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Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade

by

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POLICY IN FLUX: THE EUROPEAN UNION'S LAWS ON AGRICULTURAL BIOTECHNOLOGY AND THEIR EFFECTS ON INTERNATIONAL TRADE*

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I. INTRODUCTION

The United States and the European Union share the world's largest trading relationship.[1] This relationship is not without difficulties, and perhaps the greatest area of trade conflict between the two involves agriculture. Disputes between the United States and the European Union over the trade of hormone treated beef, disagreements over agricultural export subsidies, the inability to finalize a veterinary equivalency agreement, and trade measures proposed as a result of bovine spongiform encephalopathy (BSE) ("mad cow" disease) regularly dominate the headlines of the international trade press. Biotechnology and its application to agriculture is another major source of conflict between the European Union and the United States.

The cultivation of agricultural products derived through modern biotechnology is rapidly becoming commonplace on American farms.[2] While the introduction of genetically modified food products into the U.S. market has been challenged by consumer groups on grounds of possible health risks, the use of biotechnology appears accepted by the American public.[3] The United States has an established regulatory system for the approval of genetically modified organisms (GMOs), which makes the process of introducing a genetically modified food or agricultural product into the market fairly predictable.[4]

In contrast, the sale and cultivation of GMO agricultural products in the European Union has been and continues to be heavily contested by consumers. Consumer concerns about GMOs can be attributed in part to the recent BSE crisis in Europe as well as to past abuses in Europe related to genetic engineering.[5] Consumer anxieties, combined with the concerns of industry and some government officials about European competitiveness in biotechnology, have led to a situation in which few Europeans appear satisfied with the European Union's laws in this area. Consequently, these laws are frequently changing and will likely continue

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1. *See* U.S. TRADE REPRESENTATIVE, 1996 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 91 (1996).

2. *See Labelling the Mutant Tomato*, THE ECONOMIST, Aug. 9, 1997, at 54. For example, while farmers in the United States planted one million acres of genetically modified soybeans in 1996, they planted ten million acres in 1997. *See id.*

3. *See, e.g.*, Robert A. Bohrer, *Food Products Affected by Biotechnology*, 55 U. PITT. L. REV. 653, 670-77 (1994) (discussing case studies on challenges to the introduction of two genetically modified food products into the United States market: Calgene's Flavr-Savr tomato and milk obtained from cows treated with recombinant bovine somatotropin (r-BST)).

4. *See generally id.* (concluding that U.S. regulations are predictable based on the specific regulations enumerated).

5. *See* Michael Specter, *West Germany's Anguished Science: Genetically Engineered Petunias Raise Bitter Memories of Nazi Past*, WASH. POST, Apr. 11, 1990, at A16.

changing in the foreseeable future. This legal uncertainty significantly impacts U.S. agricultural producers seeking access to the European market.

This Article examines the current situation in the European Union regarding biotechnology and the production of agricultural products. For purposes of contrast, it begins by briefly describing the laws of the United States that pertain to agricultural biotechnology, which vary greatly from the European Union's laws. Before analyzing the European Union's rules themselves, the Article discusses the European Union's policy making process, and in particular the European Parliament's growing power, which partially explains the apparent inability of the European Union to decide conclusively what its laws on biotechnology will be.[6] The Article then concentrates on the two major laws related to agricultural biotechnology: Council Directive 90/220/EEC and the Novel Foods Regulation.[7] The Article examines the highly contested approval process of one GMO product, Ciba-Geigy's (Novartis) Bt-maize, the negative reaction to this approval, changes to the European Union's laws in response to this negative reaction, and a recent law on Bt-maize revisiting the requirements of placing this product in the market.[8] It also discusses the European Union's policies on biotechnology in light of the World Trade Organization's (WTO) rules and concludes with a case study of a possible U.S. challenge at the WTO to one of the European Union's laws regulating GMOs.[9]

II. OVERVIEW OF U.S. POLICIES REGARDING AGRICULTURAL BIOTECHNOLOGY

The United States does not have any major statutes that specifically address biotechnology. Instead, GMOs are regulated under laws that apply to existing similar non-GMO products.[10] This arrangement reflects the U.S. view that products derived through biotechnology are simply an extension of products that already exist.[11] At present, unlike with the European Union, it appears that U.S. laws regarding agricultural biotechnology are fairly well settled, so major revisions to them are not foreseen.

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6. *See* discussion *infra* Part III.
7. *See* discussion *infra* Part IV.
8. *See* discussion *infra* Part VI.
9. *See* discussion *infra* Part XV.
10. *See* T. MORATH, OFFICE OF U.S. TRADE REPRESENTATIVE, U.S. REGULATION OF PRODUCTS DERIVED FROM BIOTECHNOLOGY 3 (1998).
11. *See id.*

A. *Federal Laws and Appropriate Regulating Agencies*

1. *Foods Derived Through Biotechnology*

The U.S. Food and Drug Administration (FDA) has the authority under the Federal Food, Drug, and Cosmetic Act (FFDCA)[12] to ensure the safety of most foods, including foods obtained through biotechnology.[13] As a general rule, the FDA regulates GMOs no differently than food products developed through traditional plant breeding techniques.[14]

In contrast with the European Union, companies introducing foods derived through biotechnology into the U.S. market do not necessarily have to obtain approval for such action from federal authorities; rather, these companies have the option of consulting voluntarily with the FDA before the product is marketed.[15] It is often in the best interests of companies to participate in consultations, and companies have traditionally requested them before marketing their products.[16] If consultations reveal that a new product raises health concerns,[17] the FDA has authority under the FFDCA to require a pre-market review.[18] For example, certain foods are known to cause allergic reactions.[19] If a variety of corn is genetically engineered to contain a gene obtained from a tree nut, a common allergen, special testing would be needed for determining the safety of the GMO, and the GMO's producer would be expected to discuss testing requirements with the FDA.[20]

In addition, section 402(a)(1) of the FFDCA places a legal obligation upon those introducing a new food product into the market to ensure that the food is safe.[21] If a food is sold in the market and is subsequently proven unsafe, the FDA can stop the product's distribution.[22] Further, manufacturers who do not comply with their obligations under the FFDCA, i.e., who introduce an unsafe food into

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12. 21 U.S.C. §§ 301-395 (1994).

13. *See* J.H. Maryanski, *FDA's Policies for Foods Developed by Biotechnology*, *in* GENETICALLY MODIFIED FOODS: SAFETY ISSUES, 12, 12 (1995) (visited Mar. 22, 1999) <http://jm.cfsan.fda.gov/~lrd/>.

14. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 (1992). The FDA notes that "[m]ost, if not all, cultivated food crops have been genetically modified." *Id.* at 22,984 n.3.

15. *See* MORATH, *supra* note 10, at 5.

16. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,989. In 1992, the FDA released guidelines intended to assist companies discern whether they are required to obtain FDA approval before marketing GMO food products. *See id.* at 22,984.

17. *See id.* at 22,989.

18. *See id.* at 22,988.

19. *See id.* at 22,987.

20. *See id.*

21. *See id.* at 22,988.

22. *See id.*

the market, can face criminal prosecution.[23] Thus, ultimately, under the U.S. system, "it is the food producer who is responsible for assuring safety."[24]

2. *GMOs with Pesticidal Characteristics*

The U.S. Environmental Protection Agency (EPA) approves pesticides derived through biotechnology and bioengineered plants with pesticical characteristics,[25] e.g., plants that are bioengineered to contain *Bacillus thuringiensis*, which is toxic to certain maize pests.[26] The EPA regulates GMOs with pesticidal characteristics through two laws: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[27] and the FFDCA.[28] Under FIFRA, a manufacturer must register a pesticide, including plants with pesticidal qualities, with the EPA before the product is sold in the U.S. market.[29] The EPA through the FFDCA sets maximum tolerance levels for pesticide residues in foods.[30] In addition, before new microorganisms, including "intergeneric" organisms derived through biotechnology, can be manufactured or imported, a notice must be submitted to the EPA in accordance with the Toxic Substances Control Act.[31]

3. *Regulation of GMOs as "Plant Pests"*

The Animal Plant and Health Inspection Service (APHIS) of the United States Department of Agriculture regulates GMOs to the extent they might act as plant pests.[32] Developers of a new GMO plant submit a petition, based upon field trials, to APHIS demonstrating that the plant is safe and does not pose risks as a plant pest.[33] APHIS conducts an environmental assessment to determine possible effects

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23. *See id.*
24. *Id.* at 22,991.
25. *See* MORATH, *supra* note 10, at 1.
26. *See* Novartis Seeds; Approval of a Pesticide Product Registration, 63 Fed. Reg. 43,935, 43,935 (1998).
27. 7 U.S.C. §§ 136-136y (1994).
28. *See* MORATH, *supra* note 10, at 1.
29. *See id.* at 4.
30. *See id.* at 1. It should be noted that the EPA addresses food safety aspects of GMOs only as they pertain to pesticidal characteristics. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 23,005 (1992). All other food safety concerns fall under the jurisdiction of the FDA. *See id.*
31. *See* 15 U.S.C. § 2603(d).
32. *See* MORATH, *supra* note 10, at 1.
33. *See id.* at 5.

of the GMO on human health and the environment.[34] In past evaluations, APHIS has specifically sought to determine whether genetically modified plants have exhibited plant pathogenic properties or are more likely to become weeds than similar non-genetically modified plants.[35]

If APHIS finds that the GMO is not a plant pest, APHIS will issue a "determination of non-regulated status."[36] Upon attaining such a status, the GMO is no longer subject to regulation by APHIS' plant pest rules[37] and may be released into the environment, i.e., planted. APHIS has provided non-regulated status to thirty-six genetically modified plants since 1992.[38] With the number of field tests for new genetically modified plants doubling almost annually, the list of such approved products can be expected to grow rapidly.[39]

APHIS receives its authority to regulate plant pests, including GMO plant pests, through the Federal Plant Pest Act[40] and the Plant Quarantine Act.[41]

B. *Labeling Under U.S. Law*

1. *No General Requirement to Label*

The United States does not generally require the labeling of agricultural products derived through biotechnology.[42] This policy comports with the view of U.S. officials that GMO products do not differ significantly from similar products obtained through traditional means of breeding.[43] In some circumstances, however, a label might be required. For example, if a genetically modified food product differs significantly from its traditional counterpart in its nutritional content, or if it

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34. *See id.* at 4. *See, e.g.*, AgrEvo USA Co.; Availability of Determination of Nonregulated Status for Canola Genetically Engineered for Glufosinate Herbicide Tolerance, 63 Fed. Reg. 6703, 6704 (1998).

35. *See* Interpretive Ruling on Calgene, Inc., Petition for Determination of Regulatory Status of FLAVR SAVR™ Tomato, 57 Fed. Reg. 47,608, 47,608 (1992).

36. MORATH, *supra* note 10, at 1.

37. *See* Interpretive Ruling on Calgene, Inc., Petition for Determination of Regulatory Status of FLAVR SAVR™ Tomato, 57 Fed. Reg. at 47,608.

38. *See* Animal and Plant Health Inspection Service, U.S.D.A., *Crop Lines No Longer Regulated by USDA* (visited Nov. 28, 1998) <http://www.aphis.usda.gov/biotech/not_reg.html>. *See also* Animal and Plant Health Inspection Service, U.S.D.A., *Current Status of Petitions* (visited Nov. 28, 1998) <http://www.aphis.usda.gov/biotech/petday.html>.

39. *See* Animal and Plant Health Inspection Service, U.S.D.A., *BSS Biotechnology Update* (May 1998) (visited Aug. 18, 1998) <http://www.aphis.usda.gov/biotech/newsletter.html>.

40. 7 U.S.C. §§ 150aa-150jj (1994).

41. 7 U.S.C. §§ 151-167 (1994).

42. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (1992).

43. *See id.*

poses a health threat, a label might be required.[44] So if a genetically modified food product were to contain a protein derived from a peanut, a common allergen, the FDA would likely require the labeling of the GMO product to warn consumers allergic to peanuts that the product contains such proteins.[45]

2. *U.S. Federal Appeals Court Holds Mandatory Labeling Possibly Unconstitutional*

In 1994, the state of Vermont passed a law requiring the labeling of milk and milk products derived from cattle treated with recombinant bovine somatotropin (r-BST).[46] R-BST is a drug produced through recombinant DNA technology that is injected into dairy cows to increase their milk production.[47] Prior to the passage of Vermont's law, the FDA determined that milk obtained from cows treated with r-BST presents no threats to human health, and Vermont officials did not claim that their measure was intended to protect the health of Vermont's citizens.[48] Rather, Vermont contended that the purpose of its mandatory labeling law was to protect the interest of consumers who have a "right to know" about the foods they consume.[49] Surveys showed that Vermont residents supported the labeling law in part due to concerns about the unknown long-term effects of the use of r-BST.[50]

Alleging that Vermont's law violated the First Amendment, a group of trade associations whose members produced or marketed dairy products challenged Vermont's law in federal district court and sought a preliminary injunction prohibiting Vermont from enforcing the law.[51] In 1995, the district court held that while the First Amendment protects the right of parties "not to speak," i.e., not to label, Vermont had a substantial interest in informing its consumers of the use of r-BST in the production of dairy products sold in the state.[52]

The district court's decision was appealed. The Second Circuit in a two to one decision overturned the lower court's findings stating that the "dairy

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44. *See id.*; World Trade Organization, Committee on Technical Barriers to Trade, *European Council Regulation No. 1139/98 Compulsory Indication of the Labelling of Certain Foodstuffs Produced from Genetically Modified Organism: Submission by the United States*, G/TBT/W/94 (Oct. 16, 1998) [hereinafter Submission by the United States to Committee on Technical Barriers to Trade].

45. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,991.

46. *See* International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246, 249 (D. Vt. 1995).

47. *See id.* at 248.

