An Agricultural Law Research Article

The State of Genetically Engineered Crops in the European Union Following *Monsanto v. Italy* and the Adoption of a New Regulatory Framework for Genetically Modified Food and Feed

by

Jesse Male

Originally published in DRAKE JOURNAL OF AGRICULTURAL LAW
9 DRAKE J. AGRIC. L. 439 (2004)

THE STATE OF GENETICALLY ENGINEERED CROPS IN THE EUROPEAN UNION FOLLOWING *MONSANTO V. ITALY* AND THE ADOPTION OF A NEW REGULATORY FRAMEWORK FOR GENETICALLY MODIFIED FOOD AND FEED

*Jesse Male**

---

* Candidate for Doctorate of Jurisprudence, Drake University Law School (2005). Bachelor of Arts, Drake University (2000). The author would like to thank the Office of Biotechnology at Iowa State University for bringing Mr. Jean Ferriere of the European Commission Directorate General for Trade to Iowa to speak, as well as the Iowa Grain Quality Initiative, ISU Institute of Science and Society, Iowa, Iowa Corn Growers Association, Iowa Department of Agriculture and Land Stewardship, Iowa Department of Economic Development, and the Iowa Soybean Association for cosponsoring the forum at which Mr. Ferriere spoke. The author would also like to thank Mr. Ferriere himself for answering many of the author's questions as well as providing insight into the goals of the Commission in regards to the EU's new regulatory structure.

I. INTRODUCTION

This Note will explain the current regulatory state of genetically-modified crops in the European Union ("EU"). These are sometimes referred to as biotech crops, or they are generally included in the category of Genetically Modified Organisms ("GMOs"). The EU initially described the food products derived from GMOs as "novel foods,"[1] but now describes them in a more straightforward manner as genetically modified ("GM") food and feed.[2] Particular attention will be paid to the recent ruling from the European Court of Justice ("ECJ") in *Monsanto v. Italy*[3] and to the newly-adopted EU regulations on GMOs.[4] These new regulations and the *Monsanto v. Italy* case help clarify EU regulations concerning trade in biotech crops and products, as well as how EU regulations operate in practice.

Starting by examining the background of GMOs and the different ways they are regulated, this note will contrast the approach of the United States with that of the EU, paying particular attention to the effect of Regulation 1829/2003. It will then examine the role and participation of the EU in the Cartagena Protocol on Biosafety[5] and contrast the more European-leaning Cartagena with the more U.S.-leaning World Trade Organization ("WTO") Sanitary-Phytosanitary ("SPS") Agreement.[6] This will be followed by an analysis of how the conflicting approaches in the two treaties might be judicially resolved within the EU. This

---

1. Council Regulation 1829/2003 of 22 September 2003 On Genetically Modified Food and Feed, 2003 O.J. (L 268) 1, 1 [hereinafter Regulation 1829/2003].

2. *Id.*

3. Case C-236/01, Monsanto v. Italy, 2003 E.C.R. I-8105.

4. Regulation 1829/2003, *supra* note 1, at 1; Council Regulation 1830/2003 of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced From Genetically Modified Organisms and Amending Directive, 2003 O.J. (L 268) 24, 25 [hereinafter Regulation 1830/2003].

5. Secretariat of the Convention on Biological Diversity, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Text and Annexes, Jan. 29, 2000, *available at* http://www.biodiv.org/biosafety/protocol.asp [hereinafter Cartagena].

6. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, *available at* http://www.wto.org/english/docs_e/legal_e/final_e.htm [hereinafter SPS Agreement].

Note will then examine the case of *Monsanto v. Italy*—how it arose, the holding, and the impact of its disposition. Last, a summary of the ongoing and unresolved WTO dispute between the EU and the United States will be given.

II. BACKGROUND

The styles of regulation adopted by the United States and the EU are different, and this difference can be viewed as a reflection of the differing philosophies the two have adopted. The EU appears to have adopted an approach that is much more concerned with preventing a potential disaster involving "frankenfoods," while the United States is apparently much more eager to certify crops as safe for humans and get them to market.[7] This can be seen in the United States' treatment of GMOs in a similar manner to other crops and food products, while the EU has created rules and procedures specific to GMOs as living organisms and as derived food products.[8]

A. *The Differing Approaches*

1. *The U.S. Approach*

The United States has no major statutes that deal specifically with the regulation of GMOs.[9] However, engineered crops are subject to review under an administrative process first organized by the White House Office of Science and Technology Policy called The Coordinated Framework for the Regulation of Biotechnology.[10] Under this process, GMOs are reviewed by one or more federal agencies depending upon the changed characteristics.[11] For genetic modifications that might affect an organism's suitability for release into the environment, such as a plant modified out of its environmental niche, GMOs are screened by the U.S. Department of Agriculture ("USDA") through the Plant Protection Act.[12]

---

7. *See generally* George E.C. York, Note, *Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agriculture Trade*, 7 COLUM. J. EUR. L. 423, 434-53 (2001) (providing a helpful overview of the "frankenfood" narrative).

8. *See* section II-A, *infra*, for further discussions on these topics.

9. Terence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243, 247 (1999).

10. The Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,303 (proposed June 26, 1986).

11. *See* Les Levidow & Susan Carr, *Normalizing Novelty: Regulating Biotechnological Risk at the U.S. EPA*, 11 RISK 9, 14 (2000).

