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An Agricultural Law Research Article

**Traceability and Labeling of Genetically Modified  
Crops, Food, and Feed in the European Union**

by

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# TRACEABILITY AND LABELING OF GENETICALLY MODIFIED CROPS, FOOD, AND FEED IN THE EUROPEAN UNION

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## I. INTRODUCTION

In the last several years, European Union (E.U.) policy has encouraged development of biotechnology, including genetically modified (GM) (that is, bioengineered)<sup>1</sup> agricultural crops. The E.U. developed a strategy for life sciences and biotechnology, directed toward improving the competitiveness of the European biotechnology sector and the general situation for European biotechnology.<sup>2</sup> E.U. documents have acknowledged the potential significance of genetically modified crops—for example, the conclusion in a recent report that “the potential of plant genomics and biotechnology to deliver major advances in our lifestyles and prosperity is enormous. [Biotechnology] can also maintain and enhance the competitiveness of E.U.

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1. Regulatory measures refer to GM crops, though the U.S. Food and Drug Administration (FDA) prefers the more accurate term “bioengineered.” Mark Mansour & Sarah Key, *From Farm to Fork: The Impact on Global Commerce of the New European Union Biotechnology Regulatory Scheme*, 38 INT’L LAW. 55, 65 (2004).

2. See generally *Life Sciences and Biotechnology—A Strategy for Europe: Second Progress Report and Future Orientations*, COM(2004)250 final.

farmers and food producers.”<sup>3</sup> Nonetheless, producers and consumers in the E.U. have been reluctant to grow GM crops or to consume GM foods,<sup>4</sup> and scientists disagree about the risks and net benefits of GM crops and food products. European Community (E.C.) legislators enacted new regulatory measures only after long deliberation, and some Member States continue to object to the use of GM crops and foods in their territories.

Under the new regulatory measures, the E.C. has started to approve GM products. In July 2004, the European Commission approved the import and processing of Monsanto’s GM maize, NK603, for use in animal feed and for industrial purposes, but not for cultivation or for food.<sup>5</sup> The maize was approved for ten years under stringent new regulations. A scientific risk assessment ensured that it poses no danger to the environment, and an assessment by the European Food Safety Authority concluded that it is as safe as non-GM corn.<sup>6</sup> When sold, the corn must be labeled clearly as genetically modified, and its unique identifier will ensure that it can be traced through the process of post-market monitoring.<sup>7</sup> In October 2004, the Commission authorized the placing on the market of food and food ingredients derived from the same NK603 maize.<sup>8</sup> Monsanto had submitted its initial request to place NK603 on the market in April 2001, and the regulatory process for authorization of food and feed uses had lasted three and one-half years.<sup>9</sup>

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3. EUROPEAN COMMISSION, *PLANTS FOR THE FUTURE—2025: A EUROPEAN VISION FOR PLANT GENOMICS AND BIOTECHNOLOGY* 19 (2004).

4. In 2002, only about 25,000 hectares of GM crops were sown, mostly in Spain. DIRECTORATE-GENERAL FOR AGRICULTURE, *AGRICULTURE IN THE EUROPEAN UNION, STATISTICAL AND ECONOMIC INFORMATION* 2003 at 4.23 (Feb. 2004).

5. Commission Decision 2004/643, 2004 O.J. (L 295) 35. Art. 5 indicates that the Decision does not apply until NK603 has also been approved for food.

6. European Food Safety Authority, *Opinion of the Scientific Panel on Genetically Modified Organisms*, 2003 E.F.S.A. J. 10, 1-13, *available at* [http://www.efsa.eu.int/science/gmo/gmo\\_opinions/176/opinion\\_gmo\\_03\\_final\\_en1.pdf](http://www.efsa.eu.int/science/gmo/gmo_opinions/176/opinion_gmo_03_final_en1.pdf).

7. *See* Proposal for a Council Decision concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L. line NK 603) genetically modified for glyphosate tolerance, COM(2004)193 final.

8. Press Release, European Commission, Genetically modified NK603 maize authorised for both food and feed (IP/04/1305, Oct. 26, 2004). The authorizations do not allow cultivation in the E.U.

9. Proposal for a Council Decision authorizing the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97, COM (2004)439 final, at 2.

Similarly, in May 2004, the Commission authorized the placing on the market of a GM sweet corn, Syngenta's Bt11.<sup>10</sup> This corn was authorized for import in 1998, and the recent authorization applies to canned corn. The corn will be labeled as genetically modified, can be traced by its unique identifier, and will be entered in the Community Register of Genetically Modified Food and Feed.<sup>11</sup> With these approvals, eighteen GM foods and nine GM feeds have been approved for sale in the European Union since 1996.