48. *See id.* at 248-49.

49. *See id.*

50. *See id.* at 250.

51. *See id.* at 247.

52. *See id.* at 253-54.

manufacturers' constitutional right *not* to speak is a serious one" and that Vermont's law "requires them to speak when they would rather not."[53] The appeals court wrote that in the commercial context "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement."[54] Accordingly, as Vermont demonstrated "no cognizable harms," the Second Circuit held that the statute would likely be found unconstitutional, so the case was remanded for injunction.[55] The decision of the district court was not appealed.[56]

III. THE EUROPEAN UNION'S LEGISLATIVE PROCESS

The legislative process of the European Union and its continuing evolution explain much about the European Union's laws on agricultural biotechnology. Therefore, it is useful to discuss this legislative process before examining the European Union's biotechnology laws themselves.

A. *Legislative Institutions*

1. *European Commission*

The European Commission (Commission) is at the core of the European Union's policy making process and has no equivalent in the U.S. government.[57] All legislative proposals of the European Union originate in the Commission.[58] The Commission also acts as the executive body for the laws and programs of the European Union.[59] The Commission is composed of twenty members who are designated by the fifteen national governments of the member states after these states consult with the Commission's president, who is chosen jointly by the member states.[60] The members act independently of their national governments as their mandate is to further the interests of the European Union.[61] The Commission

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

54. *Id.* at 74.

55. *See id.* The dissenting judge on the appeals court was convinced that Vermont's labeling law was based on substantial state interest. *See id.* (Leval, J., dissenting). The judge, contending that numerous drugs approved by the FDA were later found to present health risks to humans, wrote that consumer concerns about the unknown potential for adverse health effects were "unquestionably a substantial interest." *Id.* at 78 (Leval, J., dissenting).

56. At the time of publication, no further action had been taken opposing the remand.

57. *See* EUROPEAN COMM'N, HOW DOES THE EUROPEAN UNION WORK? 8 (2d ed. 1998).

58. *See id.* at 10.

59. *See id.*

60. *See id.* at 9.

61. *See id.* at 8.

also consists of a large bureaucracy that assists the Commission members in their work.[62] In summary, the Commission is a civil service with the ability to propose legislation.[63]

2. *Council of Ministers*

The Council of Ministers (Council) is composed of representatives of the European Union's fifteen member states, and the representatives work on behalf of their national governments.[64] The Council functions as the main legislative body of the European Union as legislation is debated and adopted in the Council.[65] Therefore, in the traditional legislative process of the European Union, the Commission proposes legislation and the Council decides whether to adopt it.[66]

3. *European Parliament*

The members of the European Parliament (Parliament) are the only directly elected members of the European Union's policy making system.[67] In comparison with the U.S. Congress, the Parliament is a weak legislative body. Throughout most of its history, the major role of the Parliament in the European Union's policy making process has been an advisory one.[68] For example, in many instances in the legislative process, the Parliament's opinion must be sought on a proposal issued by the Commission before the Council decides whether to adopt it.[69] However, the Commission, in most cases, is not under an obligation to take into consideration Parliament's views.[70]

Perhaps due to the relative weakness of this legislative body, some commentators have stated that many European voters view European Parliament elections as a means to register protests or to signal emotional concerns.[71] As already discussed, in an effort to make the European Union more democratic, new procedures have provided the Parliament with increased power to influence

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62. *See id.* at 8-9.
63. *See Capitol Hill Comes to Europe*, THE ECONOMIST, Apr. 15, 1995, at 45, 46.
64. *See* KLAUS-DIETER BORCHARDT, EUROPEAN COMM'N, THE ABC OF COMMUNITY LAW 24 (4th ed. 1994).
65. *See* EUROPEAN COMM'N, *supra* note 57, at 9.
66. *See id.* at 17.
67. *See id.* at 16; *Capitol Hill Comes to Europe*, *supra* note 63, at 46.
68. *See* BORCHARDT, *supra* note 64, at 19.
69. *See id.*
70. *See id.*
71. *See Capitol Hill Comes to Europe*, *supra* note 63, at 46.

legislation.[72] The power of the Parliament will most likely continue to grow *vis-à-vis* the Commission and the Council.[73]

B. *Legislative Procedures of the European Union*

The European Union has four main legislative procedures, three of which will be discussed here.[74]

1. *Consultation Procedure*

Under the consultation procedure (also referred to as the proposal procedure), the Commission proposes legislation and the Council decides whether to adopt it.[75] The treaties of the European Union require that the Parliament be consulted on certain important issues.[76] But the Parliament's opinions are merely advisory.[77] The consultation procedure is used when neither the cooperation nor the co-decision procedures apply.[78]

2. *Cooperation Procedure*

The cooperation procedure increases the ability of the Parliament to influence legislation.[79] With the cooperation procedure, the Commission proposes legislation and sends it to both the Parliament and the Council.[80] Taking into consideration the Parliament's views, the Council adopts a "common position."[81] The Parliament then has the option of accepting, rejecting, or proposing amendments to the common position.[82] If the Parliament proposes amendments, the Commission may either accept Parliament's amendments or reject the amendments with the result that the legislative proposal must receive a unanimous vote in the Council to be adopted.[83] In addition, the Council may in effect veto amended legislation by

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72. *See* EUROPEAN COMM'N, *supra* note 57, at 17.
73. *See Capitol Hill Comes to Europe*, *supra* note 63, at 46.
74. The fourth, the assent procedure, is used when the European Union is making major international decisions, such as the admittance of new member states. *See* EUROPEAN COMM'N, *supra* note 57, at 17.
75. *See id.*; BORCHARDT, *supra* note 64, at 44.
76. *See id.* at 45.
77. *See id.*
78. *See id.* at 44.
79. *See id.* at 45.
80. *See id.* at 44; EUROPEAN COMM'N, *supra* note 57, at 17.
81. *See id.*
82. *See id.*
83. *See id.*

deciding not to act upon it.[84] The cooperation procedure is used with legislation concerning, among other areas, the environment.[85]

3. *Co-Decision Procedure*

The co-decision procedure further strengthens the role of the Parliament in the legislative process.[86] The Maastricht Treaty of 1992 provided the Parliament with the power of "co-decision" with the Council in some legislative areas.[87] With the co-decision procedure, the Commission proposes legislation, which is sent to both the Council and the Parliament.[88] After receiving an opinion from the Parliament, the Council adopts a common position.[89] If the Parliament and the Council do not agree upon the common position, a conciliation committee is formed to negotiate a compromise.[90] If the Parliament is not satisfied with the outcome of the conciliation committee, the Parliament may reject the proposal, so the Parliament in effect has the right of veto under the co-decision procedure.[91] The co-decision procedure applies to legislation concerning consumer protection, health, and other areas.[92]

The Amsterdam Treaty of 1997 will extend the use of the co-decision procedure to most areas currently covered by the cooperation procedure, so the use of the co-decision procedure will be more common in the future, which will result in increased power for the Parliament in the European Union's legislative process.[93]

C. *Forms of European Union Legislation*

The legislation of the European Union can take one of three forms.[94] "Directives" obligate the national legislatures of the member states to conform their laws to certain objectives established by the European Union.[95] "Regulations"

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84. *See id.* at 47.
85. *See* EUROPEAN COMM'N, *supra* note 57, at 17.
86. *See* BORCHARDT, *supra* note 64, at 45.
87. *See* EUROPEAN COMM'N, *supra* note 57, at 8; EUROPEAN COMM'N, AMSTERDAM 17 JUNE 1997: A NEW TREATY FOR EUROPE 13 (2d ed. 1997) [hereinafter NEW TREATY FOR EUROPE]; BORCHARDT, *supra* note 64, at 48.
88. *See* BORCHARDT, *supra* note 64, at 23.
89. *See id.* at 48.
90. *See id.*
91. *See* EUROPEAN COMMISSION, *supra* note 57, at 17.
92. *See id.*
93. *See* A NEW TREATY FOR EUROPE, *supra* note 87, at 13.
94. *See* EUROPEAN COMM'N, *supra* note 57, at 18.
95. *See id.*

apply directly throughout the European Union once they are adopted, so national implementing legislation is not needed.[96] "Decisions" concern specific legislative issues and are binding upon those to whom the decisions are addressed, which may be member states, businesses, or individuals.[97]

IV. TWO MAIN EUROPEAN UNION LAWS ON AGRICULTURAL BIOTECHNOLOGY

The European Union has two major laws concerning biotechnology that should be of concern to agricultural producers in the United States.[98] The first such law, Council Directive 90/220/EEC,[99] concerns the placing in the market of GMO products that may be described as raw materials.[100] The second law, Regulation No. 258/97, applies to the placing in the market of "novel foods," including foods containing GMOs.[101] Novel foods differ from the raw materials covered by Directive 90/220/EEC in that they are further processed[102] and are the finished product that is bought by consumers.[103] A purpose of both laws is to strengthen the internal market of the European Union by creating uniform laws on certain biotechnology products.

V. COUNCIL DIRECTIVE 90/220/EEC

Directive 90/220 was adopted by the Council on April 23, 1990, through the cooperation procedure.[104] The European Communities' member states were required to bring their national laws into compliance with Directive 90/220/EEC by October 23, 1991, some six months after the directive's adoption.[105] The objective of the directive was to approximate the laws of the various member states of the

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96. *See id.*

97. *See id.*

98. *See generally* 1990 O.J. (L 117) 15 (concerning raw materials); 1997 O.J. (L 43) 1 (concerning novel foods). Other European Union policies, such as rules concerning the contained use of, and the patent process for, biotechnology products are of interest to U.S. entities involved in the research and manufacture of GMO products. However, as these issues are not of direct interest to U.S. agricultural producers, they are not discussed in this Article.

99. 1990 O.J. (L 117) at 15.

100. *See id.* at 15; Ritt Bjerregaard, Press Conference in Brussels: Note to National Bureaus, BIO/97/137, at 4 (Apr. 2, 1997) (transcript available from *Drake Journal of Agricultural Law*).

101. *See* 1997 O.J. (L 43) 1, 1.

102. *See* Bjerregaard, *supra* note 100, at 4.

103. *See Biotechnology: Commission to Issue Labelling Guidelines for GMOs*, EUR. REP., No. 2197, Feb. 8, 1997, at 10, 11.

104. *See* 1990 O.J. (L 117) 15, 16.

105. *See* Council Directive 90/220, art. 23, 1990 O.J. (L 117) 15, 21.

European Union regarding the placing of GMOs in the market that will subsequently be released into the environment.[106]

Part B of Directive 90/220/EEC establishes rules for the deliberate release of GMOs into the environment for purposes of research and development and is not of direct relevance to U.S. agricultural producers.[107] Part C of the directive directly impacts U.S. producers as it sets forth the procedures for placing GMO products, including possibly U.S. grown products, into the market of the European Union.[108] The remainder of this section will describe these procedures.

A. *Notification to Individual Member State*

1. *Requirements of Notification*

Article 11 requires the manufacturer or importer of the GMO to notify the authorities of the member state where the GMO will be placed into the market for the first time.[109] The notification must comport with the requirements of Annex II, which lists a number of factors that must be addressed in the notification.[110] These requirements include basic information such as the scientific name of the GMO and information relating to the consequences of releasing the GMO into the environment, such as possible health risks posed by the product and the potential for an excessive increase in the population of the GMO once it is released.[111] In the notification, the notifying party must mention information regarding previous releases of the GMO.[112] Article 11.1 specifically states that a risk assessment must be conducted concerning the possible effects of the GMO on human health and the environment.[113]

2. *No Requirement to Label as GMO*

Directive 90/220/EEC does not require that products approved for release in the environment contain labels stating that the products are, or are comprised of, GMOs.[114] Specifically, Article 11.1 states that the notifying party must indicate in its notification to the member state "a proposal for labeling and packaging" if the

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106. *See id.* art. 1, 1990 O.J. (L 117) at 16.
107. *See id.* art. 10, 1990 O.J. (L 117) at 17.
108. *See id.*, 1990 O.J. (L 117) at 18.
109. *See id.* art. 11.1, 1990 O.J. (L 117) at 18.
110. *See id.*, 1990 O.J. (L 117) at 18-19.
111. *See id.* Annex II, arts. II(A)(1), II(C)(2)(i), IV(C)(1), 1990 O.J. (L 117) at 23-26.
112. *See id.* art. 11.2, 1990 O.J. (L 117) at 19.
113. *See id.* art. 11.1, 1990 O.J. (L 117) at 18.
114. *See id.*, 1990 O.J. (L 117) at 19.

product is approved for placement in the market.[115] Such a label should comport with the requirements of Annex III.[116] Annex III.B.5, which sets forth rules for labeling, provides that a label must contain certain information, including the name of the GMO, measures to take if the product is unintentionally released, and information pertaining to the handling of the product [117] However, Article 11.1 goes on to state that if the notifying party considers that the product is not harmful to human health or the environment, the notifying party can "propose not to comply with one or more of the requirements of Annex III.B" concerning labeling.[118]

3. *Dossier Forwarded to Commission*

Once the member state receives a notification, it is required to examine the notification to ensure that it comports with the requirements of Council Directive 90/220/EEC, "giving particular attention to the environmental risk assessment."[119] Within ninety days of receiving the notification, the authorities of the member state must either reject the proposed release or forward the dossier of technical information to the Commission with a favorable opinion.[120]

B. *Adoption or Rejection by the European Union*

1. *No Objection by Other Member States*

The Commission will then forward the dossier to the appropriate authorities in all of the member states of the European Union.[121] If no objections are received from other member states within sixty days, the member state that received the notification shall provide its consent to the placing of the GMO in the market; it must inform the Commission and the other member states of its consent.[122]

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115. *Id.*, 1990 O.J. (L 117) at 19.
116. *See id.*, 1990 O.J. (L 117) at 19.
117. *See id.* Annex III, art. III(B)(5), 1990 O.J. (L 117) at 27. The spelling of the word "labeling" in the United States differs from the spelling of "labelling" in European English. Except where citing documents developed in Europe, the authors, attorneys in the United States, will use the word "labeling." *See id.*, 1990 O.J. (L 117) at 27.
118. *Id.* art. 11.1, 1990 O.J. (L 117) at 19.
119. *Id.* art. 12.1, 1990 O.J. (L 117) at 19.
120. *See id.* art. 12.2, 1990 O.J. (L 117) at 19.
121. *See id.* art. 13.1, 1990 O.J. (L 117) at 19.
122. *See id.* art. 13.2, 1990 O.J. (L 117) at 19.