12. 7 U.S.C. §§ 7701-7772 (2000). (The Plant Protection Act includes the relevant content of the now repealed Federal Plant Pest Act and the Plant Quarantine Act); *see* D.L. Ucht-

The Environmental Protection Agency ("EPA") regulates GMOs modified to enhance pest resistance through the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")[13] as well as through the Federal Food, Drug, and Cosmetic Act ("FFDCA").[14] Finally, for genetic modifications that might affect use as food or animal feed, the Food and Drug Administration ("FDA") also reviews GMOs under the authority of the FFDCA.[15] By having its administrative agencies review GMOs under existing grants of authority, the United States simply chose to apply the laws it already had to GMOs. In so doing, the United States "implies that GMOs are not so new as to require new legislation and that regulation of GMOs should proceed as it does with familiar substances, on a product-by-product basis."[16] This has been termed a "permissive strategy."[17] It is the result of a faith in the historical narrative of "Better Living Through Chemistry,"—a belief that technology brings improvement, is beneficial for society, and should not be feared merely because of doubt.[18] As a consequence of this belief, the American regulatory scheme is based only on the end product and does not change because a product resulted from a process different from those traditionally used.[19] In accordance with this view, the FDA poignantly states:

> [t]he method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.[20]

---

mann, *Starlink™—A Case Study of Agricultural Biotechnology Regulation,* 7 DRAKE J. AGRIC. L. 159, 209-11 (2002) (noting that regulations made pursuant to old laws are still good under the new law).

13. 7 U.S.C. § 136 – 136y (2000); *see* 7 C.F.R. § 340.0 (2004).

14. 21 U.S.C. §§ 301 – 397 (2000).

15. *See* 21 U.S.C. §§ 342(a), 346(a)(3).

16. John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms,* 9 IND. J. GLOBAL LEGAL STUD. 207, 232 (2001) (citations omitted).

17. Kim JoDene Donat, Note, *Engineering Akerlof Lemons: Information Asymmetry, Externalities, and Marketing Intervention in the Genetically Modified Food Market,* 12 MINN. J. GLOBAL TRADE 417, 427 (2003) (citations omitted).

18. *See generally* Applegate, *supra* note 16, at 222-28 (containing a good overview of the "Better Living Through Chemistry" narrative and its application to the regulation of GMOs in the United States).

19. *See id.*

20. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984-85 (May 29, 1992).

2. *The EU Approach and the Precautionary Principle*

The EU, in a marked contrast to the lack of statutes in the United States, has adopted many statutes and written several administrative directives specifically dealing with biotech crops.[21] Some of the most important are Council Directive 90/220, Regulation 258/97, Directive 2001/18, and Regulation 1829/2003.[22] The two directives deal with the environmental release of GMOs either for trade or experiment, though it should be noted Directive 2001/18 repealed and replaced Directive 90/220.[23] Regulation 258/97 is concerned specifically with novel foods, which includes GMOs that become foodstuffs, as well as foodstuffs produced from GMOs that, due to processing, no longer contain genetically-modified material.[24] The newest regulations, Regulation 1829/2003 and Regulation 1830/2003, create a new authorization regime and new requirements on traceability for GM Food and Feed.[25] Regulation 1829/2003 also attempts to streamline previous EU regulations by creating a single EU-wide clearinghouse for approving trade in genetically-modified crops.[26]

The European approach is guided by what can be called a "Frankenstein" narrative—a fear of the consequences of meddling with "the secrets of life itself."[27] It is from this perspective that opponents of GMO foods often refer to them as "frankenfoods."[28]

> The principal concerns raised by the Frankenstein narrative are the unknown and unintended consequences of the technology, the potential for catastrophic and irreversible invasions of alien species, and familiar products that hide malign character-

---

21. *See generally* Mary Lynne Kupchella, Note, *Agricultural Biotechnology: Why It Can Save the Environment and Developing Nations, but may Never Get a Chance*, 25 WM. & MARY ENVTL. L. & POL'Y REV. 721, 731-35 (2001) (covering in greater scope various older EU regulations concerning GMOs).

22. *See, e.g.*, Regulation 1829/2003, *supra* note 1; Council Regulation 258/97 of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. (L 43) 1 [hereinafter Regulation 258/97]; Council Directive 2001/18 of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) 1 [hereinafter Directive 2001/18]; Council Directive 90/220 of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. (L 117) 15 [hereinafter Directive 90/220].

23. Directive 2001/18, *supra* note 22.

24. Regulation 258/97, *supra* note 22.

25. *See* Regulation 1829/2003, *supra* note 1 (it should also be noted that 1829/2003 indicates that where it regulates the same space as 258/97, it prevails, and the portions of 258/97 are considered repealed); Regulation 1830/2003, *supra* note 4.

26. *See* Regulation 1829/2003, *supra* note 1, at 7 (noting that all applications have to be forwarded to the European Food Safety Authority).

27. Applegate, *supra* note 16, at 212.

28. *Id.* at 210.

> istics. These concerns cannot be expiated by identifying individual products as safe or unsafe by conventional measures, because the products have not been created in conventional ways and their dangers are as yet unknown. The danger is not the apparent characteristics of the product, but genetic modification . . ., and a process-based regulatory regime is designed to anticipate and prevent these harms.[29]

As a consequence of the concerns arising from genetic manipulation of crops and the resulting food, the EU has adopted an approach that does pay attention to the process of creation and production of food.[30] This approach is a result of an EU adherence to the Precautionary Principle,[31] a principle enshrined in EU treaties and legal decisions.[32]

> The Community has consistently endeavored to achieve a high level of protection, among others in environment and human, animal or plant health. In most cases, measures making it possible to achieve this high level of protection can be determined on a satisfactory scientific basis. However, when there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation, the precautionary principle has been politically accepted as a risk management strategy in several fields.[33]

The preamble to Directive 2001/18 can be seen as showing that a number of the "Frankenstein" concerns are among the reasons why the EU decided to apply the precautionary principle to GMOs.[34]

> The Commission in its communication on the precautionary principle stated:
>
> [w]here action is deemed necessary, measures based upon the precautionary principle should be, *inter alia*: *proportional* to the chosen level of protection, *non-discriminatory* in their application, *consistent* with similar measures already taken, *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),

---

29. *Id.* at 229.

30. *See id.* (stating that the EU's regulation of GMOs is built on the Frankenstein narrative model).

31. *See* Marc Victor, Comment, *Precaution or Protectionism? The Precautionary Principle, Genetically Modified Organisms, and Allowing Unfounded Fear to Undermine Free Trade*, 14 TRANSNAT'L LAW. 295, 315-18 (2001) (providing a brief but comprehensive history of the "Precautionary Principle").