Approvals of GM crops for cultivation in the E.U. have progressed more slowly. For the first time, in September 2004, the Commission listed genetically modified seeds in the E.U. Common Catalogue of Varieties of Agricultural Plant Species.<sup>12</sup> The seventeen varieties were derived from Monsanto's MON 810 maize, authorized in 1998. Listing in the Common Catalogue allows the maize to be sold and planted in all Member States.<sup>13</sup>

The approval of NK603 corn signaled the end of a *de facto* moratorium on approvals of GM crops for import since 1998. To some extent, the *de facto* moratorium was the result of a perception that regulatory measures were inadequate to govern GM crops, food, and feed. In 2001, after a lengthy regulatory process, the E.C. began to enact new measures to ensure that GMOs are regulated during the experimental stage, when they are placed on the market, and afterwards; that those products can be identified and traced through their life cycle; and that labeling will provide adequate information and consumer choice.

The most important measures directed specifically toward GMOs are

- Directive 90/219 on the contained use of genetically modified microorganisms, as amended.<sup>14</sup>

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10. Commission Decision 2004/657, 2004 O.J. (L 300) 48.

11. See Proposal for a Council Decision authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredients under Regulation (EC) no 258/97, COM(2004)10 final; Press Release, European Commission, Commission authorises import of canned GM-sweet corn under new strict labelling conditions—consumers can choose (IP/04/663, May 19, 2004).

12. The Common Catalog is governed by Council Directive 2002/53, 2002 O.J. (L 193) 1, as amended.

13. Press Release, European Commission, Inscription of MON 810 GM maize varieties in the Common EU Catalogue of Varieties (IP/04/1083, Sept. 8, 2004).

14. Council Directive 90/219, 1990 O.J. (L 117) 1, as amended; consolidated text at CONSLEG 1990L0219–20/11/2003.

- Directive 2001/18 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220, as amended.<sup>15</sup>
- Regulation 1829/2003 on genetically modified food and feed.<sup>16</sup>
- Regulation 1830/2003 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 2001/18.<sup>17</sup>

The last two measures replace several Regulations (1139/98,<sup>18</sup> 49/2000,<sup>19</sup> and 50/2000<sup>20</sup>), as well as the Novel Foods Regulation,<sup>21</sup> which had governed pre-market authorization and labeling for GM foods, insofar as it applied to GMOs.

The Commission has proposed a Decision to establish minimum thresholds for adventitious or technically unavoidable traces of GM seeds in other products,<sup>22</sup> but at a September 2004 meeting, the measure was not agreed. The Food Law, Regulation 178/2002,<sup>23</sup> sets out general principles and establishes the European Food Safety Authority. In addition, the Environmental Liability Directive applies to allocate responsibility for some types of damage for contained use, deliberate release, transport, or placing on the market of GMOs.<sup>24</sup> Other measures, mentioned below, also apply.

#### *A. Lawmaking in the E.C.*

The European Union, now twenty-five Member States, is governed by primary legislation—its founding Treaties, as amended—and by secondary legislation.

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15. Parliament and Council Directive, 2001 O.J. (L 106) 1, as amended; consolidated text at CONSLEG 2001L0018–07/11/2003.

16. Parliament and Council Regulation 1829/2003, 2003 O.J. (L 268) 1.

17. Parliament and Council Regulation 2001/18, 2003 O.J. (L 268) 24.

18. Council Regulation 1139/98, 1998 O.J. (L 159) 4 (labeling of food produced from GMOs).

19. Commission Regulation 49/2000, 2000 O.J. (L 6) 13 (amending Regulation 1139/98).

20. Commission Regulation 50/2000, 2000 O.J. (L 6) 15 (labeling for GM additives and flavorings).

21. Parliament and Council Regulation 258/97, 1997 O.J. (L 43) 1. Parts of the Regulation remain in effect.

22. Draft Commission Decision establishing minimum thresholds for adventitious or technically unavoidable traces of genetically modified seeds in other products, [http://www.genfood.at/download/com\\_draft\\_seeds\\_04\\_2004.pdf](http://www.genfood.at/download/com_draft_seeds_04_2004.pdf).

23. Parliament and Council Regulation 178/2002, 2002 O.J. (L 31) 1.

24. Parliament and Council Directive 2004/35, 2004 O.J. (L 143) 56.











of GMOs in the E.C., and much commentary has focused on its application to the management of risk from GMOs.<sup>54</sup>

Early E.C. legislation that governed GMOs used a precautionary approach, but without referring directly to the precautionary principle. For example, Directive 90/220 did not cite the principle, though it did invoke the related principle that preventive action should be taken.<sup>55</sup> Nonetheless, the precautionary approach played a role in implementation of this and other measures, and it was one basis for the *de facto* moratorium on authorizations of GM varieties that began in October 1998.<sup>56</sup>

Directive 2001/18 again mentions the prevention principle and directly invokes the precautionary principle: “The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.”<sup>57</sup> In addition, “Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs.”<sup>58</sup> Various provisions of Directive 2001/18, especially for risk assessment and post-approval monitoring, implement the principle.

