 315.

105. UNEP, Convention on Biological Diversity, Conference of the Parties to the Convention on Biological Diversity, Draft Report of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity, U.N. Doc. UNEP/CBD/ExCOP/1/L.2/Rev. 1, para. 28, Feb. 23, 1999 [hereinafter Cartagena Report].

106. *Id.* para. 22.

ion,[107] the Miami Group,[108] and the third on behalf of the "like-minded group of countries."[109] The meeting adjourned, deferring the solution for the next meeting in Montreal.[110]

The period between the Cartagena meeting and the resumed session in Montreal provided members with an opportunity to continue informal discussions. Although there was concern that the Montreal negotiations might also collapse, meeting a similar fate as those at Cartagena, the Montreal session succeeded with the parties reaching an agreement, to the surprise of many negotiators.[111] As *The Economist* reported, while the Cartagena session had failed because of the opposition of the Miami Group, "the softening-up process that has occurred during the past eleven months—the consumer and producer revolt, and the vacillation about the technology by the purveyors themselves, seems to have made these countries more amenable to a deal."[112]

B. Content and Analysis

The Biosafety Protocol reflects the commitment of the international community to provide for safety in biotechnology and is, indeed, a historic attempt to reconcile economic and trade policies with environmental concerns. It incorporates the precautionary principle in the process of decision-making, and underscores the need to enhance the capacity building of the developing states to ensure biotechnology safety.

The Protocol establishes that strict "Advanced Informed Agreement" procedures be applied to LMOs, including seeds, plants, live fish and other organisms, that are to be intentionally introduced into the environment. The exporter in these cases is required to provide detailed information to each importing country in advance of the first shipment, and the importer must then authorize the shipment. This procedure is designed to ensure that recipient countries have both the opportunity and the capacity to assess risks pertaining to the products of modern biotechnology.[113] However, this procedure does not apply to the intentional transboundary movement of LMOs if they are "not likely

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107. *Id.* Annex II.

108. *Id.* Annex III.

109. *Id.* Annex IV.

110. For the contents of the Draft Protocol on Biosafety, *see id.* Annex to decision EM-I/3.

111. *See* Edward Alden, *Greens and Free-Traders Join to Cheer GM Crop Deal*, FIN. TIMES (London), Jan. 31, 2000, at 11; Pollack, *supra* note 8; John Burgess, *Trade Rules Set on Food Genetics; Compromise Gained on Labeling Issue*, WASH. POST, Jan. 30, 2000, at A1.

112. *A Conventional Argument*, ECONOMIST, Jan. 29, 2000, at 95.

113. *See* Biodiversity Protocol, *supra* note 2, arts. 7-16; 25-26.

to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."[114]

The Protocol, however, applies to neither pharmaceuticals,[115] nor to commodities such as soybeans or maize, intended for direct use as food, feed, or processing.[116] These were among the contentious issues primarily responsible for the failure of the Cartagena meeting to reach an accord on the Biosafety Protocol. The United States, although not a party to the Convention on Biological Diversity and hence not an official participant at the Cartagena and Montreal meetings, expressed its concerns through its allies in the Miami Group, and was the major opponent of any regulation pertaining to food commodities and pharmaceuticals in the proposed Protocol.

The procedure calls for a party that decides to place on the market an LMO commodity "that may be subject to a transboundary movement for direct use as food or feed, or for processing," to inform the parties through the Biosafety Clearinghouse.[117] The Biosafety Clearinghouse is established under the Protocol to:

> (a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
>
> (b) Assist parties to implement the Protocol, taking into account the special needs of developing country Parities, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centers of origin and centers of genetic diversity.[118]

Another contentious issue on which a compromise was eventually reached was the labeling of any commodity shipment containing GMOs. The European Union and developing countries sought provisions for clear labeling by exporters of any shipment of commodities containing GMOs. To illustrate, at the Cartagena meeting, the European Union had submitted its proposal under which an exporter would be required to clearly indicate as Living Modified Organisms commodities "intended for direct use as food, feed or processing."[119] The United States and other exporting countries had claimed that such labeling would be impossible for bulk commodity shipments where grain is mixed from many

114. *Id.* art. 7(4).