32. *See, e.g.*, CONSOLIDATED VERSION OF THE TREATY ESTABLISHING THE EUROPEAN COMMUNITY, Dec. 24, 2002, O.J. (C 325) 33 (2002), *available at* http://europa.eu.int/eur-lex/en/treaties/dat/EC_consol.pdf [hereinafter EC TREATY]; Case T-70/99, Alpharma Inc. v. Council, 2002 E.C.R. II-3495.

33. Communication from the Commission on the Precautionary Principle, COM(2000) 1, 9 [hereinafter COM].

34. *See* Applegate, *supra* note 16, at 229; *see also* Directive 2001/18, *supra* note 22, at 1-4 (emphasizing that the precautionary principle was taken into account in drafting the Directive).

> *subject to review*, in the light of new scientific data, and *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment.[35]

The Commission is of the opinion that its enunciation of these guidelines will help ensure the principle is not invoked unnecessarily or as a means to disguise protectionism.[36] Thus, the Commission believes the proper usage of the precautionary principle will not be in conflict with any of the EU's obligations under the WTO.[37]

B. *The Regulatory History of Genetically Engineered Crops in the EU*

The first EU law concerning GMOs was Directive 90/220, adopted on April 23, 1990.[38] A directive is a regulation that each member state must transcribe in its national legislation, meaning it is not directly applied through the Union, but instead each member government is directed to create or modify their legislation so they are in compliance.[39] Directive 90/220 initially concerned itself with GMO products as living organisms.[40] It was amended twice,[41] and finally, the EU repealed it and replaced it with Council Directive 2001/18.[42] The second law adopted was Regulation 258/97.[43] As mentioned earlier, it deals with GMOs by regulating market placement of 'novel foods', including foodstuffs that contain GMOs.[44] Over time, the EU framework has evolved from regulations concerned with the danger of environmental release, into regulations wary of modification to foods and feeds. Even so, the EU has felt the need to change and refine its regulations. The main reasons for the change in structure can be seen as re-

---

35. COM, *supra* note 33, at 4 (emphasis in the original).

36. *See id.* at 9.

37. *See generally id.* (explaining that the Commission envisages use of the precautionary principle as a way to comply with WTO obligations, not evade them).

38. Directive 90/220, *supra* note 22, at 15.

39. *See* JOHN H. JACKSON ET AL., LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS: CASES, MATERIALS, AND TEXT ON THE NATIONAL AND INTERNATIONAL REGULATION OF TRANSNATIONAL ECONOMIC RELATIONS 152 (4th ed. 2002) (noting that directives can have direct effect if a member state fails to conform and the particular directive meets the *van Gend & Loos* test).

40. Stewart & Johanson, *supra* note 9, at 256.

41. The amendments were only for the purpose of changing the technical requirements of the information required for dossiers. Email from Jean Ferriere, European Commission Directorate General for Trade to Jesse Male (Mar. 8, 2004) (on file with the author).

42. Directive 2001/18, *supra* note 22.

43. Regulation 258/97, *supra* note 22.

44. *Id.*

sulting from the turmoil of the late 1990s from both mad cow disease and the arrival of the first shipments of GM soy products and corn in Europe.[45]

The balances struck in the new framework result from the conflict between the desire to embrace a potentially lucrative new technology, and the safety concerns reflected by public reaction to GMOs, embodied in the precautionary principle.[46] In the mid-1990s, the Commission became concerned that the EU's regulatory structure was making it uncompetitive in the field of biotechnology.[47] Yet at the same time, the European Parliament was increasingly concerned with public skepticism of GMOs and with pleasing member states who did not want to approve them.[48] In fact, after the Commission approved a genetically-modified corn variant, Bt-maize, the Parliament issued a highly critical resolution condemning the approval.[49] In light of public concern, and perhaps the concerns expressed by Parliament, the EU amended Directive 90/220 and added new requirements for labeling, thereby bringing labeling requirements to the same level as those introduced in Regulation 1139/1998.[50] The EU thus ensured equivalent regulation of GMOs as foodstuffs and as crops.[51] The processes created to certify a GMO for release into the EU market became so controversial that the EU imposed a de facto moratorium on approving new crops until the Commission, Parliament, and Member States sorted some of the issues out and created a new regulation.[52]

---

45. Email Interview with Jean Ferriere, European Commission Directorate General for Trade (Mar. 8, 2004) (on file with the author).

46. *Id.*; *see, e.g.*, Secretariat-General of the Commission, *Parliament Resolution on Genetically Modified Maize*, 4 BULL. OF THE EU 5/11 (1997) (noting the EU Parliament's safety concerns), *available at* http://europa.eu.int/abc/doc/off/bull/en/9704/p103170.htm [hereinafter BULLETIN].

47. *See* Stewart & Johanson, *supra* note 9, at 255.

48. *See generally id.* at 265 (discussing the Parliament of the European Union's hostile reception to the biotechnology industry).

49. *See id.*; *see also* BULLETIN, *supra* note 46.

50. *See, e.g.*, Council Regulation 1139/98 of 26 May 1998 Concerning the Compulsory Indication of the Labeling of Certain Foodstuffs Produced from Genetically Modified Organisms of Particulars Other than Those Provided for in Directive 79/112/EEC, 1998 O.J. (L 159) 4 [hereinafter Regulation 1139/98].

51. *See id.*

52. *See EU Environment Ministers Strengthen de Facto Ban on GMOs Pending New Law*, 16 INT'L REP., June 30, 1999, *available at* http://www.global-reality.com/biotech/articles/news070.htm.