2. *Objection by Other Member States and Possible Adoption by Commission*

However, if another member state objects to the release of the GMO into the environment and the competent authorities of the two member states cannot reach an accord, the Commission will make the decision on the measure's adoption through the process described in Article 21.[123] Under Article 21, the Commission will submit the proposed measure to a committee comprised of the representatives of member states.[124] The Commission shall adopt the measures "if they are in accordance with the opinion of the Committee."[125] If the measures "are not in accordance with the opinion of the Committee" or if the Committee does not provide an opinion, the Commission will forward the proposal to the Council, which will vote upon the proposed measures.[126] If the Council does not vote upon the proposal within three months, the Commission will adopt the proposed measures.[127] If the proposed measures are adopted by the Commission, the member state that received the notification shall give its written consent to the placing of the GMO in the market and shall notify other member states that its consent has been given.[128]

C. *Authorization of GMO Applies Throughout European Union*

Importantly, once the member state that was notified consents to the marketing of the GMO, the GMO "may be used without further notification throughout the [European Union]."[129] Directive 90/220/EEC specifies that "Member States may not . . . restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive."[130]

D. *Provisional Restrictions on GMO if Evidence of Harm*

In cases in which a product has been approved for placing in the market under Directive 90/220/EEC and a member state has "justifiable reasons" to consider that the GMO poses risks to human health or the environment, the concerned member state can "provisionally restrict" the product from its

123. *See id.* art. 13.3, 1990 O.J. (117) at 19.
124. *See id.* art. 21, 1990 O.J. (117) at 21.
125. *Id.*, 1990 O.J. (117) at 21.
126. *Id.*, 1990 O.J. (117) at 21.
127. *See id.*, 1990 O.J. (117) at 21.
128. *See id.* art. 13.4, 1990 O.J. (117) at 20.
129. *Id.* art. 13.5, 1990 O.J. (117) at 20.
130. *Id.* art. 15, 1990 O.J. (117) at 20.

territory.[131] The member state restricting the product in this manner must notify the other member states of the European Union and the Commission of its action, and the Commission will make a decision within three months regarding the concerned member state's action through the process set forth in Article 21, which is described in Part V.B.2 of this Article.[132]

VI. BT-MAIZE AUTHORIZATION UNDER DIRECTIVE 90/220/EEC: COMMISSION DECISION 97/98/EC

The authorization processes of several GMO products under Directive 90/220/EEC have been contentious. The Article now discusses the authorization of one GMO product, Bt-maize manufactured by Ciba-Geigy,[133] under Directive 90/220/EEC and the controversy caused by this authorization.

A. *Favorable Opinion Forwarded by France*

On March 15, 1995, the Commission was forwarded a favorable opinion from France for placing on the market GMO maize (*Zea mays L.*) developed by Ciba-Geigy,[134] a Swiss-based company.[135] The maize in question was modified to contain the pesticidal properties conferred by the Bt-endotoxin gene as well as to

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131. *Id.* art. 16.1, 1990 O.J. (117) at 20.

132. *See id.* art. 16.1-.2, 1990 O.J. (117) at 20.

133. The placement of Ciba-Geigy's Bt-maize in the European market did not involve the only, or first, controversy over authorizations for GMO products under Directive 90/220/EEC. *See, e.g., Agriculture: Hybrid Rape Sows Seeds of Discord Across the EU*, EUR. REP., No. 2089, Dec. 2, 1995, at 5. The authors chose to use the Ciba-Geigy GMO maize authorization as a case study due to this dispute's ample documentation, which was caused in part by the European Parliament's reaction to this authorization and the refusal of some countries to permit the sale of this product despite the Commission's approval of it, which will be discussed later in this Article. For background information on another dispute involving Directive 90/220/EEC, see *id.* at 5.

134. Since the time it petitioned for approval of GMO maize under Directive 90/220/EEC, Ciba-Geigy merged with Sandoz. *See* Novartis, *FTC Clears Novartis Merger, Creating the World's Leading Life Sciences Company*, PR NEWSWIRE (Dec. 17, 1996) <http://www.prnewswire.com>. The new company that formed out of this merger was formally established on December 20, 1996, and took the name "Novartis." *See id.* As the documents of the European Communities concerning the GMO maize approved under Directive 90/220/EEC continued to refer to Ciba-Geigy even after Novartis was founded, this Article will also refer to Ciba-Geigy. *See id.*

135. *See* Commission of the European Communities, Report on the Review of Directive 90/220/EEC in the Context of the Commission's Communication on Biotechnology and the White Paper, COM(96)630 final at 15 [hereinafter Report on the Review of Directive 90/220/EEC]. *See also* European Commission, Background Note Spokesmen's Service: Authorization for the Placing on the Market of Genetically Modified Maize Notified by Ciba-Geigy in Accordance with Directive 90/220/EEC 1, 1 (Apr. 9, 1997) [hereinafter Background Note Spokesman's Service] (on file with the *Drake Journal of Agricultural Law*).

have "increased tolerance to the herbicide glufosinate ammonium."[136] Ciba-Geigy's Bt-maize is grown in the United States.[137]

B. *Objections of Other Member States*

As established through the procedures of Directive 90/220/EEC, the other member states of the European Union were forwarded the notification.[138] Austria, Belgium, Germany, Denmark, Italy, Sweden, and the United Kingdom objected to the proposal for several reasons, including that the proposal did not mandate the product be labeled as a GMO.[139]

C. *Proposal Rejected by Regulatory Committee*

Following the procedures set forth in Articles 13.3 and 21 of Directive 90/220/EEC, the Commission on March 8, 1996, sought the opinion of the Regulatory Committee on a draft decision of the Commission.[140] The Commission's draft decision requested consent to place the GMO maize on the market for all uses.[141]

The Regulatory Committee, which was composed of representatives of the member states, voted on April 11, 1996, on the Commission's proposal.[142] Of the European Unions' fifteen member states, six states voted in favor of placing the maize on the market, four voted against the proposal, four abstained, and the vote of one state was considered invalid as the state sought to change the proposal.[143] Under the European Unions' voting system in which member states with larger populations have more votes, the proposal passed with thirty-four votes in favor, twenty-one votes against, and twenty-seven abstentions.[144] However, the number of votes in favor of the proposal in the Regulatory Committee did not reach the

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136. Commission Decision 97/98/EC, 1997 O.J. (L 31) 69, 70.

137. *See* Tim Galvin, Remarks at the FAS Session on Plant Technology, Regulatory Oversight, and Export Issues, NCGA/ASA "Commodity Classic" (Feb. 23, 1998) <http://www.fas.usda.gov/info/speeches/TG02239.html>.

138. *See* Background Note Spokesman's Service, *supra* note 135.

139. *See* Commission of the European Communities, Proposal for a Council Decision Concerning the Placing on the Market of Genetically Modified Maize *(Zea mays L.)* with the Combined Modification for Insecticidal Properties Conferred by the Bt-endotoxin Gene and Increased Tolerance to the Herbicide Glufosinate Ammonium Pursuant to Council Directive 90/220/EEC, COM(96)206 final at 1 [hereinafter Proposal Concerning Genetically Modified Maize].

140. *See* Background Note Spokesman's Service, *supra* note 135, at 1.

141. *See id.*

142. *See id.*

143. *See id.*

144. *See id.*

qualified majority needed to approve the draft decision.[145] Member states opposing or abstaining from the vote were specifically concerned about the proposal's failure to provide for labeling of the product as a GMO and the long-term environmental risks that the GMO maize might pose.[146]

D. *Proposal Sent to Council*

As the Regulatory Committee did not approve the draft decision, the Commission in accordance with Article 21 of Directive 90/220/EEC next sent a proposal to the Council for this body to decide whether to permit the placement of the GMO maize on the market.[147] The Commission's proposal stated that the GMO posed no threats to humans and the environment, that a label was not required due to this lack of threat, and that the product should be approved for unrestricted use, including as food for humans and animals.[148]

The draft decision also proved controversial in the Council. On June 25, 1996, the Council met but did not vote upon the measure.[149] The majority of the member states expressed concerns about the proposal, and only one member state supported it.[150] Under Article 21 of Directive 90/220/EEC, a proposed measure is adopted by the Commission if the Council fails to act on it within a three month period, and the deadline for the Council to decide upon the maize proposal was August 31, 1996.[151] However, before the three month deadline was met, Austria presented new information that it claimed raised questions concerning the safety of the maize.[152] In response to Austria's claims, the Commission decided on July 24, 1996, to have the scientific basis of its proposed measure reviewed by three scientific committees.[153]

E. *Three Scientific Committees Deem Bt-Maize Safe*

The three committees, the Scientific Committee for Food, the Scientific Committee for Animal Nutrition, and the Scientific Committee for Pesticides,

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145. *See id.*
146. *See id.*
147. *See id.*
148. *See* Proposal Concerning Genetically Modified Maize, *supra* note 139, at 2-3.
149. *See* Background Note Spokesman's Service, *supra* note 135.
150. *See id.*
151. *See id.*
152. *See* European Commission, Directorate General VI (Agriculture): Report of the Scientific Committee for Animal Nutrition (SCAN) on the Safety for Animals of Certain Genetically Modified Maize Lines Notified by Ciba-Geigy in Accordance with Directive 90/220/EEC for Feedingstuff Use 3 (Dec. 13, 1996) [hereinafter Report of the Scientific Committee].
153. *See id.*; Background Note Spokesman's Service, *supra* note 135, at 1.

released opinions favoring the Commission's proposal in December 1996.[154] The Scientific Committee for Food determined that the GMO maize was substantially equivalent to maize already being sold in Europe and that the GMO product did not pose toxicological threats to humans.[155] The Scientific Committee for Pesticides held that the possible development by insects of a tolerance to Bt-toxin would not harm the environment.[156] According to the Scientific Committee for Animal Nutrition, evidence did not indicate that feeding animals the GMO maize in question would have "any adverse effect" on them.[157]

F. *Commission Authorizes Placing Bt-Maize in Market*

Following the favorable opinion of the three scientific committees, the Commission on January 23, 1997, adopted Commission Decision 97/98/EC, which granted authority for France to permit the placing of Ciba-Geigy's GMO maize on the market.[158] As the product did not present safety concerns, the Commission's decision did not require the placing of a label on the product indicating that it was developed through genetic modification.[159]

VII. BT-MAIZE AUTHORIZATION—COMMISSION'S CONCERNS ON EUROPE'S COMPETITIVENESS IN BIOTECHNOLOGY

In 1993, the Commission issued a White Paper on Growth, Competitiveness, and Employment (White Paper), and the Commission released a Communication on Biotechnology in 1994.[160] These two documents suggested that a review be conducted of Directive 90/220/EEC, and this review was released by the Commission on December 10, 1996.[161] The December 1996 report, which came out one month before Commission Decision 97/98/EC was adopted, sheds light on

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154. *See id.*

155. *See* European Commission, Scientific Committee for Food, Directorate General III (Industry), Opinion on the Potential for Adverse Health Effects from the Consumption of Genetically Modified Maize (*Zea Mays L.*), CS/NF/CGMAIZE/11-final at 5 (Dec. 13, 1996).

156. *See* European Commission, Scientific Committee for Pesticides, Opinion of the Scientific Committee for Pesticides on the Genetically Modified Maize Lines Notified by Ciba-Geigy at 2 (Dec. 9, 1996).

157. *See* Report of the Scientific Committee, *supra* note 152, at 6.

158. *See* Commission Decision 97/98, 1997 O.J. (L 31) 69, 69.

159. *See id.*, 1997 O.J. (L 31) at 69.

160. *See Biotechnology: Inter-Institutional Dialogue Resumes*, EUR. REP., No. 2099, Jan. 17, 1996, at 10.