115. *Id.* art. 5: "[T]his Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations."

116. *Id.* art. 11.

117. *Id.* art. 11(1); Annex II (information required to be given under article 11).

118. *Id.* art. 20(1).

119. Cartagena Report, *supra* note 105, Annex II, para. 2(2)(c).

different sources.[120]

As it stands, Article 18, paragraph 2(a) now reads:

> Each Party shall take measures to require that documentation accompanying:
>
> a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.[121]

Thus, there is no specific identification required of the type or nature of GMOs and there is a two- year period following the Protocol's ratification by fifty states when it will enter into force,[122] before any further action can be taken regarding the commodities.

Article 7 of the Protocol exempts "living modified organisms intended for direct use as food or feed, or for processing" from the advance informed agreement procedure.[123] States are to develop their own national regimes.[124]

Another contentious issue regards the incorporation of the precautionary principle in the Protocol, embodied as Principle 15 of the Rio Declaration on Environment and Development[125] at the 1992 Earth Summit. Calling for wide application of the precautionary approach, the Principle adds that where there is a threat of "serious or irreversible damage, lack of full certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[126] At Cartagena, the Miami Group took the position that reference to the precautionary approach in the Protocol must be simply noted, rather than that the Protocol state in its objective that it is in accordance with the precautionary approach.[127] In addition, the Group

120. *See* Alden, *supra* note 111.

121. Biosafety Protocol, *supra* note 2, art. 18(2)(a). *See also id.* paras. 87-88 for a report on the parties' adoption of the above paragraph as an amendment.

122. *Id.* art. 37.

123. Biosafety Protocol, *supra* note 2, art. 7(2).

124. *See id.* arts. 10-16; 25-26.

125. UNCED, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I), Annex I, at 3 (1992), *reprinted in* 31 I.L.M. 874 (1993) [hereinafter Rio Declaration].

126. *See*, Rio Declaration, *supra* note 125, principal 15.

127. Cartagena Report, *supra* note 105, Annex III, para. 4(a).

wanted to delete any reference to the precautionary approach from the decision procedure.[128]

The Miami Group was unsuccessful in its attempt. The Protocol reaffirms the precautionary approach in its preamble and retains the language: "[i]n accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development . . . the objective of this Protocol is . . . ."[129] Furthermore, the language contained in the decision procedure is unequivocal:

> [l]ack 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 . . . in order to avoid or minimize such potential adverse effects.[130]

The same language is also used pertaining to the procedure for LMOs intended for direct use as food or feed, or for processing.[131]

Finally, the question of the relationship between the Protocol and the World Trade Organization (WTO) was resolved by noting in the preamble that the Protocol would not be subordinate "to other international agreements," which in this context, meant primarily the WTO. The point of contention was that under trade rules it was not the precautionary approach but certain scientific evidence that would determine if an importing country could block the shipment of a GMO. To illustrate the applicable law, the Agreement on the Application of Sanitary and Phytosanitary Measures requires that measures that are undertaken by an importing country and designed to protect human, animal or plant life, must be scientifically supported and verifiable.[132] It may be recalled that at the WTO meeting in Seattle in the fall of 1999,[133] no decision could be taken about the regulation of biotechnology under the WTO processes.

The Protocol provides for risk assessment[134] and risk management.[135] The Biosafety Clearinghouse is designed to assist parties in

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128. *Id.* para. 4(b)

129. Biosafety Protocol, *supra* note 2, art. 1.

130. *Id.* art. 10(6).

131. *See id.* art. 11(8).

132. Agreement on the Application of Sanitary or Phytosanitary Measures, GATT Doc. M.T.N./FA II-A1A-4, art. 2.2 (Dec. 15, 1993), *reprinted in* THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 69, 70 (1995).