C. *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity*

The Cartagena Protocol on Biosafety ('the protocol') was adopted to guard against "adverse effects on the conservation and sustainable use of biological diversity."[53] It was adopted unanimously under the United Nations Convention on Biodiversity.[54] It applies only to "living modified organism[s]" ("LMOs"), a term defined to include "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[55] The protocol only applies to trade in LMOs that may have adverse affects on the conservation and sustainable use of biological diversity, as well as human health. The protocol has three main effects: First, it allows governments to restrict imports.[56] Second, it requires the labeling of bulk shipments of LMOs intended to be used for food, feed, or processing.[57] Third, it has an advance informed agreement provision for LMOs intended for intentional introduction into the environment.[58]

1. *European Participation and Adoption*

The EU was an active participant in the negotiations leading up to the creation of the Cartagena Protocol, and a key portion of its negotiation effort was the EU's desire to ensure the precautionary principle was adopted in the protocol.[59] Indeed, the EU was successful and the protocol is the first international agreement that specifically includes, by reference, the precautionary approach.[60]

---

53. Cartagena, *supra* note 5, at art. 1.

54. *See* United Nations Conference on Environment and Development: Convention on Biological Diversity, *Text of the Convention*, U.N. Doc. UNEP/Bio.Div/N7-INC.S/4 (1992), *reprinted in* 31 INT'L LEGAL MATERIALS 818 (1992).

55. Cartagena, *supra* note 5, at art. 3(g).

56. *Id.* at art. 10.

57. *Id.* at art. 18.

58. *Id.* at art. 7.

59. Terence P. Stewart & David S. Johanson, *A Nexus of Trade and the Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization*, 14 COLO. J. INT'L ENVTL. L. & POL'Y 1, 17 (2003).

60. Jonathan H. Adler, *The Cartagena Protocol and Biological Diversity: Biosafe or Bio-Sorry?*, 12 GEO. INT'L ENVTL. L. REV. 761, 763 (2000) (stating that previous treaties have only alluded to its provisions) (citations omitted).

2. *Potential Conflict with the SPS and TBT Agreements of the WTO*

The World Trade Organization's Agreement on Sanitary and Phytosanitary Measures ("SPS") covers the restrictions a government can impose on trade in order to protect plant, animal, or human health.[61] The WTO's SPS Agreement adopts a standard of precaution under Articles 5.2 and 5.7 for cases of insufficient scientific evidence; however, members are bound to seek the additional necessary information to make a final determination within a reasonable period of time.[62] Consequently, measures taken under the SPS approach should only be provisional.[63] This means a state can only restrict an import as a precaution while it conducts a full scientific review.[64] Under the non-provisional precautionary principle of the protocol, a state could prevent an import indefinitely until evidence convinces it otherwise.[65] To the contrary, the SPS would require scientific evidence for a state to maintain a ban on importation.[66] Though the SPS does not fix a time frame, arguably the effect of either the SPS approach or the Cartagena Protocol approach would be the same, because a member could consistently assert the necessary information was still being collected.

If a conflict arose, it would most likely do so at a WTO dispute panel. However, a dispute could also be brought under the compliance mechanism of Article 34 of the Cartagena Protocol.[67] The resolution of the conflict would depend, in large part, on whether parties on both sides of the dispute were parties to the Protocol as well.[68] The requirements of the Protocol will be interpreted differently by a dispute panel under the Vienna Convention on the Law of Treaties[69] depending on whether both sides are signatories to the Cartagena Protocol or if only one side is a signatory.[70]

In the unlikely event a WTO panel decides that a use of the precautionary principle, such as maintaining a moratorium on GMOs, was a barrier to trade,

---

61. SPS Agreement, *supra* note 6, at para. 1.
62. *Id.* at arts. 5.2 & 5.7.
63. Stewart & Johanson, *supra* note 59, at 33.
64. *Id.* at 30.
65. *See id.* at 33.
66. *See id.* at 32 (stating a requirement of a scientific risk assessment for the SPS and Protocol).
67. *See* Cartagena, *supra* note 5, at 24 (explaining the use of institutional mechanisms to promote compliance and address non-compliance).
68. *See* Stewart & Johanson, *supra* note 59, at 34-38 (providing the use of different agreements when both parties are parties to the germane agreement).
69. G.A. Res. 2166 & 2287, U.N. GAOR, UN Conf. on the Law of Treaties, 1st & 2d Sess., 1155 U.N.T.S. 331 (1969), *available at* http://www.un.org/law/ilc/texts/treaties.htm.
70. *See* Stewart & Johanson, *supra* note 59, at 32-38.

the EU would be subject to retaliatory countermeasures.[71] Furthermore, because of the potential for a future EU law remedy for an EU failure to abide by WTO panel decisions, the EU could potentially make itself subject to suit within its own courts. Currently, there is no legal link between EU and WTO rulings; nevertheless, in *Biret v. Council*, the plaintiff and the advocate general advocated for such a link.[72]

In the EU, a link between a treaty and domestic law can occur if the treaty creates an "unconditional obligation that is central to the purpose of the agreement."[73] This concept is analogous to the distinction in American jurisprudence between a self-executing treaty and a non self-executing treaty. If the position of the advocate general, as argued in *Biret v. Council*, is adopted, then a WTO decision against the precautionary principle would, in effect, double the EU's penalty for maintaining bans on importation that are justified by the precautionary principle.[74]

III. THE EUROPEAN COURT OF JUSTICE'S INTERPRETATION UNDER *MONSANTO*

A. *Why the Case Arose*

Monsanto v. Italy is the only case in which the ECJ was called on to interpret the EU's old regulatory framework for biotech foods, in particular, Regulation 258/97.[75] The case arose as a test of the fast-track approval procedure,[76] whereby genetically-modified foodstuffs could be placed on the market if the resulting food was recognized as "substantially equivalent to existing foods or food ingredients."[77] The governments of France and the United Kingdom approved the maize varieties Bt-11 and MON 810 to be placed on the market under the substantial equivalence process.[78] Because of its doubts about the absolute certainty of the safety of foodstuffs made from the genetically-modified maize,[79]

---

71. *See* JACKSON ET AL., *supra* note 39, at 266-67.

72. *See* Case C-93/02, Biret v. Council, 2003 E.C.R. I-10497, *dismissing appeal from* Case T-174/00, Biret v. Council, 2002 E.C.R. II-17; *see also* Matthew Newman, *EU Top Court Throws out Hormone Beef Case*, DOW JONES INT'L NEWS, Sept. 30, 2003, at 1.