161. *See* European Commission, Commission Presents Report on Directive 90/220/EEC on Genetically Modified Organisms, ip/96/1148 (Dec. 10, 1996).

a possible motivation of the Commission for authorizing Ciba-Geigy's GMO maize despite significant opposition by some member states.[162]

The December 1996 report expressed concerns about the rates of approval of GMO products in the European Union in comparison with other members of the international community.[163] For example, the Commission noted that only four GMO agricultural products, as well as three pharmaceutical products, had been approved for placing in the European Union's market as of September 1996.[164] In contrast, some twenty-three agricultural GMO products were being sold in the United States, eleven in Canada, and seven in Japan.[165] The December 1996 report specifically criticized the "cumbersome administrative procedures and approval system" of Directive 90/220/EEC.[166] The Commission mentioned that streamlined approval procedures for GMOs posing "no, negligible or low risk" were available outside of Europe and that they should be adopted by the European Union.[167] The Commission also noted that the lack of a label requirement for GMOs was controversial and stated that a new GMO labeling provision might be amended to Directorate 90/220/EEC.[168]

The Commission's White Paper of 1993 and its Communication on Biotechnology of 1994 also recognized the importance of biotechnology and the need to foster the development of competitive biotechnology industries in the European Union.[169] For example, the White Paper noted that "biotechnology has emerged as one of the most promising and crucial technologies for . . . the next century," but "technology hostility" regarding biotechnology, as well as an inadequate regulatory framework, were impeding European competitiveness in this industry.[170]

Other statements by Commission officials prior to the approval of GMO maize in January 1997 indicated that the Commission was concerned about the international competitiveness of the European Union in the rapidly growing field of biotechnology.[171] For example, in an address delivered on January 11, 1996, Jacques Santer, the President of the Commission, stated that "in terms of competitiveness, the position of [the] European biotechnology sector is giving cause

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162. *See id.*
163. *See id.*
164. *See* Report on the Review of Directive 90/220/EEC, *supra* note 135, at 4.
165. *See id.* at 16.
166. *Id.* at 10.
167. *See id.* at 8.
168. *See id.* at 9.
169. *See id.* at 2.
170. EUROPEAN COMM'N, WHITE PAPER—GROWTH, COMPETITIVENESS, EMPLOYMENT: THE CHALLENGES AND WAYS FORWARD INTO THE 21ST CENTURY 115, 117-18 (1994).
171. *See generally Biotechnology: Inter-Institutional Dialogue Resumes*, *supra* note 160.

for concern. . . . It is becoming increasingly apparent that European companies prefer to invest elsewhere than in Europe."[172]

President Santer's concerns were understandable. In January 1996, some 485 biotechnology companies were operating in the European Union as opposed to approximately 1300 in the United States.[173] As early as 1990, the German companies Bayer AG and BASF AG had moved research facilities to the United States in response to public opinion opposed to biotechnology in Europe.[174] These moves were also possibly instigated in part by the inconsistency of laws regarding GMOs in the various member states.[175]

With the approval of the sale of Ciba-Geigy's GMO maize in the European Union, the Commission was perhaps seeking to send a message to European industry and the rest of the world that Europe was becoming more receptive to biotechnology.

VIII. EUROPEAN PARLIAMENT'S REACTION TO BT-MAIZE DECISION

While the Commission might have wanted to signal to the world that the European Union welcomed the biotechnology industry, the Commission's actions received an overtly hostile reception in the Parliament. On April 8, 1997, the Parliament issued a resolution that severely criticized the Commission.[176] In its resolution, the Parliament contended that the Commission acted despite the opposition of thirteen out of the fifteen member states to placing the GMO maize in the market.[177] The resolution claimed that the Commission ignored new scientific evidence on the dangers posed by the GMO in question.[178] The Parliament regretted that trade considerations, as opposed to health and safety, were determining the Commission's actions.[179] The Parliament went on to state that it

> . . . [c]ondemns the lack of responsibility of the Commission in unilaterally taking a decision to authorize the marketing of genetically modified maize in spite of the negative positions of most Member States and the European Parliament . . . ;
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172. *Id.*

173. *See id.* at 11.

174. *See* Catherine Arnst, *Europe's Biotech Firms Move Overseas to Avoid Rules, Protests*, REUTERS, Feb. 9, 1990.

175. *See id.*

176. *See* EUR. PARL. MINS., Resolution on Genetically Modified Maize (final ed. Apr. 8, 1997).

177. *See id.*

178. *See id.*

179. *See id.*

> . . . [d]emands therefore that the authorization procedure be reopened . . . ; [and]
> . . . [d]emands that the procedures to authorize the marketing of genetically modified products be revised so that they correctly reflect the democratically expressed opinions of the Member States and the European Parliament.[180]

At least officially, the Commission paid little heed to the Parliament's resolution.[181] The Commission's spokesman, Klaus van der Pas, responded on April 9, 1997, by stating that "[t]here is no question of suspending" the authorization to place Ciba-Geigy's GMO maize on the market unless new scientific evidence is presented on possible dangers of this product.[182] Mr. van der Pas condemned the resolution's "firm and energetic style . . . which is unjustified" and stated that Parliament's document was "based on factual errors."[183]

IX. MEMBER STATE REACTIONS TO BT-MAIZE AUTHORIZATION

A. *Austria and Luxembourg*

1. *Banning of Bt-Maize*

The Parliament was not alone in its objection to the Commission's decision to permit the placing of GMO maize on the market. Austria issued a decree on February 14, 1997, prohibiting, in line with Article 16 of Directive 90/220/EEC, the marketing of GMO maize within its territory and notified the Commission of its action.[184] Under Article 16, a member state may "provisionally restrict" a GMO approved for sale under Directive 90/220/EEC if the state has "justifiable reasons" to believe that the product might adversely affect human health or the environment.[185] Austria based its position upon research that indicated that an antibiotic-resistant gene, ampicillin, could be passed to humans and animals through GMO maize.[186] Luxembourg followed Austria's actions and notified the Commission on March 17, 1997, that it was provisionally banning the use and sale

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180. *Id.*

181. *See Biotechnology: Parliament and Commission Lock Horns Over Transgenic Maize*, EUR. REP., No. 2215, Apr. 12, 1997, at 14.

182. *Id.*

183. *Id.*

184. *See* European Commission, Note to National Bureaus: Austrian Ban on Genetically Modified Maize, BIO/97/202 (May 14,1997).

185. *See id.*

186. *See Biotechnology: Parliament and Commission Lock Horns over Transgenic Maize*, *supra* note 181, at 14-15.

of this product.[187] Luxembourg provided the same reasons as Austria for implementing its ban.[188]

The Commission consulted again with the three scientific committees on the possible threats posed by Bt-maize.[189] The committees concluded that the information submitted by Austria contained no new evidence, further review was thus unwarranted, and evidence did not indicate that the product in question presented risks for human health or the environment.[190]

2. *Maize Prohibitions Remain in Place*

In accordance with the provisions of Directive 90/220/EEC, the Commission on September 10, 1997, forwarded a proposal to the Council requesting that Austria and Luxembourg repeal their measures regarding GMO maize.[191] The Regulation Committee, which is composed of member states, failed to give an opinion, and the regulations of Austria and Luxembourg remained legally justified.[192] Under the procedures of Directive 90/220/EEC, the Committee next forwarded its draft decision to the Regulatory Committee.[193] The possibility of the European Union taking action against Austria and Luxembourg for refusing to abide by the Commission's decision on Ciba-Geigy's Bt-maize remains unresolved with the Council continuing to discuss options.[194] This situation has continued despite the European Union's concerns that the actions of Austria and Luxembourg are "threatening the integrity of the Internal Market."[195]

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187. *See* European Commission, Commission Proposes to Repeal National Bans on GMO Maize in Austria, Italy and Luxembourg, ip/97/784 (Sept. 10, 1997) [hereinafter Commission Proposes to Repeal National Bans]; European Commission, Committee of Member States Fails to Deliver Opinion on Austria's and Luxembourg's Bans on Genetically Modified Maize, ip/98/358 (Apr. 16, 1998) [hereinafter Committee Fails to Deliver Opinion].

188. *See* Commission Proposes to Repeal National Bans, *supra* note 187.

189. *See id.*

190. *See id.*

191. *See Biotechnology: Amended Directive on Labelling and Marketing of GMOs*, EUR. REP., No. 2272, Nov. 29, 1997, at 23, 24; Committee Fails to Deliver Opinion, *supra* note 187.

192. *See Biotechnology: Amended Directive on Labelling and Marketing of GMOs*, *supra* note 191, at 24.

193. *See* Committee Fails to Deliver Opinion, *supra* note 187; European Commission, Genetically Modified Maize, 9402/98, Presse 205-G at 30 (June 16-17, 1998) [hereinafter Genetically Modified Maize].

194. *See* Genetically Modified Maize, *supra* note 193, at 30. *See also EU: EU Set for May 18 Vote on Gene Food Labels Plan*, REUTERS, Apr. 20, 1998.

195. *Text: EU Paper on GMO Labeling*, INSIDE U.S. TRADE, July 11, 1997 <http://www.insidetrade.com>.

B. *France*

France announced on February 2, 1997, that it would permit the placement of GMO maize in its market, but only if the product was labeled as a GMO.[196] Thus, the very country that had requested the authority in the first place to have this product marketed was unwilling to follow the guidelines of Commission Decision 97/98/EC, which did not provide for the labeling of Ciba-Geigy's Bt-maize.[197]

X. DIRECTIVE 90/220/EEC AMENDED TO REQUIRE LABELING: COMMISSION DIRECTIVE 97/35/EC

In December 1996, shortly before it authorized the placing of Bt-maize in the market, the Commission intimated that it might in the future add a GMO labeling provision to Directive 90/220/EEC.[198] However, while the Commission had discussed the possibility of labeling prior to the GMO maize row, it demonstrated little enthusiasm for such a policy.[199] Then, on April 2, 1997, the Commission proposed to amend Directive 90/220/EEC to require the labeling of products that contain, or may contain, GMOs.[200] The Commission announced that this measure would be only transitional as the Commission planned a comprehensive revision of Directive 90/220/EEC.[201]

A. *Impetus for Labeling Amendment*

According to Ritt Bjerregaard, the European Union's Environmental Commissioner, the strong support of member states for labeling was a major impetus behind the Commission's decision.[202] With France requiring the labeling of Ciba-Giegy's product, Austria and Luxembourg prohibiting the sale of Bt-maize

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196. *See Foodstuffs: Labelling of Transgenic Foodstuffs Compulsory in France*, EUR. REP., No. 2197, Feb. 8, 1997, at 1.

197. *See* Bjerregaard, *supra* note 100, at 4.

198. *See* European Commission, Proposal for a Council Decision Authorizing the Placing on the Market of Genetically Modified Maize (*Zea mays L.*), 12434/96, Presse 360-G at 24 (Dec. 9, 1996).

199. *See id.* For an example of the Commission's tepid response, prior to the authorization of Ciba-Geigy Bt-maize, to proposals to require the labeling of GMOs, see Report on the Review of Directive 90/220/EEC, *supra* note 164, at 9.

200. *See* European Commission, The European Commission Has Decided to Propose Further Labelling of Genetically Modified Organisms, ip/97/259 at 1 (Apr. 2, 1997) [hereinafter Commission Has Decided to Propose Further Labelling].

201. *See id.* at 3; Bjerregaard, *supra* note 100, at 2.

202. *See* Bjerregaard, *supra* note 100, at 2.

altogether, and other member states objecting to the placing of GMO maize in the market due to the lack of a labeling requirement, the Commission was at odds with member states on whose behalf it might be expected to act.[203] The actions of the Commission regarding Ciba-Geigy's Bt-maize also angered members of the Parliament.[204] The positions of the Parliament and member states seemed to mirror those of the populations they represented who were wary of biotechnology in general and appeared to support labeling.[205]

In addition, the objective of the Commission in proposing Directive 90/220/EEC was to create a uniform policy within the internal market for the sale of raw GMO products.[206] This goal was being frustrated as member states, by refusing to adopt the Commission's decision to permit the marketing of Bt-maize without labeling, were in effect maintaining inconsistent rules concerning GMOs within the European Union.[207] The Commission also noted that due to objections from member states it appeared unlikely that products in line for review under Directive 90/220/EEC would obtain the qualified majority necessary to authorize them for placement in the market.[208]

B. *Expedited Procedure for Labeling Amendment*

The Commission proposed to use a "fast track" procedure to amend Directive 90/220/EEC to require labeling.[209] Under this procedure, the Commission would make changes to Directive 90/220/EEC to adapt it to technical progress, which would require only the approval of the Commission and the Regulatory Committee, which is composed of representatives of the member states and was established by Article 21 of Directive 90/220/EEC.[210] While this procedure would in effect bypass the traditional legislative process, which would involve the Council and the Parliament, it would permit the adoption of the labeling amendment in a period of weeks rather than one or two years as required by the

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203. *See id.*

204. *See* European Commission, The European Commission Approves the Labelling of Genetically Modified Organisms, ip/97/528 at 2 (June 18, 1997) [hereinafter Commission Approves Labelling].

205. *See id.*

206. *See* Council Directive 90/220, 1990 O.J. (L 117) 15, 15.

207. *See Biotechnology: Commission to Issue Labelling Guidelines for GMOs*, *supra* note 102, at 10.

208. *See* Commission Has Decided to Propose Further Labelling, *supra* note 200, at 2.

209. *See* Patrick Chalmers, *EU Gene-Produce Label Rules Possible Within Weeks*, REUTERS, Mar. 21, 1997.

210. *See id.*; *Genetic Engineering: Labelling Proposals for GMOs Will Still "Leave Consumers in the Dark"*, EUR. REP., No. 2213, Apr. 5, 1997, at 1.

regular legislative process.[211] Environment Commissioner Bjerregaard emphasized that the Commission would involve the Parliament and the Council throughout the entire process.[212]

Some within the Commission were reportedly concerned that this fast track procedure was legally unsound.[213] However, the Commission's attorneys determined that technical developments in biotechnology warranted the use of this procedure to require the labeling of GMOs.[214]

In line with the "fast track" procedure, the Regulatory Committee approved the Commission's proposal on May 29, 1997.[215] The Commission adopted the labeling amendment, Commission Directive 97/35/EC, on June 18, 1997.[216] Member states were required to bring their national laws into conformity with this decision by July 31, 1997.[217]

C. *Labeling Amendment and "May Contain GMO" Option*

Specifically, Commission Directive 97/35/EC amended Annex III of Directive 90/220/EEC to require the labeling of products that contain GMOs. The Commission's directive provided that in situations in which GMO products placed in the market are mixed with non-GMO products, "information on the possibility that the genetically modified organisms *may* be present, is sufficient."[218]

D. *Labeling Amendment Not Retroactive*

The amendment to Annex III of Directive 90/220/EEC applied only to future applications of placing GMO products in the market, not to the eleven applications that had already been received, as the Commission is unable to legislate retroactively.[219] To deal with this situation, the Commission suggested that

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211. *See* Chalmers, *supra* note 209.

212. *See* Bjerregaard, *supra* note 100, at 1.

213. *See* Chalmers, *supra* note 209.

214. *See id.*

215. *See* Commission Approves Labelling, *supra* note 204.