133. On the Seattle meeting, *see, e.g.*, Ved Nanda, *Battle in Seattle*, DENVER POST, Nov. 30, 1999, at 11B.

134. Biosafety Protocol, *supra* note 2, art. 15; Annex III.

135. *Id.* art. 16.

implementing the Protocol, with special attention to the needs of developing countries.[136] Special provisions address capacity-building of developing countries, including appropriate scientific and technical training; risk assessment and risk management for biosafety; and the enhancement of technological and institutional capacities in biosafety.[137] The importing country may make its decision by taking into account "socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."[138] As to liability and redress for damage resulting from transboundary movements of LMOs, the Protocol postpones any decision to the first meeting of the Conference of the Parties.[139] Every five years the parties are to assess the effectiveness of the Protocol.[140] The Protocol does not allow any reservations.[141]

As the Executive Director of the United Nations Environment Program, Klaus Topfer, said after the adoption of the Protocol, it "was a historic event that gave the right signal for future global cooperation."[142] As the first treaty to recognize GMOs as distinctive and apply the precautionary principle, it certainly is an important step forward in the development of international environmental law.

V. REGULATION OF GMOS IN EUROPE

A. *Introduction*

The European Union has undertaken extensive measures to regulate GMOs, mainly in response to consumers' concerns with the potential hazards of GMO foods and crops. In addition, many European states have unilaterally imposed even more stringent regulations. Four European laws will be discussed here: Council Directive 90/220/EEC of April 23, 1990, on the deliberate release of GMOs into the environment;[143] Regulation No. 258/97 of January 27, 1997, the Novel Foods Regulation;[144] Commission Directive 97/35/EC of June 18, 1997, amending Annex III of Directive 90/220/EEC, to require the labeling of prod-

136. *Id.* art. 20(b).
137. *Id.* art. 22.
138. *Id.* art. 26.
139. *Id.* art. 27. The Conference of the Parties is to serve as the meeting of the Parties to the Biosafety Protocol. *Id.* art. 29.
140. *Id.* art. 35.
141. *Id.* art. 38.
142. *See* Biosafety Protocol, *supra* note 2.
143. *See generally* 1990 O.J. (L 117).
144. *See* 1997 O.J. (L 43).

ucts that contain GMOs;[145] and Council Regulation No. 1139/98 of May 26, 1998, concerning the compulsory indication of the labeling of certain foodstuffs produced from GMOs.[146]

B. Council Directive 90/220

In the preamble to Council Directive 90/220, the Council of the European Communities provided its rationale for prescribing a legal framework specifically regarding the deliberate release of GMOs: (1) the need to take preventive action; (2) the potential effects of GMO releases on the environment which may be irreversible; and (3) the need to approximate the laws of the member states to ensure that the likely unequal conditions of competition or barriers to trade because of disparity between member states' regulations of products containing GMOs do not adversely affect the functioning of the Common Market.[147] The Directive seeks to provide "a high level of protection throughout the Community" on health, safety, environmental and consumer protection and to ensure the safe development of industrial products utilizing GMOs.[148] Thus, the objective of the Directive is to approximate the laws of the EU member states on the placing into the market of products containing GMOs that are intended for subsequent release into the environment.[149]

The Directive obligates each member state to take "appropriate measures" to avoid adverse effects on human health and the environment from the deliberate release or placing into the market for the deliberate release of GMOs.[150] Each member state is to designate the competent authority responsible for the implementation of the Directive and to ensure that such authority takes appropriate control measures for such implementation.[151] The Directive provides distinct yet similar norms and procedures regarding the deliberate release of GMOs into the environment for research and development purposes[152] and for placing products containing GMOs into the market.[153]

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145. *See* Commission Directive 97/35/EC, 1997 O.J. (L 169), June 18, 1997 (it should be noted that in April 1994, Council Directive 90/200/EEC was amended by Commission Directive 94/15, 1994 O.J. (L 103), which changed Annex II, "Information Required in the Notification").

146. Council Regulation (EC) No. 1139/98 of May 26 1998, Concerning the Compulsory Indication of the Labelling of Certain Foodstuffs Produced From Genetically Modified Organisms of Particulars Other Than Those Provided For in Directive 79/112/EEC, 1998 O.J. (L 159).

147. *See* Council Directive 90/220/EEC, 1994, pmbl.

148. *Id.*

149. 1990 O.J. (L 117), art. 1.

150. *Id.* art. 4(1).

151. *Id.* art. 4(2), (3).