73. JACKSON ET AL., *supra* note 39, at 162; *see, e.g.*, Case 104/81, Hauptzollamt Mainz v. C.A. Kupferberg & CIE, 1982 E.C.R. 3641(finding that the international agreement at issue imposes on the parties "an unconditional rule against discrimination in matters of taxation").

74. *See* Newman, *supra* note 72, at 1 (recommending that "...Biret be allowed to seek damages because the ban continued after the WTO's 1999 deadline to lift the embargo").

75. Case C-236/01, Monsanto v. Italy, 2003 E.C.R. I-8105.

76. *See id.*

77. Regulation 258/97, *supra* note 22, at art. 3(4).

78. *Monsanto*, *supra* note 75, at para. 17.

79. *Id.* at para. 4.

Italy invoked Article 12 of Regulation 258/97.[80] Article 12 is a codified version of the precautionary principle that allows member states to temporarily ban products if there are "detailed grounds for considering that the use of a food or a food ingredient . . . endangers human health or the environment."[81] In response, the Commission referred the matter to the Scientific Committee for Food.[82] The scientific committee felt Italy "did not provide specific scientific grounds for considering that the use of the novel foods at issue endangers human health."[83] The Commission then asked the Regulatory Committee for Foodstuffs to contest the Italian ban, but the meeting of the foodstuffs committee broke down, as several member states felt that clarification of the application of substantial equivalence should occur before any response.[84] The Commission decided "that it was not necessary to invite the committee to deliver a formal opinion,"[85] and it made no reply as it was supposed to under Article 12(2) of Regulation 258/97.[86] Monsanto, Pioneer, Syngenta, and the Italian National Association for the Development of Biotechnology then filed suit to challenge the Italian ban.[87]

B. *The Italian Argument Against the Substantial Equivalence Fast Track*

The Italian health ministry originally objected to the use of the substantial equivalence fast-track procedure,[88] on the basis that it did not feel the products were substantially equivalent,[89] and that the concept of substantial equivalence was ambiguous.[90] In the particular case of the GMO maize variants at issue, Italy argued that because transgenic proteins were still present in foodstuffs made from these maize variants, the fast-track procedure should not have been utilized.[91] The position of the Italian government was that if any transgenic materials were found in a GMO-derived foodstuff, then a full review under the normal procedures of Regulation 258/97 was necessary, and the foodstuff in no way

---

80. *Id.* at para. 31.
81. Regulation 258/97, *supra* note 22, at art. 12(1).
82. *Monsanto*, *supra* note 75, at para. 34.
83. *Id.* at para. 35.
84. *See id.* at para. 37.
85. *Id.* at para. 38.
86. Regulation 258/97, *supra* note 22, at art. 12-13 (requiring, *inter alia*, the committee to deliver an opinion on the committee's recommendation).
87. *Monsanto*, *supra* note 75, at para. 2.
88. *Id.* at para. 22.
89. *Id.* at para. 23.
90. *Id.* at para. 26.
91. *Id.* at para. 55.

could be considered substantially equivalent in order to qualify for the fast track.[92]

C. *How the Holding Interpreted the Old Framework*

The ECJ ruling left both sides claiming victory, while other commentators felt the "ruling underscored a widespread feeling that European rules on the sale of genetically-modified foods are ambiguous."[93] On the issue of foodstuffs containing transgenic materials, the ECJ ruled "the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those foods on the market."[94] The Court also ruled the fast track does not apply if, at the time of the initial assessment, there is scientific knowledge "of a risk of potentially dangerous effects on human health."[95] On the issue of GMO foodstuff bans made pursuant to Article 12, the Court ruled a member state does not have to challenge the granting of consent before imposing a ban.[96] Article 12 measures can be imposed, but only after a complete risk assessment is carried out, and "it is apparent that, in the light of the precautionary principle, the implementation of such measures is necessary in order to ensure that novel foods do not present a danger for the consumer."[97] Italy applauded the ruling because the court upheld the right to impose a ban.[98] Monsanto claimed, however, that the ruling would lead to the removal of the ban upon remand to the Italian court, because the ECJ ruling required detailed grounds for a ban.[99] Moreover, the Italian scientific institute that conducted Italy's assessment in 2000 "found no evidence of health risks."[100]

---

92. *Id.*

93. *Compare* Robin Pomeroy, *Both Sides Claim Victory in European Ruling on GM Crops*, THE INDEP. (London) Sept. 10, 2003, at 10, *with* Brandon Mitchener et al., *A Global Journal Report: European Ruling Backs Banning of Biotech Crops*, WALL ST. J., Sept. 10, 2003, at A22.

94. *Monsanto*, *supra* note 75, at para. 84.

95. *Id.*

96. *See id.* at para. 114 (discussing the precautionary principle of Article 12 and the ability of Member States to adopt protective measures when human health is at risk).

97. *Id.*

98. *See* Mitchener et al., *supra* note 93, at A22.

99. Paul Geitner, *European Union Court Upholds Ban on Biotech Crops*, DES MOINES REG., Sept. 10, 2003, at 1D.

100. *Id.*

IV. THE NEW FRAMEWORK

Since it first began regulating the area, the EU has modified its regulatory framework for GMOs and products derived from them in response to changes in attitude and availability.[101] The result, after much review and discussion, has been a series of new regulations that will create a new regulatory structure for all food and feed products produced from GMOs, starting with GMOs.[102] The new regulatory framework for GMOs consists of three parts.[103] First, Directive 2001/18 concerns itself with the environmental release of GMOs.[104] Second, Regulation 1829/2003 creates a new authorization procedure for food and feed products containing or produced from GMOs (GM food and GM feed),[105] as well as new standards for the labeling of GM food and GM feed.[106] Last, Regulation 1830/2003 covers both labeling and traceability standards for GMOs and traceability for food and feed produced from GMOs.[107]

A. *Authorization*

The new authorization process established by Regulation 1829/2003 is one the EU calls a "one door-one key" system.[108] An application must include a number of things such as: (1) the designation of the product; (2) any transformational events; (3) methods of production or manufacture; (4) copies of any studies conducted, such as an analysis showing the food or feed item is not different from its conventional counterpart and that its use does not implicate ethical or religious concerns; (5) a proposal for labeling it as a GMO; (6) methods of detection; (7) control samples; (8) a proposal for any appropriate post-market monitoring of health effects; (9) copies of a risk assessment or a determination carried out under the previous framework; (10) a list of any other ingredients that might be subject to labeling, and; (11) any proposed requirements for handling or use.[109] The application for authorization will still be "sent to the national competent au-

101. *See* part II-B, *supra*.