216. Council Directive 90/220/EEC was amended previously in April 1994. *See* Commission Directive 94/15, 1994 O.J. (L 103) 20, 20. The 1994 amendment changed Annex II, Information Required in the Notification, into two categories: Annex IIA of the amended Directive applies to releases of GMOs that are not higher plants, while Annex IIB applies to releases of higher plants ("higher plants" are defined as plants belonging to the taxonomic groups *Gymnospermae* and *Angiospermae*). *See id.*, 1994 O.J. (L 103) at 22-27. The authors did not find any literature indicating that the 1994 amendment was controversial.

217. *See* Council Directive 97/35, art. 2, 1997 O.J. (L 169) 72, 72.

218. *Id.* Annex III(C), 1997 O.J. (L 169) at 73 (emphasis added).

219. *See* Bjerregaard, *supra* note 100, at 1.

companies that had already submitted notifications voluntarily label their products to state that they contain GMOs.[220] At the time that Directive 90/220/EEC was adopted by the Commission, most such companies had agreed to this proposal.[221]

E. *Reactions to Amendment*

According to press reports, European Trade Commissioner Sir Leon Brittan opposed the proposed labeling provision and would have preferred a more flexible approach.[222] In contrast, recognizing the need to address the concerns of their potential customers, the European Association for Bioindustries (EuropaBio), an industry organization representing more than 500 biotechnology companies in Europe, supported the labeling requirement.[223] Although the amendment was intended to appease environmentalists, the environmental group Greenpeace was disappointed with the amendment because it did not require the segregation of GMO from non-GMO products.[224]

XI. PROPOSED COMPREHENSIVE REVISION OF DIRECTIVE 90/220/EEC

As described, *supra*, the Commission saw the expedited labeling amendment to Annex III of Directive 90/220/EEC as only a stopgap measure until a comprehensive revision of this directive could be adopted. At present, such a revision has not been implemented by the European Union.

A. *Legislative Procedure*

The proposed revisions to Directive 90/220/EEC are proceeding through the co-decision process.[225] Accordingly, both the Parliament and the Council must

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220. *See id.* at 1-2; Commission Approves Labelling, *supra* note 204.

221. *See* Commission Approves Labelling, *supra* note 204.

222. *See* Chalmers, *supra* note 209.

223. *See* Bjerregaard, *supra* note 99, at 1; *Genetic Engineering: Labelling Proposals for GMOs Will Still "Leave Consumers in the Dark"*, *supra* note 210, at 2.

224. *See Genetic Engineering: Labelling Proposals for GMOs Will Still "Leave Consumers in the Dark"*, *supra* note 210, at 2.

225. *See* European Commission, The Commission Proposes Modification of Directive on Deliberate Release into the Environment of Genetically Modified Organisms, ip/97/1044 at 72 (Nov. 26, 1997); European Commission, Deliberate Release of Genetically Modified Organisms, 9402/98, Presse 205-G at 31 (June 16-17, 1998) [hereinafter Deliberate Release of GMOs].

give their consent to the legislation before it becomes law.[226] The Parliament was scheduled to deliver its opinion on the proposed amendments in October 1998.[227]

B. *Drafting of Proposed Legislation by Commission*

In July 1997, the Commission announced that it had developed guidelines for the drafting of proposed amendments to Directive 90/220/EEC.[228] The Commission stated that the proposed legislation would comport with the European Union's international obligations and would not require the segregation of GMO from non-GMO products.[229] In an effort to create coherent policies on GMOs throughout the European Union, the proposed legislation would provide for the labeling of GMOs using a "science-based approach" that would operate "without stigmatizing modern biotechnology."[230] Furthermore, in situations in which it is not possible to determine whether a product contains GMOs, the guidelines stated that the label would indicate that the product "may contain" GMOs.[231] The "may contain" label would make Directive 90/220/EEC accord with the labeling provisions of the Novel Foods regulation, which had been adopted just months earlier.[232]

C. *Provisions of Proposed Amendments*

1. *Provisions Unrelated to Labeling*

The formal proposed amendments were submitted by the Commission to the Council and the Parliament on February 23, 1998.[233] They provide new procedures for the authorization process of Directive 90/220/EEC.[234] The amendments call for consultations between the Commission and a Scientific Committee when determining whether a product that is being considered for

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226. *See Biotechnology: Amended Directive on Labelling and Marketing of GMOs*, *supra* note 191, at 23-24.

227. *See* Deliberate Release of GMOs, *supra* note 225, at 31.

228. *See The European Commission Agrees on Guidelines for EU Labelling of GMO Products*, EUR. UNION NEWS, No. 51/97, July 25, 1997, at 1.

229. *See id.*

230. *Id.*

231. *See id.* at 2.

232. *See European Union: Commission Aims at Coherent Policy on Labeling of Goods Containing GMOs*, 20 Int'l Env't Rep. (BNA) 749, 749-50 (Aug. 6, 1997).

233. *See* European Commission, Proposal for a European Parliament and Council Directive Amending Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms, 1998 O.J. (C 139) 1, 1.

234. *See id.*, 1998 O.J. (C 139) at 1, 2.

placement in the market poses risks to humans and the environment.[235] The amendments provide that the Commission can consult with any committee it has established if it seeks advice on the ethical implications of biotechnology.[236]

If the amendments are adopted, the public will have more access to the decision making process on authorizations. The amendments provide that the public can submit comments on the possible approval of a GMO.[237] They also propose new transparency rules that would permit the release to the public both of assessment reports related to the GMOs and the opinions of the Scientific Committee.[238]

The amendments indicate that the precautionary principle should be taken into account when conducting risk assessments of GMOs that are being considered for placement in the market.[239] In instances in which GMOs are approved, the amendments propose that the period of consent for placing the product on the market would be seven years.[240] In addition, the party that applied for consent would be responsible for monitoring the GMO for possible adverse effects on human health or the environment.[241]

2. *Labeling Provisions*

Consistent with the Commission's earlier guidelines, the amendments do not provide for the segregation of GMOs from non-GMOs. The proposed amendments call for the labeling of products containing GMOs.[242] In the case of products in which the presence of GMOs cannot be determined but their presence cannot be ruled out, products shall be labeled that they "may contain GMOs."[243]

D. *Debates Surrounding Proposed Revisions*

As might be expected, significant debate has occurred concerning the proposed amendments to Directive 90/220/EEC. According to press reports, the release by the Commission in November 1997 of a clear set of principles on which

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235. *See id.*, 1998 O.J. (C 139) at 7, 9.

236. *See id.*, 1998 O.J. (C 139) at 2.

237. *See id.*, 1998 O.J. (C 139) at 7.

238. *See id.*, 1998 O.J. (C 139) at 9.

239. *See id.*, 1998 O.J. (C 139) at 12. In Annex II, which establishes the principles for risk assessments for GMOs, the proposed amendments state that "[i]t is important not to discount any hazard on the basis that it is likely to occur." *Id.*, 1998 O.J. (C 139) at 12. This sentence signals that the Commission sought to incorporate the precautionary principle into the risk assessment framework.

240. *See id.*, 1998 O.J. (C 139) at 7.

241. *See id.*, 1998 O.J. (C 139) at 5, 8.

242. *See id.*, 1998 O.J. (C 139) at 22.

243. *See id.*, 1998 O.J. (C 139) at 22.

to base the proposed reforms was postponed three times due to sharp differences among the members of the Commission.[244] Industry Commissioner Martin Bangemann and Trade Commissioner Sir Leon Brittan apparently disagreed strongly with Consumer Policy Commissioner Emma Bonino and Environment Commissioner Ritt Bjerregaard over the proposals.[245]

Business leaders and the Commission appear to agree that some type of reform of Directive 90/220/EEC is needed to create consistent rules throughout the European Union.[246] However, industry contends that the seven year limit on authorizations is unnecessary as Directive 90/220/EEC at Article 16 already permits the withdrawal of authorizations if it is determined that a product presents risks.[247] Some member states also reportedly have reservations about the seven year limit; they would rather not revisit highly controversial GMO authorizations every seven years.[248]

While industry contends that the proposed revisions are too strict, some in the Parliament, as well as certain environmentalists, contend that they do not go far enough.[249] The Parliament has indicated that the amendments could be defeated in that body unless more thorough risk assessments are required and unless strict civil liability rules are added.[250] Greenpeace insists that the proposed revisions should provide for the segregation of GMOs.[251]

XII. THE NOVEL FOODS REGULATION: REGULATION (EC) NO. 258/97

Regulation (EC) No. 258/97, the Novel Foods Regulation, was adopted on January 27, 1997, approximately seven years after the adoption of the European Union's other major law concerning agricultural biotechnology, Directive 90/220/EEC.[252] While both Directive 90/220/EEC and the Novel Foods Regulation concern the placing of GMOs in the market, the former law is addressed to GMOs in the form of raw materials, and the latter law applies to

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244. *See Biotechnology: Amended Directive on Labelling and Marketing of GMOs*, *supra* note 191, at 24.

245. *See id.*

246. *See European Union: Commission Aims at Coherent Policy on Labeling of Goods Containing GMOs*, *supra* note 232, at 749.

247. *See* Gillian Handyside, *EU: Plans to Reform EU Gene Law Draw Heavy Criticism*, REUTERS, Apr. 29, 1998.

248. *See U.S. Pressing EU for Quick GMO Decisions to Ensure Trade in Corn*, INSIDE U.S. TRADE, Dec. 12, 1997 <http://www.insidetrade.com>.

249. *See* Handyside, *supra* note 247.

250. *See id.*

251. *See European Union: Commission Aims at Coherent Policy on Labeling of Goods Containing GMOs*, *supra* note 232, at 750.

252. Commission Regulation 258/97, 1997 O.J. (L 43) 1, 1.

GMOs in further processed foods that are likely to be purchased by final consumers. Drafted following the implementation of Directive 90/220/EEC, the Novel Foods Regulation takes a more restrictive approach to GMO products than the directive. In the intervening years between the adoptions of these two laws, the BSE crisis in Europe heightened consumer concerns about food safety, and these concerns are reflected in part in the Novel Foods Regulation.

At the time that the proposed Novel Foods Regulation was being written, some member states had implemented their own laws concerning novel foods while others were waiting for European Union legislation to address this subject.[253] With the adoption of Regulation (EC) 258/97, the Commission sought to establish a uniform law on novel foods throughout the European Union that would facilitate the functioning of the internal market.[254]

A. *Legislative Procedure*

The legislative procedure for adopting Regulation 258/97 might also explain the Novel Foods Regulation's stricter rules on GMOs as compared to the rules of Directive 90/220/EEC. Regulation 258/97 was adopted through the co-decision procedure, which provided the Parliament a significant role in the development of this regulation.[255] Under the co-decision procedure, the Council and the Parliament share decision-making power.[256]

B. *Process Leading to Adoption of Novel Foods Regulation*

1. *Commission Presents Legislative Proposal to Council*

The Commission presented its draft legislative proposal to the Council on July 7, 1992.[257] This proposal did not provide for the compulsory labeling of novel foods containing GMOs. Upon being presented the proposal, the Council decided to consult with the Economic and Social Committee and forwarded the Commission's proposed regulation to that committee for comment.[258] The

253. Commission of the European Communities, Proposal for a Council Regulation (EEC) on Novel Foods and Food Ingredients, COM(92)295 final at 18.

254. *See* Commission of the European Communities, Proposal for a Council Regulation (EEC) on Novel Foods and Food Ingredients, Preamble 1992 O.J. (C 190) 2, 3.

255. *See* EUROPEAN COMM'N, *supra* note 57, at 17 (discussing the division of power in the co-decision procedure).

256. *See id.*

257. *See* European Commission, Proposal for a Council Regulation (EEC) on Novel Food Ingredients, Preamble, 1992 O.J. (C 190) 2, 3.

258. *See* Economic and Social Committee, Opinion on the Proposal for a Council Regulation (EEC) on Novel Foods and Novel Food Ingredients, 1993 O.J. (C 108) 8, 8.

committee recommended that the proposal state explicitly that the legislation would apply to novel foods containing GMOs.[259] It also suggested that the proposed legislation be revised to provide for the labeling of certain foods, including possibly foods containing GMOs.[260]

2. *Parliament Adopts Opinion*

The Parliament adopted an opinion on the proposed legislation on October 27, 1993.[261] Included in its opinion, the Parliament noted that genetic engineering is "incompatible with the principles of organic agriculture" and called for civil and criminal liability for persons marketing GMO food products that cause damage to human health or the environment.[262] The Parliament proposed that marketers of GMO foods be required to carry sufficient liability insurance to cover disasters before being granted authorizations under the Novel Foods Regulation.[263] The Parliament also called for the mandatory labeling of foods produced through genetic technology.[264]

3. *Commission Revises Proposal*

The Commission released a revised proposal that took into account some of the Parliament's concerns on December 1, 1993.[265] The Commission rejected, however, calls from the Parliament to label systematically novel foods containing, or produced through, genetic modification.[266] The Commission stated that "it considers that such provisions tend to stigmatize biotechnology while providing little useful information for the consumer."[267]

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259. *See id.*, 1993 O.J. (C 108) at 9.

260. *See id.*, 1993 O.J. (C 108) at 8-10.

261. *See* European Parliament, Proposal for a Council Regulation on Novel Foods and Novel Food Ingredients, 1993 O.J. (C 315) 139, 139.

262. *See id.*, 1993 O.J. (C 315) at 140-41.

263. *See id.*, 1993 O.J. (C 315) at 141.

264. *See id.*, 1993 O.J. (C 315) at 145.

265. *See* Amended Proposal for a European Parliament and Council Regulation (EC) on Novel Foods and Novel Food Ingredients, COM(93)631 final—COD 426 at 2 [hereinafter Amended Proposal for a Regulation]. *See also Novel Foods: Parliament and Council Agreement in Conciliation Talks*, EUR. REP., No. 2179, Nov. 30, 1996, at 19.