152. *Id.* arts. 5-9.

153. *Id.* arts. 10-18.

Before deliberately releasing a GMO for research purposes, the person proposing such release must notify the competent national authority within the pertinent territory of the risks involved and the conditions and the environment in which the release is to take place.[154] The competent authority must examine the notification, evaluate the risks and give its written consent as a prerequisite for release.[155] After completion of a release, the person is to send to the competent authority the result of such release regarding any risk to human health or the environment.[156] The competent authorities are to send to the Commission a summary of each notification, and the Commission in turn is to forward these summaries to other member states.[157] The competent authorities are to then inform the other member states and the Commission of the final decision whether the notification is in compliance with this Directive, thus allowing the release or rejecting the notification in the event that the release does not fulfill the Directive's conditions.[158]

The procedure is similar for the deliberate release of a commercial GMO product. The manufacturer or importer of a GMO is to notify the competent authorities of the member state where the GMO is to be placed into the market for the first time.[159] The requirements for such notification are listed in Annex II.[160] A risk assessment must be conducted concerning the possible effects on human health and the environment.[161] The notifying party must also provide its "Proposal for Labeling and Packaging."[162] The competent authority of the member state, after receiving a notification, is required to examine it for compliance with the Directive, "giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product."[163] The competent authority is also required to forward the dossier to the Commission with a favorable opinion, or reject the proposed release within 90 days of receiving the notification.[164] A release requires written consent by the Commission and the other member states.[165]

The Commission is then to inform the competent authorities in

154. *See id.* art. 5(1), (2).
155. *See id.* art. 6.
156. *Id.* art. 8.
157. *Id.* art. 9(1) and (2).
158. *Id.* art. 9(3); pursuant to art. 6(2) conditions.
159. *See id.* art. 11(1).
160. *See id.* Annex II.
161. *Id.* art. 11(1).
162. *Id.*
163. *Id.* art. 12(1).
164. *Id.* art. 12(2).
165. *Id.* art. 11(5).

other member states, forwarding the dossier.[166] In case of no objection from any others, the competent authority that received the original notification is to give its consent for the release, informing the Commission and other member states.[167] However, if there is any objection from the competent authority of another state, the Commission is to submit the proposed measures to a committee composed of the representatives of the member states and chaired by the representative of the Commission.[168] The Commission is to "adopt the measures . . . if they are in accordance with the opinion of the committee."[169] However, if they are not in accordance with the opinion of the committee or if no opinion is delivered, the Commission is to forward the proposal to the Council, which will decide by a majority vote.[170] If the Council does not act within a period of three months, the Commission is to adopt the proposed measures.[171] If the Commission has taken a favorable decision, the competent authority that had received the notification is to give its written consent to the placing of the GMO product and is to inform the other member states and the Commission that it has done so.[172] After such written consent the GMO product may be used without further notification throughout the EU.[173] No member state of the EU is to "prohibit, restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive."[174]

The Directive authorizes provisional restrictions by a member state on the use and/or sale of GMOs in its territory if there are "justifiable reasons" to consider that such product "constitutes a risk to human health or the environment."[175] Finally, intellectual property rights relating to the data received are to be protected by the Commission and the competent authorities are not to divulge to third parties any confidential information notified or exchanged under this Directive.[176]

The Commission decisions approving GMO products for release pursuant to the procedures prescribed under Directive 90/220 have caused considerable concern and controversy in member states and in the European Parliament.[177] There have been several attempts to

166. *See id.* art. 13(1).
167. *Id.*
168. *Id.* arts. 13(3), 21.
169. *Id.* art. 21.
170. *Id.*
171. *See id.*
172. *Id.* art. 13(4).
173. *Id.* art. 13(5).
174. *Id.* art. 15.
175. *Id.* art. 16 (1).
176. *Id.* art. 19(1).
177. For a discussion of these developments, *see* Stewart & Johanson, *supra* note 42, at 259-68.

strengthen prior prescriptions regarding the release of GMOs and to extend the scope of European regulations regarding GMOs. A few important developments will be noted here.