102. Jean Ferriere, European Commission Directorate General for Trade, Address to the Public Forum on Meeting EU Community Expectations on Traceability and Labeling of GMOs and GM Food and Feed at Iowa State University (Nov. 14, 2003) (presentation slides and notes on file with author).

103. *Id.*

104. *See* Directive 2001/18, *supra* note 22.

105. Regulation 1829/2003, *supra* note 1, at 14-15.

106. *Id.* at 16-17.

107. Regulation 1830/2003, *supra* note 4, at 26.

108. Press Release, European Commission, European Legislative Framework for GMOs Is now in Place, IP/03/1056 (July 22, 2003), *available at* http://europa.eu.int/eur-lex/en/index.html.

109. *See* Regulation 1829/2003, *supra* note 1, at 7.

thority of a Member State."[110] Under the new framework, however, instead of a Member State's authority reviewing the application, the recently created European Food Safety Authority ("EFSA")[111] will conduct the scientific risk assessment for the EU.[112] This assessment will be forwarded to the Commission, which will create a draft decision that is forwarded to the Member State-run Standing Committee on the Food Chain and Animal Health.[113] If the draft decision is not in accordance with the EFSA opinion, the Commission shall provide an explanation for the difference.[114] Under this procedure, if the Standing Committee fails to deliver an opinion by qualified majority, the Commission will refer the decision to the Council, which will have three months to adopt the measure by qualified majority. If the Council does not adopt a decision within the prescribed period of time, the Commission shall adopt the decision.[115] Therefore, authorization decisions presented by the Commission may only be vetoed if a majority of member states oppose it.[116]

Because the EU is a signatory of the Cartagena Protocol, and the protocol has become effective,[117] successful applications will have to provide all the required information for submission to the Biosafety Clearing House established under the protocol.[118] Also, authorizations made under the new framework are limited to a ten-year period, whether for environmental release, placement on the market, or both.[119] Authorizations can be renewed for additional ten-year periods,[120] and if no decision on an in-progress renewal application is made, then the authorization is automatically extended until such a decision is made.[121]

---

110. *Id.*

111. *See* Council Regulation 178/2002 of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, 2002 O.J. (L 31) 1, 12 [hereinafter Regulation 178/2002].

112. Press Release IP/03/1056, *supra* note 108.

113. Regulation 1829/2003, *supra* note 1, at 9, 19.

114. *Id.* at 9.

115. *See generally* Council Decision 99/468, Laying Down the Procedures for the Exercise of Implementing Powers Conferred on the Commission, 1999 O.J. (L 184) 23 (indicating the procedures the Commission should follow).

116. Email Interview with Jean Ferriere, *supra* note 45; *see generally* Case C-6/99, Ass'n Greenpeace France v. Ministère de l'Agriculture et de la Pêche, 2000 E.C.R. I-1651, para. 1 (holding that if there is no objection the competent authority must allow the product to be placed on the market unless there is new information indicating the product is a risk).

117. Nick Gillies, *A Monthly Round-Up of Changes in the Law*, TIMES (London), Sept. 9, 2003, at 8 (noting that "The Cartagena Protocol on Biosafety comes into force on September 11.").

118. *See* Regulation 1829/2003, *supra* note 1, at 8-9.

119. *Id.* at 9; *see* Ferriere, *supra* note 102.

120. *See* Regulation 1829/2003, *supra* note 1, at 10-11; *see also* Ferriere, *supra* note 102.

121. Regulation 1829/2003, *supra* note 1, at 10-11.

The new single EFSA risk assessment should eliminate one of the complications from the *Monsanto v. Italy* case—that of the conflicting assessments of different national competent authorities. Indeed, Regulation 178/2002 established a procedure to follow, in case of diverging scientific opinions between the EFSA and national or other Community Reference Center scientific bodies.[122] The other change that was part of the *Monsanto* dispute—the substantial equivalence simplified procedure fast track—has been eliminated.[123] It is interesting to note that, while Italy may have incorrectly interpreted Regulation 258/97, Italy has managed to convince the Council and Parliament that its interpretation is how the EU should run its framework.

B. *Tracing*

The new tracing requirements for GMOs included in Regulation 1830/2003 were set up to harmonize with the tracing requirements established under Directive 2001/18.[124] The tracing is based on the one-step-forward one-step-back principle.[125] The EU's traceability systems have been developed to allow swift retrieval of a product in the food supply system in the event of a food safety crisis.[126] Thus, any problem with the food supply, such as animal diseases like BSE and Avian Flu, or a GMO that turns out to be allergenic, can be quickly located, contained, and resolved. Traceability systems are also instrumental in the implementation of the labeling requirements for GM food and GM feed.[127]

If a product gets a favorable risk assessment from the EFSA, the applicant will have to provide a method of detecting the product in samples or in locating transformational events that occur in the product, and this method would be "validated by the Community [R]eference [L]aboratory."[128] The EU specifically created the Community Reference Laboratory to serve as the validating authority for detection methods.[129] In addition to validating detection methods, the Community Reference Laboratory will hold and distribute the control samples.[130] The laboratory "shall be assisted by a consortium of national reference laboratories, which will be referred to as the "European Network of GMO labora-