266. *See* Amended Proposal for a Regulation, *supra* note 265, at 3.

267. *Id.*

4. *Council Issues Common Position*

On October 23, 1995, the Council, taking into consideration the positions of the Commission and the Parliament, issued a common position on the proposed legislation.[268] Included among the proposed products requiring labeling, the common position listed any product containing ingredients that might cause ethical concerns and any product with the presence of GMOs that do "not correspond solely to modifications of its agricultural characteristics."[269] The Commission interpreted this statement to mean that labeling would be required for a food product with changed food properties, such as yogurt containing GMOs, but not for a product with unchanged food properties but changed agronomic characteristics, such as corn that is genetically modified to resist insects.[270] Thus, the Council rejected the Parliament's call for compulsory labeling of all food containing GMOs.[271] The Council noted at the end of its common position that, three years after the submission of the original proposal of the Commission, it believed that the "right balance" was finally reached.[272] The Commission accepted the Council's proposal on labeling as "practical and enforceable."[273]

5. *Commission Responds to Parliament's Suggestions on Labeling*

On May 23, 1996, the Commission elaborated on its disagreement with the Parliament over the issue of labeling.[274] The Commission wrote that labeling should only be required in instances in which the presence of a GMO affects the characteristics of the food product.[275] The Commission noted that labeling all products that contain GMOs would require the establishment of separate

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268. *See* Council of the European Union, Common Position (EC) No. 25/95 with a View to Adopting Regulation (EC) No . . . /95 of the European Parliament and of the Council Concerning Novel Foods and Novel Food Ingredients, 1995 O.J. (C 320) 1, 1 [hereinafter Common Position (EC) No. 25/95].

269. *Id.* art. 8(1)(c)-(d), 1995 O.J. (C 320) at 4-5.

270. *See* European Commission, Communication from the Commission to the European Parliament: Common Position of the Council Concerning the Proposal for a European Parliament and Council Regulation on Novel Foods and Novel Food Ingredients, SEC(95)1802 final—COD 426 at 5 [hereinafter Communication from the Commission to the European Parliament].

271. *See id.* at 4.

272. *See* Common Position (EC) No. 25/95, *supra* note 268, art. 8.1(c)-(d), 1995 O.J. (C 320) at 4-5.

273. Communication from the Commission to the European Parliament, *supra* note 270, at 4.

274. *See* European Commission, Opinion of the Commission on the European Parliament's Amendments to the Council's Common Position Regarding the Proposal for a European Parliament and Council Regulation (EC) on Novel Foods and Novel Food Ingredients, COM(96)229 final—COD 426 at 4.

275. *See id.*

distribution systems for GMO and non-GMO products, in effect mandating segregation of the products.[276] Furthermore, the labeling of all foodstuffs containing GMOs could create problems for imports as no major trading partners of the European Union had such policies and as GMO and non-GMO products are commonly mixed.[277]

6. *Conciliation Committee Resolves Differences Between Parliament and Council*

The Conciliation Committee, composed of representatives of the Council and the Parliament, was unable to reach agreement at its meetings on October 16, 1996, and November 4, 1996.[278] Finally, on November 27, 1996, the members of the Conciliation Committee resolved their differences.[279] The provisions of the agreed upon legislation are described below.

C. *Provisions of Novel Foods Regulation*

Regulation 258/97 was adopted by the European Parliament and the Council on January 27, 1997.[280] It went into effect on May 15, 1997.[281]

1. *Coverage of Regulation*

At Article 1, the Novel Foods Regulation states that it applies to foods "which have not hitherto been used for human consumption to a significant degree within the Community."[282] These foods include products containing GMOs within the meaning provided in Council Directive 90/220/EEC; food produced by, but not containing, GMOs; and foods "with a new or intentionally modified primary molecular structure."[283]

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276. *See id.*

277. *See id.*

278. *See* European Commission, Press Release: European Parliament—Council Conciliation Committee, Novel Foods and Novel Food Ingredients, 12105/96, Presse 347-G at 1 (Nov. 27, 1996).

279. *See id.*

280. *See* Commission Regulation 258/97, 1997 O.J. (L 43) 1, 1.

281. *See Biotechnology: Amended Directive on Labelling and Marketing of GMOs, supra* note 191, at 23, 24.

282. Commission Regulation 258/97, art. 1.2, 1997 O.J. (L 43) 1, 2.

283. *Id.* art. 1.2(a)-(c), 1997 O.J. (L 43) at 2. Regulation 258/97 does not apply to food additives and food flavorings, which are covered by separate directives. *See id.* art. 2.1(a)-(b), 1997 O.J. (L 43) at 3.

2. *Notification to Individual Member State*

Similar to the approval procedure set forth in Council Directive 90/220/EEC, the party seeking to introduce the novel food into the European Union is required to submit a request to the government of the member state in which the product will be put into the market for the first time.[284] The applicant must at the same time forward the request to the Commission.[285]

In its request, the applicant must include copies of studies that have been conducted on the GMO demonstrating that the product does not present risks to consumers.[286] If the GMO was granted consent under Council Directive 90/220/EEC for deliberate release into the environment for purposes of research and development, the request under Regulation 258/97 must be accompanied with a copy of the written consent as well as any evidence shown by the releases authorized under Council Directive 90/220/EEC that the GMO poses risks to human health and the environment.[287]

The Novel Foods Regulation requires the applicant to submit the technical dossier as well as the environmental assessment that was provided under Council Directive 90/220/EEC to the member state where the GMO will be placed in the market for the first time.[288] This requirement apparently assumes that the GMO submitted for approval under Regulation 258/97 was previously reviewed under Council Directive 90/220/EEC.[289]

3. *Labeling*

a. *General Labeling Requirements.*

The request that is provided to the member state where the product will be marketed for the first time must specify how the product will be labeled.[290] Labels must indicate whether characteristics of a food make it no longer equivalent to an existing food.[291] The decision of whether a food is not equivalent to an existing food, and thus novel, shall be determined by a "scientific assessment."[292]

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284. *See id.* art. 4.1, 1997 O.J. (L 43) at 4.
285. *See id.* 1997 O.J. (L 43) at 4.
286. *See id.* art. 6.1, 1997 O.J. (L 43) at 4.
287. *See id.* art. 9.1, 1997 O.J. (L 43) at 5.
288. *See id.*, 1997 O.J. (L 43) at 5.
289. *See id.*, 1997 O.J. (L 43) at 5.
290. *See id.* art. 6.1, 1997 O.J. (L 43) at 4.
291. *See id.* art. 8.1(a), 1997 O.J. (L 43) at 5.
292. *See id.*, 1997 O.J. (L 43) at 5.

Consistent with U.S. laws, the regulation provides for the labeling of a product that contains an ingredient not found in an original food product that poses health risks to portions of the population, e.g., the presence of a Brazil nut protein, which is recognized as a common allergen.[293] In addition, labels must indicate to final consumers the presence in a novel food of material "which gives rise to ethical concerns," e.g., to notify vegetarians of a GMO derived from the genes of an animal.[294]

b. *Labeling of GMOs*

The regulation specifies that the final consumer must be informed through the label of the presence of GMOs.[295] As with the amended Directive 90/220/EEC, Regulation 258/97 provides that products that "may contain" GMOs can be labeled as such.[296]

4. *Assessment of Novel Food*

Once the member state receives the request, it must see that an assessment is conducted on the novel food.[297] The member state receiving the request will notify the Commission that an initial assessment is being conducted, and the Commission will forward to all member states a summary of the applicant's request as well as the identity of the competent body selected to conduct the initial assessment.[298] The initial assessment report must be completed within three months, and the food assessment body issuing the report must indicate whether any additional assessment is required.[299]

5. *Commission Forwards Assessment Report to Member States*

If it is determined that further assessment is not needed, the member state must forward the report to the Commission, which will then forward the same information to the member states.[300] The other member states will then have sixty

293. *See id.*, 1997 O.J. (L 43) at 5. *See also* Communication from the Commission to the European Parliament, *supra* note 270, at 5.

294. *Id.*, 1997 O.J. (L 43) at 5. *See also* Communication from the Commission to the European Parliament, *supra* note 270, at 5.

295. *See* Council Directive 258/97, art. 8.1(d), 1997 O.J. (L 43) 1, 5.

296. *See* Commission Regulation 258/97, 1997 O.J. (L 43) 1, 2.

297. *See* Council Directive 258/97, art. 6.2, 1997 O.J. (L 43) 1, 4.

298. *See id.*, 1997 O.J. (L 43) at 4.

299. *See id.* art. 6.3, 1997 O.J. (L 43) at 4.

300. *See id.* art. 6.4, 1997 O.J. (L 43) at 4.

days in which to make comments or objections regarding the approval of the novel food.[301] Any such comments or objections, which may address labeling as well as other concerns, shall be forwarded to the Commission, which will subsequently forward them to the member states.[302] If an additional assessment is not required, and if no other member states object to the novel food, the member state receiving the request shall notify the applicant that the product may be placed in the market.[303]

6. *Commission Makes Authorization Decision*

However, if an objection is received or if the food assessment body determines that further research is needed, the Commission shall make an authorization decision.[304] Under Article 13, the authorization decision entails the Commission submitting the proposed measure to the Standing Committee for Foodstuffs.[305] The Commission shall adopt the measures "if they are in accordance with the opinion of the Committee."[306] In a situation in which "the measures envisaged are not in accordance with the opinion of the Committee," or if the Standing Committee on Foodstuffs fails to issue an opinion, the Commission must present to the Council a proposal concerning the proposed measures, and the Council will vote upon it.[307] If the Council does not vote upon the measures within three months, the Commission shall adopt the proposed measures.[308]

7. *Provisional Restrictions on GMO if Evidence of Harm*

If a member state through new information has reason to believe that a GMO approved for use as a food under Regulation 258/97 poses risks to human health or the environment, the state may temporarily suspend trade of the product.[309] The Commission "shall then take the appropriate measures in accordance with the procedure laid down in Article 13," which sets forth the authorization decision process.[310]

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301. *See id.*, 1997 O.J. (L 43) at 4.
302. *See id.*, 1997 O.J. (L 43) at 4.
303. *See id.* art. 4.2, 1997 O.J. (L 43) at 4.
304. *See id.* art. 7.1, 1997 O.J. (L 43) at 4.
305. *See id.* art. 13.3, 1997 O.J. (L 43) at 6.
306. *Id.* art. 13.4(a), 1997 O.J. (L 43) at 6.
307. *Id.* art. 13.4(b), 1997 O.J. (L 43) at 6.
308. *See id.* art. 13.4, 1997 O.J. (L 43) at 6.
309. *See id.* art. 12.1, 1997 O.J. (L 43) at 6.
310. *Id.* art. 12.2, 1997 O.J. (L 43) at 6. *See also* discussion *infra* Part XII.

XIII. MANDATED LABELING OF BT-MAIZE: COMMISSION REGULATION (EC) NO. 1139/98

Following the adoption of the Novel Foods Regulation, the Commission decided to apply the same rules found in Article 8 of Regulation 258/97, which concerns labeling, to GMO products that were approved for sale in the market through Directive 90/220/EEC before the Novel Foods Regulation was adopted.[311] Accordingly, the Commission adopted Regulation (EC) No. 1139/98, which mandated the labeling of Ciba-Geigy's Bt-maize as well as certain GMO soybeans;[312] both of these products had been authorized under Directive 90/220/EEC. The Commission stated that the labeling of these particular products was needed to provide for consumer protection and to ensure a coherent policy on biotechnology throughout the internal market.[313]

A. *Debate Surrounding Adoption of Commission Regulation (EC) No. 1139/98*

1. *Criticism of "May Contain GMOs" Provision*

The Commission's original proposal for the mandatory labeling legislation for the relevant GMO maize and soya provided that in cases in which it is uncertain as to whether a product contains these GMO products, the label should state "may contain GMOs."[314] This policy would be consistent with the requirements of Directive 90/220/EEC as currently amended and the Novel Foods Regulation. In the course of discussions on the Commission's proposal, however, it became clear that some member states as well as consumer groups were dissatisfied with the "may contain" option as they saw it as lacking significant meaning.[315] Displeasure with the "may contain" provision caused the Council, composed of single market

311. *See id.*, 1997 O.J. (L 43) at 6; European Commission, Proposal for a Council Regulation (EC) Concerning the Compulsory Indication on the Labelling of Certain Foodstuffs Produced from Genetically Modified Organisms of Particulars Other Than Those Provided for in Directive 79/112/EEC, COM(98)99 final at 2 [hereinafter Proposal for Regulation Concerning the Compulsory Indication on Labelling].

312. *See* Commission Regulation 1813/97, 1997 O.J. (L 257) 7, 7. The GMO soybeans being regulated (*Glycine max L.*) had increased tolerance to glyphosate and were given consent by the Commission on April 3, 1996, through Commission Decision 96/281/EC. *See id.*, 1997 O.J. (L 257) at 7.

313. *See* Commission Regulation 258/97, art. 12.2, 1997 O.J. (L 43) 1, 6; Proposal for Regulation Concerning the Compulsory Indication on Labelling, *supra* note 311, at 2.

314. *See* European Commission, *Labelling of Certain Foodstuffs Produced from Genetically Modified Organisms*, 8528/98, Presse, 148-G, May 18, 1998, at 18.

315. *See EU: EU Set for May 18 Vote on Gene Food Labels Plan*, *supra* note 194.

ministers, to reject the Commission's proposed amendments in May 1998.[316] Only three of the fifteen member states of the European Union supported the Commission's proposal.[317]

2. *Commission Concerned That Removing "May Contain" Provision Would Make Law Unworkable*

The Commission was concerned that removing the "may contain" option for the GMO maize and soybeans would in effect make the proposed law unworkable.[318] In particular, small manufacturers of food products, such as local bakeries, would not have the necessary equipment with which to test for GMOs.[319] This could create a situation in which food manufacturers out of prudence might label all their products as containing GMOs or ignore the labeling law altogether.[320] Given that GMOs authorized for the market have been certified as posing no risks to human health or the environment, local food safety inspectors would likely not concentrate on searching for violators of the GMO labeling law.