The 2002 Food Law, which lays down general principles and requirements for food safety, devotes an article to the precautionary principle:

In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.<sup>59</sup>

Measures enacted should be “proportionate and no more restrictive of trade than is required . . . [with] regard being had to technical and economic feasibility and other factors.”<sup>60</sup>

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54. *E.g.*, Zeynep Kivilcim Forsman, *Community Regulation of Genetically Modified Organisms: A Difficult Relationship Between Law and Science*, 10 EUR. L.J. 580 (2004).

55. Council Directive 90/220, pmbl., 1990 O.J. (L 117) 15, 15.

56. See Silvia Francescon, *The New Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment: Changes and Perspectives*, 10 REV. EUR. CMTY. & INT’L ENVTL. L. 309, 311 (2001).

57. Parliament and Council Directive 2001/18, pmbl. (8), 2001 O.J. (L 106) at 1.

58. Directive 2001/18, art. 4(1), 2001 O.J. (L 106) at 5.

59. Parliament and Council Regulation 178/2002, art. 7(1), 2002 O.J. (L 31) 1, 9.

60. Regulation 178/2002, art. 7(2), 2002 O.J. (L 31) at 9.





threaten human health and the environment.<sup>72</sup> It imposed more stringent measures for environmental risk assessment, added a post-market monitoring requirement, limited the authorization for release of GMOs to ten years, and required Member States to ensure traceability and labeling of GMOs at all stages of placing on the market.

A number of other regulatory measures supplement Directive 2001/18 with detailed guidance notes (e.g., Council Decision 2002/811,<sup>73</sup> Commission Decision 2002/623<sup>74</sup>), format instructions for submitting information (e.g., Council Decisions 2002/812, 2002/813;<sup>75</sup> Commission Decision 2003/701<sup>76</sup>), and arrangements for GMO registers (e.g., Commission Decision 2004/204<sup>77</sup>). Member States were to have implemented Directive 2001/18 in their national laws by 17 October 2002. Not all States have done so. As of August 2004, seven of the fifteen Member States and eight of the ten new States had communicated implementation measures. The Commission filed legal actions against eight of the fifteen Member States for failure to enact national measures.<sup>78</sup>

Under the Directive, a genetically modified organism is “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.”<sup>79</sup> General provisions in the Directive—e.g., environmental risk assessment, confidentiality, consultation requirements—apply to all GMOs.

Anyone who plans to seek authorization for release of a GMO must carry out an environmental risk assessment.<sup>80</sup> The Directive identifies the types of information that might be needed to carry out

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72. Directive 2001/18, pmb. (5), (48), 2001 O.J. (L 106) at 3. *See also* Estelle Brosset, *The Prior Authorisation Procedure Adopted for the Deliberate Release into the Environment of Genetically Modified Organisms: the Complexities of Balancing Community and National Competences*, 10 EUR. L.J. 555 (2004).

73. Council Decision 2002/811, 2002 O.J. (L 280) 27.

74. Commission Decision 2002/623, 2002 O.J. (L 200) 22.

75. Council Decision 2002/812, 2002 O.J. (L 280) 37; Council Decision 2002/813, 2002 O.J. (L 280) 62.

76. Commission Decision 2003/701, 2003 O.J. (L 254) 21.

77. Commission Decision 2004/204, 2004 O.J. (L 65) 20.

78. Report from the Commission to the Council and the European Parliament on the experience of member states with GMOs placed on the market under Directive 2001/18/EC and incorporating a specific report on the operation of parts B and C of the Directive, COM(2004)575 final at 4. This document is a report on Member State experience under Directive 2001/18.