122. Regulation 178/2002, *supra* note 111, at 17.
123. Press Release IP/03/1056, *supra* note 108.
124. Ferriere, *supra* note 102.
125. *Id.*
126. E-mail Interview with Jean Ferriere, *supra* note 116.
127. *Id.*
128. Regulation 1829/2003, *supra* note 1, at 14.
129. *Id.* at 23.
130. *Id.*

tories" ("ENGL").[131] The ENGL will serve not just as assistant to the Community Reference Laboratory, but will also be a "new scientific body to support food and environmental policy."[132] The participants in the ENGL will be experts from member states drawn from more than forty-five labs, and on an ad hoc basis, industry, international organizations (e.g., World Health Organization), or other governments can participate in the consortium.[133]

It is expected that controls will mainly focus on shipments that are not declared to be GMOs, but are arriving from countries known to produce GMOs.[134] For products that should not have been genetically modified, an allowance of up to 0.9 percent of approved GMOs,[135] or 0.5 percent of an unauthorized GMO which has received a favorable risk assessment by an EU scientific body before Regulation 1829/2003 came into force, will be allowed to be part of a product before it is reclassified or prohibited.[136] These permissible levels only apply, however, if the presence of the GMOs is adventitious or technically unavoidable.[137] Diluting a product for purposes of passing verification is not adventitious, and is definitely not technically unavoidable. This requirement is one that could be potentially onerous for some producers exporting to the EU. Because some crops, such as corn, cross-pollinate easily, a producer who had planted non-GMO corn could have his crop unintentionally contaminated through GMO pollen drift, causing the crop to exceed the positive GMO threshold.[138]

C. *Labeling*

The new labeling requirements apply to feed[139] as well as foods used by final consumers or mass caterers that "contain or consist of GMOs"[140] or "are produced from or contain ingredients produced from GMOs."[141] The labeling requirements do not apply to food produced *with* GMOs.[142] Thus, food products

131. *Id.*
132. Ferriere, *supra* note 102.
133. *Id.*
134. *Id.*
135. Regulation 1829/2003, *supra* note 1, at 11.
136. *Id.* at 22.
137. *Id.* at 11.
138. *See, e.g.*, Philip Brasher & Anne Fitzgerald, *Biotech Taint Found Common in Crop Seed*, DES MOINES REG., Feb. 24, 2004, at A.
139. *Id.*
140. Regulation 1829/2003, *supra* note 1, at 11.
141. *Id.*
142. Ferriere, *supra* note 102 (noting that the distinction is between foods produced *from*, which are covered, and foods produced *with*, which are not covered, and the from/with distinction is recognized by the codex).

made from animals fattened on GM feed are not subject to the regulation, and neither are fermentation products produced with conventional micro-organisms grown on GM substrate.[143] Production aids are also excluded from the scope of Regulation 1829/2003.[144] This means that spirits can be fermented with genetically-engineered yeasts, or that cheeses can be made with engineered processing aids. Interestingly enough, items that are refined to the point that they no longer contain detectable traces of recombinant DNA or novel proteins, such as highly-refined oils, must still be labeled as being from a GMO, even though they might contain no detectable trace of genetic engineering.[145] This is because the oil itself is *from* a GMO, while processing aids that a product is produced *with* are usually not present in the end product.

The labels must indicate which ingredients have been genetically modified, or if many ingredients are GMOs, the words genetically modified must be affixed to the product.[146] If the product is too small for an ingredient list, or does not have a list, the information must be permanently and visibly displayed on, or next to, the food display.[147]

The EU believes that labeling will be more than merely a tool used by consumers to avoid GMOs, but will eventually help demystify GMOs.[148] They believe that consumer choice is not necessarily going to mean GMOs will not be competitive with regular food, but that the labels will be received as an information source that will become familiar to consumers, similar to chemical additive labeling.[149] The EU believes, with time, consumers will come to accept that some ingredients in their food might contain GMOs or be produced from GMOs, just as they now accept that some food ingredients are chemical additives.[150]

D. *The Impact of the New Framework on the WTO Dispute*

In May 2003, the United States filed a complaint with the WTO in an effort to have the WTO overturn, what the United States alleges, is a five-year-old moratorium by the EU on GMO approval.[151] The EU response is that there has

143. *Id.*
144. *See* Regulation 1829/2003, *supra* note 1.
145. Ferriere, *supra* note 102.
146. Regulation 1829/2003, *supra* note 1, at 11.
147. *Id.*
148. Ferriere, *supra* note 102.
149. *Id.*
150. *Id.*
151. *See* Michael Schroeder & Scott Miller, *A Global Journal Report: U.S. to Ask WTO to Halt EU's Ban on Modified Food*, WALL ST. J., May 14, 2003, at A2 (claiming the United States wants the WTO to overturn an EU ban on genetically-modified agricultural products).

not been any moratorium on new authorization of GMOs, only a slow-down, as the EU adopted new risk assessment procedures.[152] Now that the new risk assessment procedures of the new framework have been adopted,[153] the EU says applicants will be authorized if they meet the criteria.[154] The United States, however, does not believe that the new regulatory framework has ended the moratorium.[155] Meanwhile, the dispute resolution process in the WTO can run greater than one and one-half years.[156] This affords the EU plenty of time to try and get products authorized in order to show that no moratorium exists. Indeed, the Commission has been accused of approving products simply to improve U.S. relations.[157] However, recent moves tend to indicate a greater likelihood that genetically modified foods will get approved for placement on the market than will get approved for both the market and environmental release for cultivation.[158] This result would certainly aid GMO-growing farmers in non-EU nations, but it would not help the seed companies find customers inside the EU. In terms of the trade dispute, every approval that the EU makes undercuts the U.S. argument before the WTO. A dispute panel would likely find against the EU for the moratoriums imposed by some Member States.[159] If the Commission, however, can

---

152. *See* Press Release, European Commission, European Commission Regrets the Request for a WTO Panel on GMOs, IP/03/1165 (Aug. 18, 2003) (discussing reasons why there has been a decrease in the acceptance of GMOs), *available at* http://europa.eu.int/eur-lex/en/index.html.