C. *Regulation No. 258/97*

On January 27, 1997, the European Union adopted Regulation Number 258/97. The new regulation applies to GMOs in processed foods likely to be purchased by consumers. It is aimed at providing a uniform law for novel foods throughout the European Union.[178] The regulation applies to foods "which have not hitherto been used for human consumption to a significant degree within the Community,"[179] including food products containing GMOs within the meaning of the prior Council Directive 90/220/EEC, food produced by but not containing GMOs, and foods "with a new or intentionally modified primary molecular structure."[180]

The procedure for approval is similar to the one established in the 1990 Council Directive discussed above, insofar as the one seeking to introduce the novel food into the European Union must submit a request to the member state in which the product is to be placed into the market for the first time and also to the Commission.[181] The request to the member state is to specify how the product is to be labeled,[182] indicating whether because of the food's characteristics it is no longer equivalent to an existing food.[183] Scientific assessment is to determine whether a food is not equivalent to an existing food, and thus novel.[184] The purpose is to inform the final consumer through labeling that GMOs are present in the food or that the food "may contain" GMOs which is to be labeled as such.[185] There are detailed provisions regarding the assessment of such food and the role of the Commission to authorize measures proposed by the applicant,[186] and also for provisional restrictions, which may be imposed by a member state if the food poses risks to human health or the environment.[187]

178. For the legislative process leading to the adoption of this regulation, *see id.* at 275-78.
179. Commission Regulation No. 258/97, 1997 O.J. (L 43), art. 1(2).
180. *Id.* art. 1, paras. (2)(a)-(c).
181. *See id.* art. 4(1).
182. *See id.* art. 6(1).
183. *See id.* art. 8(1)(a).
184. *See id.*
185. *See id.* art. 8(1)(d).
186. *See id.* arts. 6-7, 13.
187. *See id.* arts. 12-13.

D. *Commission Directive 97/35/EC*[188]

After having gained experience with the placing of GMOs into the market since the issuance of Council Directive of 1990, the Commission considered it necessary to amend Annex III to that Directive, which contains the additional information required in the case of notification for placing GMOs into the market.

This must include in a label or an accompanying document an indication that the product contains, or consists of genetically modified organisms. In the case of products to be placed on the market in mixtures with non-genetically modified organisms, information on the possibility that the genetically modified organisms may be present, is sufficient.[189] It should be emphasized that the amendment does not require GMO products and non-GMO products to be segregated.

E. *Council Regulation No. 1139/1998*[190]

As the Novel Foods Regulation, which mandates labeling, did not apply retroactively, the Council adopted a new regulation to apply to "foods and food ingredients which are to be delivered as such to the final consumer . . . produced, in whole or in part," from genetically modified soybeans and genetically modified maize,[191] which had been earlier authorized under Directive 90/220/EEC. The Council identified as one of the purposes of the new regulation the necessity to adopt uniform EU labeling rules for these products[192] because several member states had unilaterally taken measures on labeling and there was concern that "differences between those measures [could] impede the free movement of those foods and food ingredients and thereby adversely affect the functioning of the internal market."[193] The Council also felt it:

> necessary to ensure that the final consumer is informed of any characteristics or food property, such as composition, nutritional value or nutritional effects or the intended use of the food, which renders a food or food ingredients no longer equivalent to an existing food or food ingredient; [and] for that purpose, foods and food ingredients produced from genetically modified soyabeans or from genetically modified maize which are not equivalent to conventional counterparts should be subject to labeling requirements.[194]

It further said that labeling requirements are to be based on scien-

188. 97/35/EC, 1997 O.J. (L 169).
189. *Id.* Annex III, C.
190. 1998 O.J. (L 159).
191. *Id.* art. 1(1).
192. *Id.* pmbl, para. 4.
193. *Id.*
194. *Id.* para. 9.

tific evaluation,[195] and should not be "more burdensome than necessary but sufficiently detailed to supply consumers with the information they require."[196]

The regulation is not to apply to "food additives, flavourings for use in foodstuffs or extraction solvents used in the production of foodstuffs."[197] The additional specific labeling requirement includes the requirement for the words "produced from genetically modified soya" or "produced from genetically modified maize," as appropriate.[198] It is to appear in the list of ingredients, a footnote to the list, or some other clear location on the product, where the food consists of more than one ingredient. Where no list of ingredients exists, the words "produced from genetically modified soya" or "produced from genetically modified maize," as appropriate, is to appear clearly on the labeling of the food.[199]