3. *Undetectable GMOs*

During the negotiations that led to Commission Regulation (EC) No. 1139/98, members of both the Council and the Parliament advocated the adoption of a "negative list" of foods that would not be subject to the labeling requirement as it is impossible to detect whether these foods contain GMOs.[321] Evidence of the presence of GMOs in some foods can be destroyed through heat treatments associated with food processing.[322]

4. *Testing for Genetically Modified DNA and Proteins*

Some critics contended that the Novel Foods Regulation permits manufacturers not to label some foods containing GMOs depending upon the scientific method used to detect GMOs. [323] To address this problem, the

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316. *See* Gillian Handyside, *EU: EU Seen Adopting 'Unworkable' Gene-Food Label Law*, REUTERS, May 19, 1998.

317. *See id.*

318. *See id.*

319. *See id.*

320. *See id.*

321. *See id.*

322. *See id.*

323. *See* Gillian Handyside, *EU: EU Food Chiefs Split over Plan to Label Gene Foods*, REUTERS, Jan. 15, 1998.

Commission proposed in December 1997 that food products be tested for genetically modified DNA and proteins of the specified GMO maize and soya; if products contain such materials, they would have to be labeled.[324] According to the Commission, if not for the DNA and protein testing, it would be necessary for all persons in the food chain, from seed producer to farmer to manufacturer, to provide certificates for GMO products, a process which would be very burdensome.[325] Moreover, such a process could lead in fact to segregation.

B. *Provisions of Council Regulation (EC) No. 1139/98*

Legislation providing for the labeling of certain GMO maize and soybeans passed in the form of Council Regulation (EC) No. 1139/98 on May 26, 1998.[326] This regulation entered into force on September 3, 1998.[327] Regulation No. 1139/98 requires that products containing DNA or protein resulting from genetic modification of the relevant GMO soya and maize be labeled as "genetically modified," or produced through genetic modification, as such food products are "not equivalent to conventional counterparts . . . ."[328] The regulation does not provide for the "may contain" labeling option for products for which it is not possible to determine whether they contain the relevant GMOs. As a solution to the problem of the inability to test for the presence of GMOs in some foods that have been heat treated, Council Regulation (EC) No. 1139/98 calls for the drafting of a list of products that will not be covered by the labeling rules of the regulation.[329]

XIV. RECENT EU APPROVALS UNDER DIRECTIVE 90/220/EEC

On April 22, 1998, the Commission authorized the placing of four additional genetically modified agricultural products on the market under the process set forth in Directive 90/220/EEC.[330] The products authorized were AgrEvo's herbicide tolerant maize and Monsanto's Bt-maize, both to be used as any other maize on the market, and AgrEvo's herbicide tolerant swede-rape and Novartis' Bt-maize

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324. *See id.*

325. *See EU: EU Set for May 18 Vote on Gene Food Labels Plan, supra* note 194.

326. *See* Council Regulation 1139/98, 1998 O.J. (L 159) 4, 4.

327. *See* Submission by the United States to Committee on Technical Barriers to Trade, *supra* note 44.

328. Council Regulation 1139/98, Preamble ¶ 9, 1998 O.J. (L 159) 4, 5.

329. *See id.* art. 2, 1998 O.J. (L 159) at 6. *See also* Handyside, *supra* note 316.

330. *See Commission Proposals Authorizing Four GMO Products Approved by Regulatory Committee*, EUR. UNION NEWS, No. 19/98 (Office of Press and Pub. Affairs, European Comm'n Delegation), Mar. 19, 1998.

tolerant to glufosinate ammonium, both approved solely for processing.[331] As required by Directive 90/220/EEC, the Scientific Committee determined that these products, when used for their approved purposes, either pose no threats, or are unlikely to pose threats, to human health or the environment.[332]

These authorizations were made following the amendments to Directive 90/220/EEC of June 18, 1997, requiring the labeling of products that contain, or may contain, GMOs.[333] Accordingly, the four authorized products will be documented or labeled as being produced through genetic modification.[334] In addition, the manufacturer of one of the GMO products, Monsanto, agreed to recommend that statements accompanying the international shipments of its Bt-maize state that the shipment "may contain genetically modified grains . . . ."[335] Consistent with their concerns on GMO products in general, both Austria and Luxembourg, among other member states, did not support the authorizations.[336] These are the latest products authorized under Directive 90/220/EEC.

XV. CASE STUDY OF POTENTIAL US-EU DISPUTE AT WTO OVER REGULATION NO. 1139/98

While U.S. officials have at times threatened to resolve conflicts between the United States and the European Union concerning biotechnology through the WTO's dispute settlement process, no such disputes have actually reached the dispute settlement stage.[337] The Article next examines an ongoing dispute that

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331. *See id.*

332. *See id.*

333. *See* Commission Directive 97/35, Annex III, 1997 O.J. (L 169) 72, 73.

334. *See* Commission Decision 98/291 of 22 April 1998 Concerning the Placing on the Market of Genetically Modified Spring Swede Rape (*Brassica Napus* L. ssp. *oleifera*), Pursuant to Council Directive 90/220/EEC, 1998 O.J. (L 131) 26, 26-27; Commission Decision 98/292 of 22 April 1998 Concerning the Placing on the Market of Genetically Modified Maize (*Zea Mays* L. line Bt-11), Pursuant to Council Directive 90/220/EEC, 1998 O.J. (L 131) at 28-29; Commission Decision 98/293 of 22 April 1998 Concerning the Placing on the Market of Genetically Modified Maize (*Zea Mays* L. T25), Pursuant to Council Directive 90/220/EEC, 1998 O.J. (L 131) at 30-31; Commission Decision 98/294 of 22 April 1998 Concerning the Placing on the Market of Genetically Modified Maize (*Zea Mays* L. line MON 810), Pursuant to Council Directive 90/220/EEC, 1998 O.J. (L 131) at 32-33.

335. Commission Decision 98/294 of 22 April 1998 Concerning the Placing on the Market of Genetically Modified Maize (*Zea Mays* L. line MON 810), Pursuant to Council Directive 90/220/EEC, 1998 O.J. (L 131) at 32-33.

336. *See Genetic Engineering: More Marketing Authorisations Imminent*, EUR. REP., No. 2309, Apr. 22, 1998, at 3.

337. *See Barshefsky Warns EU of Trade War over Genetically Modified Products*, INSIDE U.S. TRADE, June 20, 1997 <http://www.insidetrade.com>; *Glickman Calls on Industry to Make Strong Case for Biotechnology*, INSIDE U.S. TRADE, July 11, 1997 <http://www.insidetrade.com>.

might eventually be resolved through the WTO's dispute settlement process. This dispute concerns Council Regulation (EC) No. 1139/98 of May 26, 1998.

A. *Issues Involved in Dispute*

In a July 1998 meeting of the Technical Barriers to Trade (TBT) Committee of the WTO, the United States discussed Regulation No. 1139/98, which mandates the labeling of certain genetically modified soya and maize, but does not include the "may contain" option.[338] This regulation entered into force on September 3, 1998.[339] The United States submitted its comments as a formal paper to the TBT Committee on October 16, 1998, and requested that the European Union address the issues raised by the United States and "comply with its obligations under the [TBT] Agreement . . . ."[340] In particular, the United States was concerned about the effects of this regulation on trade and the possible precedents that it could set.[341]

Regulation (EC) No. 1139/98 requires that foods produced from GMO maize or soybeans that contain DNA or proteins resulting from genetic modification be labeled as "produced from genetically modified soya" or "produced from genetically modified maize."[342] The United States objected to the contention of the European Union that foods produced from GMO maize and soya are not equivalent to their conventional counterparts, thus requiring special labeling.[343] In particular, the United States argued that the presence of DNA or protein resulting from genetic modification does not change the composition or nutritional effects of a food as alleged in Regulation No. 1139/98.[344] In addition, the alteration of DNA or protein can occur through traditional forms of breeding as well as through modern genetic modification.[345] While the United States understood requirements for labeling when genetic modification significantly alters a product, such as instances in which the nutritional content of a food is changed, it disagreed with the premise of Regulation No. 1139/98 that a food should be labeled due to its means of production, i.e., through modern genetic modification.[346]

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338. *See* Submission by the United States to Committee on Technical Barriers to Trade, *supra* note 44.

339. *See id.*

340. *Id.*

341. *See id.*

342. *See id.*

343. *See id.*

344. *See* Preamble ¶ 9, 1998 O.J. (L 159) 4, 5; Submission by the United States to Committee on Technical Barriers to Trade, *supra* note 44.

345. *See* Submission by the United States to Committee on Technical Barriers to Trade, *supra* note 44.

346. *See id.*

The United States also contended that the requirements of Regulation No. 1139/98 could lead to the "de facto" segregation of GMO from non-GMO products.[347] Such a result would be impracticable for exporters and difficult to justify, especially in light of the objective of Regulation No. 1139/98, which is to provide information desired by consumers, but not to warn of health hazards.[348] If the European Union thought it necessary to notify consumers of the presence of GMOs in food products, it should have adopted the "may contain" option as appeared in the original draft of the regulation; this option would have been more practical to implement.[349]

In addition, Regulation No. 1139/98 does not specify which tests would be used to detect the presence of DNA or proteins resulting from genetic modification.[350] While it is possible to test for DNA and proteins, the United States claimed that these tests are used mainly for research and are very expensive.[351] The United States alleged that the testing requirement would place an unnecessary burden on suppliers.[352]

B. *Which WTO Agreement Would Apply in Dispute?*

Biotechnology products are not directly addressed in the agreements of the WTO, so it is not entirely clear which WTO agreements would cover disputes over agricultural biotechnology involving the United States and the European Union. In its disagreement with the European Union over Regulation No. 1139/98, the United States chose the TBT Committee at the WTO as its forum for discussions. However, it might initially appear that the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which applies mainly to agricultural and food products, and not the TBT Agreement, would be the controlling agreement.[353]

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347. *See id.*
348. *See id.*
349. *See id.*
350. *See id.*
351. *See id.*
352. *See id.*
353. *See* Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, WTO Agreement, Annex A.1, art. 2.1 (visited Mar. 12, 1999) <http://www.wto.org/wto/eol/e/pdf/15-sps.pdf> [hereinafter Agreement on the Application of Sanitary and Phytosanitary Measures].

1. *Basic Provisions of SPS Agreement*

The SPS Agreement creates a framework for addressing the possible use of sanitary and phytosanitary (SPS) measures,[354] more commonly known as health and safety measures, to act as scientifically unfounded barriers to trade. Specifically, the SPS Agreement permits WTO members to maintain SPS measures that are necessary to protect human, animal, or plant life.[355] But the SPS Agreement prohibits the adoption or maintenance of SPS measures that are not based upon science and provides that SPS measures should not act as disguised barriers to international trade.[356] The SPS Agreement also requires that SPS measures be based upon risk assessments.[357] According to the SPS Agreement's definition of SPS measure, such measures can take the form of "production methods; . . . testing . . . procedures; . . . and labeling requirements directly related to food safety."[358]

2. *Basic Provisions of TBT Agreement*

The TBT Agreement provides that the technical regulations of a country shall not be applied with the "effect of creating unnecessary obstacles to international trade."[359] "Technical regulation" is defined by the TBT Agreement as including "labeling requirements as they apply to a product, process or production method."[360] Under the TBT Agreement, technical regulations may not be more trade restrictive than necessary to attain a "legitimate objective."[361] The agreement goes on to describe "[s]uch legitimate objectives" as including the "protection of human health or safety, animal or plant life or health, or the environment" and the "prevention of deceptive practices."[362] Conformity assessment procedures, which may be used to determine whether technical requirements are being met, can include testing.[363]

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354. *See id.* Sanitary measures concern human and animal health; phytosanitary measures apply to plants. *See id.* Annex A.1.

355. *See id.* art. 2.1.

356. *See id.* arts. 2.2, 2.3.

357. *See id.* art. 5.1.

358. *Id.* Annex A.1.

359. Agreement on Technical Barriers to Trade, Apr. 15, 1994, WTO Agreement, art. 2.2 (visited Mar. 15, 1999) <http://www.wto.org./wto/eol/e/pdf/17-tbt.pdf> [hereinafter Agreement on Technical Barriers to Trade].

360. *Id.* Annex 1.1-.2.

361. *See id.* art. 2.2.

362. *Id.*

363. *See id.* Annex 1.3.

3. *TBT Agreement More Likely to Apply*

In examining a potential dispute before the WTO over Regulation No. 1139/98, it might appear that either the TBT Agreement or the SPS Agreement could be operative in the dispute. After all, both agreements address "measures" or "technical regulations" involving human, animal, and plant health; the "measures" or "technical regulations" of both of these agreements include production methods and labeling; and both agreements address testing procedures. However, the TBT Agreement provides that it does not apply to SPS measures as defined in the SPS Agreement.[364] SPS measures are defined in the SPS Agreement as measures applied to "protect human or animal life or health" from certain risks including "contaminants" and "toxins."[365]

In Regulation No. 1139/98, the European Union did not contend that the relevant GMO maize or soya posed threats to human health or the environment; in fact, this regulation notes that these products were deemed safe when they earlier underwent the authorization process of Directive 90/220/EEC.[366] Instead, Regulation No. 1139/98 was adopted to inform consumers of any characteristic "which renders a food or food ingredient no longer equivalent to an existing food or food ingredient."[367] Thus, the regulatory purpose of Regulation No. 1139/98 is to provide certain information to consumers, but not health and safety information. As such, the current dispute between the United States and the European Union over Regulation No. 1139/98 would likely be adjudicated at the WTO under the TBT Agreement, which applies to technical regulations generally, and not the SPS Agreement, which is applicable to regulations in a more narrow area, health and safety measures.