153. *See* Part IV-A, *supra.*

154. Ferriere, *supra* note 102.

155. Press Release, USDA, United States Requests Dispute Panel in WTO Challenge to EU Biotech Moratorium (Aug. 7, 2003) (noting that new regulations do not affect WTO challenge) (on file with Drake J. Agric. L.).

156. Philip Brasher, *Biotech Ban Draws U.S. Action*, DES MOINES REG., May 14, 2003, at 1D.

157. *See, e.g.*, Andrew Osborn, *Brussels Clears GM Maize 'To Please U.S.'*, THE GUARDIAN (London), Jan. 29, 2004, at 11 (discussing that some European groups believe that the EU is allowing GM foods despite concerns from European citizens).

158. *See, e.g.*, John Vidal, *EU on Line to Prohibit GM Oilseed Rape Crops: Greens Hail an Environmental Victory for Biodiversity as Belgium Rejects Bayer Application and Urges All Member States to Follow Suit*, THE GUARDIAN (London), Feb. 3, 2004 (noting that the EU rejected a GM oilseed rape for environmental release, but approved it for placement on the market); Osborn, *supra* note 157, at 11; *see* part IV-B, C *supra* (discussing the main difficulties relate to co-existence of conventional and GMO crops as well as cross-pollination potential of some crops).

159. *See generally* Charles W. Smitherman III, *World Trade Organization Adjudication of the European Union—United States Dispute over the Moratorium on the Introduction of New Genetically Modified Foods to the European Common Market: A Hypothetical Opinion of the Dispute Panel*, 30 GA. J. INT'L & COMP. L. 475 (2002) (offering a reasoned hypothetical for a precautionary moratorium challenged under the WTO SPS and TBT; albeit, the article was written before formation of the dispute panel).

get new products approved and get the existing national moratoriums removed, the U.S. claim would likely become moot.

VI. CONCLUSION

The actions taken by the EU represent a very delicate balance between many factors. The first regulatory attempts of the EU, while hasty and now reconsidered, were too cautionary. The new framework is much better than the old framework. The EU has excellent tracing provisions available for all food, thereby increasing food safety record keeping, but its new framework should allow genetically-engineered products into the market and still allow consumers to make the ultimate decision. If the Commission is able to bring all of its members in alignment, it will probably be successful at the WTO.

The importance of the EU as a trading power cannot be understated. The decisions it takes regarding GMOs have repercussions around the world.[160] Many other nations should consider adopting single assessment systems and strong tracing regimes for all foods, not just GMOs. The differentials in Canadian[161] and American[162] abilities to track cattle following the recent BSE outbreaks in North America are argument enough to support a tracing program. It is this author's hope that the USDA will incorporate tracing requirements into not just its biotechnology regulations,[163] but to all food regulations.

VII. EPILOGUE

Since the original authoring of this Note in March of 2004, much has transpired. The EU has completed its enlargement, and consequently, ten more nations are now governed by the EU GM Food and Feed framework.[164] Syngenta

---

160. *See, e.g., An Amber Light for Agri-business—Biotech and Farming in Brazil*, THE ECONOMIST, Oct. 4, 2003, *available at* 2003 WL 58584329 (noting supermarkets in Britain are offering non-biotech soya in response to consumers' demand).

161. *Tracking Canada's Cattle*, CBC NEWS ONLINE, Dec. 29, 2003, *at* http://www.cbc.ca/news/background/madcow/trackingcattle.html (last visited Mar. 17, 2005).

162. *See generally* Philip Brasher, *Livestock ID System Planned for Fall*, DES MOINES REG., March 5, 2004, at 1D (noting that lacking "an ID system made it difficult for investigators to track down cattle that originated from the same herd as the [Mad Cow] infected Holstein").

163. News Release, USDA, USDA Announces First Steps to Update Biotechnology Regulations (Jan. 22, 2004), *available at* http://www.usda.gov/Newsroom/0033.04.html.

164. *See* Press Release, European Commission, GMO Screening: EU Control Network Expands to New Member States, IP/04/560 (Apr. 29, 2004), *available at* http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/04/560&format=HTML&aged=1&language=EN&guiLanguage=en (highlighting the addition of national laboratories within these ten

managed to get one of its GM maize varieties, Bt 11, approved for EU marketing because of the lack of a disapproving qualified majority in either the Standing Committee or the Council.[165] However, many products still await a determination on their applications, and many opponents of GM products have voiced their disapproval of a process in which the Commission is able to approve a product without the Council or Standing Committee.[166]

Also, within the EU, the Commission has brought suit against several Member States who failed to incorporate some of the EU's regulations concerning GMOs into their own laws.[167] This action was needed by the Commission not just to create regulatory uniformity, but also because the specific resistance of some Member States to GMOs, approved by the EU, is part of the U.S. complaint.[168]

The WTO Dispute remains unresolved. The dispute panel has announced a delay so that the parties can prepare their rebuttals, and so that the panel can hear an EU request that scientific experts be appointed to assist in the panel's deliberations.[169] This is a move that is being resisted by the United States and its co-complainants,[170] and if approved, would suggest that the panel might be leaning toward the EU position, rather than the United States' position that both the current framework for authorization and the labeling requirements are technical barriers to trade.

---

nations to the European Network of Genetically Modified Organisms' (GMO) Laboratories (ENGL)), *available at* http://europa.eu.int/eur-lex/en/index.html.

165. *See* Joe Kirwin, *Old, New EU States Block Authorization to Cultivate Gene-Engineered Corn NK603*, 21 INT'L TRADE REP. 1234, 1234 (2004) (citations omitted).

166. *See id.*

167. *See, e.g.*, Case C429/01, Commission v. France, 2003 E.C.R. I-0000.

168. *See* Daniel Pruzin, *Workload Puts GMO Authorization Ruling on Indefinite Hold, WTO Panel Chief Says*, 21 INT'L TRADE REP. 1233, 1233 (2004) (noting that Austria, France, Greece, and Italy are named specifically by the complainants in the WTO dispute).

169. *See id.*

170. *See id.*