These labeling regulations are minimum requirements and producers are not precluded from including any additional information about their products on the label, "such as the absence of foods and food ingredients produced from genetically modified soyabeans and maize, or the presence of such foods and food ingredients in cases where it is not scientifically verifiable but evidence of it is available through other means."[200]

F. Subsequent Developments

Subsequent to the adoption of this regulation, the Commission announced in Decision 98/613/EC on October 21, 1998,[201] that it intended to remove the exemption contained in Council Regulation 1139/98 for food additives and flavorings genetically modified or produced by genetic engineering.

In June 1999, Europe's environment ministers agreed on even tougher controls on GMOs by introducing new "risk assessment" rules to monitor scientific evidence and to provide for a clear label that reads: "This product contains genetically modified organisms," for products containing more than a certain percentage of GM ingredients, and substituting a reapproval process for all new GM plants and seeds approved for sale instead of the currently available permanent consent

195. *Id.* para. 10.
196. *Id.* para. 12.
197. *Id.* art. 1(2).
198. *Id.* art. 2(3)(a).
199. *Id.* art. 2(3)(b).
200. *Id.* pmbl, para. 20.
201. Commission Decision 98/613/EC, concerning a draft Decree of the Republic of Austria on the identification of genetically modified additives and flavourings used as food ingredients, 1998 O.J. (L 291).

mechanism.[202]

Among other developments, on January 12, 2000, the European Commission proposed the creation of an all-Europe food safety agency, which envisions the creation of an advisory body of scientists, unlike the US FDA, which is an independent agency.[203] And in March 2000, the Commission continued its *de facto* moratorium on authorizing GM products as it deferred for six months a decision on two Swede rapes and one fodder beet, although all these products had been approved as safe by EU scientists.[204] No new authorizations have been granted since October 1998 and fourteen applications are still awaiting approval.[205] However, in July 2000, the European Union announced that the European Commission was considering ending the two-year moratorium on licensing GM products after tighter licensing laws are approved by the EU governments and the European Parliament, although environmentalists and some governments are likely to oppose such a plan.[206]

VI. CONCLUSION

The potential benefits of GM food and food products notwithstanding, the concern with safety has steadily grown and is currently intense in Europe, although it is also prevalent in many other parts of the world. The Biosafety Protocol is a promising regulatory step internationally, but European regulations are more effective.

Perhaps the creation of a new world body to monitor biotechnology should be seriously considered. Such a proposal, with the proposed functions of such a body being to monitor the multinationals and advise governments on consumer safety and ethics, was offered by several eminent scientists at the Edinburgh conference on GM food safety held in late February 2000. Sir John Krebs, who chaired the conference, said

> [w]e need industry, regulators, scientists, consumers, and we need to consider ethics, values and beliefs, issues of world trade, intellectual property rights, and exploitation of the developing world. By ironing out these problems and reaching a consensus, then politicians can decide the way forward.[207]

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202. *See* Stephen Castle, *EU Agrees on Tougher GM Food Control*, INDEPENDENT (London), June 26, 1999 at 10.

203. *See* Donald G. McNeil, Jr., *Europe Plans Advisory Unit on Food Safety*, N.Y. TIMES, Jan. 13, 2000, at A10.

204. *See* Mike Smith, *EU Defers Modified Products Approval—Genetically Changed Foods De Facto Moratorium Stays*, FIN. TIMES (London), Mar. 10, 2000, at 12.

205. *See id.*

206. *See* Mike Smith, Europeans at odds over modified food: Environmentalists will resist Brussels' plans to ease curbs, Fin. Times (London), Jul. 14, 2000, at 1.

207. *See* Paul Brown, Call for World to Police GM Science, GUARDIAN (London), March 1, 2000, Home Pages, at 6k.

It is imperative that the world community undertake the regulation of biotechnology in a coherent and consistent fashion, because the potential risks are enormous and possibly irreversible.