As long as the European Union continues to permit the placing in the market of GMO products that it determines are safe based upon risk assessments, as happened with four GMO products on April 22, 1998,[368] the United States will likely proceed with such biotechnology disputes under the TBT Agreement.

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364. *See id.* art. 1.5.

365. Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 353, Annex A.1.

366. *See* Council Regulation 1139/98 of 26 May 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, Preamble ¶ 2, 1998 O.J. (L 159) 4, 4.

367. *Id.* Preamble ¶ 9, 1998 O.J. (L 159) at 5.

368. *See* discussion *infra* Part XIV.

4. *SPS Agreement Could Apply in GMO Disputes*

While the SPS Agreement does not appear applicable in the current dispute between the United States and the European Union over Regulation No. 1139/98, the SPS Agreement could be operative in other disputes involving GMO products. For example, the two main laws of the European Union involving agricultural biotechnology, Directive 90/220/EEC and the Novel Foods Regulation, comport with the SPS Agreement in requiring the use of risk assessments, and thus scientific evidence, in determining if GMO products under consideration pose threats to human health or the environment.[369]

When the European Union authorizes GMO products under the procedures of either Directive 90/220/EEC or the Novel Foods Regulation, it does so based upon scientific evidence. If the European Union were to reject an application for authorization of a GMO product produced in the United States, and the United States alleged that the scientific factors used by the European Union in making its decision were inaccurate or that a risk assessment was not conducted, the United States could argue that the European Union was violating its obligations under the SPS Agreement.[370]

C. *Possible Arguments in Dispute over Regulation No. 1139/98*

1. *Labeling and Testing as Unnecessary Obstacles to Trade*

In a dispute before the WTO over Regulation No. 1139/98 resolved under the TBT Agreement, the United States could allege that the European Union's labeling requirement for foods produced from GMO maize or soybeans that contain DNA or proteins resulting from genetic modification is a "technical regulation" as it is a labeling requirement applied to a "product, process or production method" per Annex 1.1 of the TBT Agreement.[371] Under Article 2.2 of the TBT Agreement, WTO members must ensure that technical regulations are not applied "with the effect of creating unnecessary obstacles to international trade."[372] Accordingly,

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369. *See* 1990 O.J. (L 117) 15, 18; 1997 O.J. (L 43) 1, 4, 5.

370. This would be similar to the scenario in the beef hormone dispute between the European Union and the United States, and the European Union and Canada, which was adjudicated through the WTO dispute settlement process. *See* Submission by the United States to Committee on Technical Barriers to Trade, *supra* note 44, at 82. In 1988, the European Union prohibited the use of growth promoting hormones in beef production, and an import ban on hormone treated meat was implemented in 1989. *See id.* The WTO Appellate Body held on January 16, 1998, that the European Union's beef hormone policy violated the European Union's obligations under Articles 3.3 and 5.1 as this policy was not supported by scientific evidence and risk assessments. *See id.*

371. *See* Agreement on Technical Barriers to Trade, *supra* note 359, Annex 1.1

372. *Id.* art. 2.2.

technical regulations "shall not be more trade-restrictive than necessary to fulfill a legitimate objective."[373] These legitimate objectives include national security, human health, and the prevention of deceptive practices.[374]

The United States could claim that the European Union's labeling requirement is operating as an unnecessary obstacle to international trade in violation of Article 2.2. As the objective of the European Union's labeling requirement is to provide information to consumers about the production process of a food, which the United States claims is not a health issue, the United States could contend that the labeling requirement is not afforded the higher permissible level of trade restriction that is provided to technical regulations fulfilling the "legitimate objectives" listed in the TBT Agreement. In other words, if the labeling restriction *were* fulfilling a legitimate objective, such as protecting human health, it would presumably be given a higher threshold for restraining trade than a technical regulation not fulfilling a legitimate purpose. Therefore, the United States could possibly prevail in the dispute by claiming that the European Union's labeling requirement operates as an unnecessary obstacle to international trade in violation of Article 2.2.

Regulation No. 1139/98 provides that a testing method will be needed for this regulation to be operative.[375] As Annex 1.1 defines "technical regulation" as including "administrative provisions, with which compliance is mandatory," the United States might allege that the requirement of suppliers to test foods produced from GMO maize or soya for the presence of DNA or proteins resulting from genetic modification is a "technical regulation."[376] As with the labeling requirement, mandatory testing, which could be burdensome and expensive for businesses, could be seen as an unnecessary obstacle to international trade, and thus be a violation of Article 2.2. The testing requirement, like the labeling requirement, would also not reach the higher threshold of fulfilling a "legitimate objective."[377]

The European Union could argue that its labeling requirement was imposed to prevent "deceptive practices," and as such, fulfills a "legitimate objective" under Article 2.2, thus meriting a higher threshold for restraining trade. For example, it is common in some countries for food products that are similar to, but vary from, other products to be labeled accordingly, e.g., labeled as "artificial." However, the European Union might have to justify its decision not to use the "may contain

373. *Id.*
374. *See id.*
375. *See* 1998 O.J. (L 159) 4, 5.
376. Agreement on Technical Barriers to Trade, *supra* note 359, Annex 1.1.
377. *Id.*

GMOs" option, which would presumably be less trade restrictive than the labeling provision set forth in Regulation No. 1139/98.

2. *Segregation of GMOs*

The United States' claim that the policies of Regulation No. 1139/98 are unnecessary obstacles to international trade in violation of Article 2.2 would be strengthened if the United States could demonstrate that the labeling procedure would lead to "de facto" segregation of GMO from non-GMO products. Segregation would in effect block all exports of some U.S. agricultural products to the European Union as the United States does not separate GMO from non-GMO products,[378] and according to U.S. Trade Representative Charlene Barshefsky, mandatory segregation could disrupt $3 to $5 billion in trade between the European Union and the United States.[379]

The Commission has also apparently recognized that mandatory segregation would violate the European Union's obligations under the TBT Agreement.[380] A confidential paper—that was leaked to the press—prepared by staff of the Commission for Jacques Santer, the President of the Commission, acknowledged that mandatory segregation of GMO products would likely violate the terms of the TBT Agreement.[381] The paper noted that technical barriers to trade must fulfill legitimate objectives, such as protecting health or the environment, and the costs of compulsory segregation would be significant in light of the European Union's finding that the products in question do not pose threats to human health or the environment.[382]

The costs of segregation would be particularly difficult to justify given the availability of a viable alternative, the "may contain GMOs" provision. It is unclear, however, whether the mandatory labeling would indeed lead to the segregation of GMO from non-GMO products.

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378. *See EU to Include Genetically Modified Soy, Corn in Novel Foods Rule*, INSIDE U.S. TRADE, Aug. 8, 1997 <http://www.insidetrade.com>.

379. *See Barshefsky Warns EU of Trade War over Genetically Modified Products*, *supra* note 337.

380. *See Text: EU Paper on GMO Labelling*, *supra* note 195.

381. *See Text: EU Paper on GMO Labelling*, *supra* note 195. *See also Confidential EU Non-Paper Reveals Three Options for Handling GMOs*, INSIDE U.S. TRADE, July 11, 1997 <http://www.insidetrade.com>.

382. *See Text: EU Paper on GMO Labelling*, *supra* note 195. It should be noted that the Commission's confidential paper does not specifically mention the TBT Agreement. *See id.* However, the paper refers to the WTO's rules regarding "technical barriers to trade." *Id.*

XVI. CONCLUSION

The European Union's laws regarding agricultural biotechnology are in a state of flux. In the past eight years, the European Union has gone from not requiring the labeling of GMOs (Directive 90/220/EEC), to requiring the labeling of GMOs but providing a "may contain" provision (Novel Food Regulation and 1997 amendment to Directive 90/220/EEC), to requiring the labeling of GMOs without offering the "may contain" option (Regulation No. 1139/98). Regulation No. 1139/98 was implemented even though the Commission contended that the absence of the "may contain" provision would make the law unworkable. In contrast, the United States does not require the labeling of GMO products, and a federal district court has held that a mandatory state labeling law for certain products derived through biotechnology might be unconstitutional.[383]

The European Union's policies might not comport with its obligations under the WTO. For example, if the United States were to challenge Regulation No. 1139/98, it could allege that the necessity of testing for certain DNA and proteins, and the compulsory labeling of foods containing such evidence of genetic modification, violate the TBT Agreement as these requirements are "unnecessary obstacles to trade," and furthermore, they do not fulfill "legitimate objectives." This argument would be strengthened if the United States could demonstrate that these rules result in "de facto" segregation of GMO from non-GMO products. The European Union could claim that its labeling provision found in Regulation 1139/98 was imposed to prevent "deceptive practices," and thus under the TBT Agreement fulfills a "legitimate objective," meriting it a higher threshold for restraining trade.

The current trend in the European Union is to provide for the further regulation of GMOs, and it appears that this trend will continue for at least the short term. With the growing use of the co-decision procedure, the power of the Parliament will increase; the more active participation of the Parliament in the legislative process will likely result in stricter laws regarding GMOs. The participation of members of the Green Party in the recently formed governing coalition in Germany might result in an even less receptive environment in Europe for biotechnology.[384]

The European public remains skeptical of the food safety policies imposed by its leaders due to the recent BSE scare. As is true in the United States, when

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383. *See* discussion *infra* Part II.B.2; International Dairy Foods Ass'n v. Amestoy, 898 F. Supp. 246 (D. Vt. 1995).

384. *See Germany's New Bundestag, Settling Down to Business, Elects Schroder Chancellor,* WEEK IN GERMANY, Oct. 30, 1998 <http://www.germany-info.org/gnew/archive/wk_10_30_98.htm>.

consumers in the European Union perceive serious risks, they can be expected to respond with strong reactions. It is unclear as to whether the European Union's unsettled policies on GMOs indeed reflect deeply held fears of European consumers or if these policies are only a political reaction to public concerns in the aftermath of the BSE scare.

While the European Union's policies regarding biotechnology do not necessarily coincide with the interests of U.S. agricultural producers, it is difficult not to feel some sympathy for officials in Brussels and the European public at large. After all, if the only democratically elected body of the European Union, the Parliament, favors strict labeling and even segregation of GMOs, it might seem wise to accept this as the democratic process and not protest such actions. But to U.S. officials, the stakes for farmers in the United States are so high, and the benefits to European consumers—the knowledge that their foods were not produced by technology deemed safe—are so comparatively low, that it is impossible to ignore the situation.

Contingent upon continued evidence that biotechnology poses no threats to human health and the environment, the European Union's laws regulating biotechnology will likely, in the long term, be liberalized. This change in policy will occur as restrictive laws on biotechnology come at a cost, and this cost does not result solely from the expenses associated with labeling and possibly segregating GMO products.

For European agricultural producers, constraints on the use of GMO seeds and animal feed will make Europe even less competitive in the international market. If farmers in the United States, Canada, Argentina, and Australia are producing agricultural products in greater volumes, of higher quality, and at less cost due to improved GMO varieties, farmers in Europe will have no choice but to advocate liberalized policies regarding agricultural biotechnology. The possible admittance of Hungary, Poland, the Czech Republic, Slovakia, Bulgaria, and Romania, all sizable agricultural producers, to the European Union will give farmers in Western Europe added incentives to become more competitive.

The European Union's officials in Brussels have already recognized the costs associated with an unwelcome environment for biotechnology in Europe. Strict regulations on biotechnology are resulting not only in less U.S. grain entering Europe, but also more European scientists and investment capital leaving Europe. An even more tangible factor, the European Union's budget, also might force officials to consider changing GMO regulations. Approximately one-half of the European Union's budget is currently allocated to agricultural support programs.[385] As the European Union grows, it will likely want to spend less on farm subsidization and more on programs associated with the lives of the vast majority of

385. *See* EUROPEAN COMM'N, *supra* note 57, at 25.

Europeans who are not involved in agriculture. The increased competitiveness of European farmers through the use of GMO technology, as well as lower agricultural costs through less dependence on expensive pesticides and herbicides, could make it possible for the European Union to decrease spending on agriculture without creating significant hardship for Europe's farmers.

Finally, European consumers will likely eventually advocate less restrictive laws on GMOs. First, individual consumers in Europe already pay significantly more for food than their counterparts in other parts of the world.[386] If Europeans see that people in other countries are paying less for food produced through biotechnology, and the health of foreign consumers is not suffering accordingly, it would be unrealistic to expect Europeans to oppose changes in policies that could lower their food costs.

Second, the European Union's laws on labeling might inadvertently contribute to greater acceptance of GMOs by consumers. Approximately sixty percent of processed foods contain soya, a commonly genetically modified product.[387] Once large numbers of processed foods labeled as containing GMOs are placed on store shelves, the stigma attached with biotechnology will possibly dissipate.[388]

In fact, consumer fears associated with biotechnology might not be as strong as suggested. One British retailer actually saw its sales of tomato paste rise after disclosing that its product was developed from GMO tomatoes.[389] With the European Union's laws on agricultural biotechnology still unsettled, many more surprises can be expected.

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386. *See Cairns Group, U.S. Coordinate Plans for Agriculture Liberalization*, INSIDE U.S. TRADE, May 22, 1998 <http://www.insidetrade.com>. Individual European consumers may be paying up to $1500 more annually for food than consumers in other countries due to the European Union's subsidization of farmers. *See id.*

387. *See Labelling the Mutant Tomato*, *supra* note 2, at 54.

388. *See id.*

389. *See* Gillian Handyside, *EU Plans to Label Gene-Altered Maize, Soya*, REUTERS, Dec. 3, 1997.