79. Directive 2001/18, art. 2(2), 2001 O.J. (L 106) at 4.

80. Directive 2000/18, art. 6, 2001 O.J. (L 106) at 6.







Commission must make the dossier summary and assessment report available to the public for comment.<sup>105</sup>

The Commission and other Member States have the opportunity to ask for information, make comments, or “present reasoned objections” to the placing of a GMO on the market.<sup>106</sup> If no objections are made, or if outstanding issues are resolved, the competent authority that assessed the GMO may give written consent to the notifier and also inform the Commission and the other Member States.<sup>107</sup> Indeed, in a case brought under Directive 90/220, the European Court of Justice held that when no objections are raised, the competent authority is obliged to give consent.<sup>108</sup>

Written consent will be explicit and will include specific conditions for use, handling and packaging of the GMO or for protection of the environment, labeling requirements (“This product contains genetically modified organisms.”), and obligations for monitoring.<sup>109</sup> After consent, notifiers must follow the prescribed monitoring plan and report regularly to the Commission and competent authorities; results of monitoring are also available to the public.<sup>110</sup> Written consent shall be given for a maximum of ten years, and the Directive prescribes a procedure for renewal.<sup>111</sup>

The standard procedure described above applies unless the Commission or a Member State raises and maintains an objection to consent. In most cases under prior law (that is Directive 90/220), objections have been raised.<sup>112</sup> Under Directive 2001/18, when objections are raised, the Commission must consult the competent Scientific Committee, the Scientific Panel on GMOs of the European Food Safety Authority.<sup>113</sup> If the scientific decision is favorable, the Commission will follow the Community inter-agency regulatory procedure to reach a decision.<sup>114</sup> The Commission submits a draft of the measure to be taken (i.e., a legislative decision to give consent to a proposed GMO) to a regulatory committee, made up of Member State repre-

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105. Directive 2001/18, art. 24(1), 2001 O.J. (L 106) at 14.

106. Directive 2001/18, art. 15(1), 2001 O.J. (L 106) at 10.

107. See Directive 2001/18, art. 15(3), 2001 O.J. (L 106) at 10.

108. Case C-6/99, Association Greenpeace France v. Ministère de l’Agriculture et de la Pêche, [2000] E.C.R. I-1651. See Francescon, *supra* note 56, at 312.

109. Directive 2001/18, art. 19(3), 2001 O.J. (L 106) at 12.

110. Directive 2001/18, art. 20, 2001 O.J. (L 106) at 12-13.

111. Directive 2001/18, arts. 15(4), 17, 2001 O.J. (L 106) at 10-11.

112. See Brosset, *supra* note 72, at 568-71 (outlining Member State failures to cooperate).

113. Directive 2001/18, art. 28, 2001 O.J. (L 106) at 14-15.

114. Directive 2001/18, arts. 18, 30(2), 2001 O.J. (L 106) at 12, 15. That procedure is set out in Council Decision 1999/468, art. 5, 1999 O.J. (L 184) 23, 25.

representatives. If that committee agrees, the Commission will grant consent. If not, the Commission submits the measure to the Council (and informs Parliament). If the Council does not agree or oppose the consent by a qualified majority, the Commission may grant consent. Under this procedure, for example, the Commission granted consent for placing Maize NK603 on the market.<sup>115</sup>

Even after consent is granted, a safeguard clause protects Member States.<sup>116</sup> A Member State may provisionally restrict or prohibit use or sale of a GMO as or in a product on its territory under limited conditions. The Member State must have detailed grounds for considering that the GMO poses a risk to human health or the environment, on the basis of either information made available since the date of consent or a reassessment of existing information using new scientific information.<sup>117</sup> The Member State must inform the Commission and other Member States, including its review of environmental risk and other information. The Commission, with assistance of the Scientific Committee, must decide whether the Member State's action is justified. A number of Member States have invoked the safeguard clause in attempted bans of GMOs.<sup>118</sup> In July 2004, for example, the European Food Safety Authority (EFSA) published opinions of the Scientific Panel on Genetically Modified Organisms that found no new scientific evidence that would justify prohibition of certain GM crops in Greece or Austria.<sup>119</sup>

The Treaty offers an additional general safeguard. Article 95(5) permits Member States to introduce national provisions after adoption of a Council or Commission harmonization measure, "based on

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115. Commission Decision 2004/643, 2004 O.J. (L 295) 35.

116. Directive 2001/18, art. 23, 2001 O.J. (L 106) at 13.

117. Directive 2001/18, art. 23, 2001 O.J. (L 106) at 13.

118. Six Member States invoked the safeguard clause, art. 16, of Directive 90/220, in nine applications. In each instance, no justification for the state ban was found. European Commission, *Questions and Answers on the Regulation of GMOs in the European Union*, at 8 & Annex 5 (Nov. 2004), [http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda\\_en.pdf](http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf). For a list of Member State invocations of the safeguard clause, see *Invocation of Article 16 under Directive 90/220/EC and Article 23 under Directive 2001/18/EC (Safeguard clause) as of 15 March 2005*, [http://europa.eu.int/comm/environment/biotechnology/safeguard\\_clauses.htm](http://europa.eu.int/comm/environment/biotechnology/safeguard_clauses.htm).

119. European Food Safety Authority, Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC, 2004 E.F.S.A. J. 78, 1-13, [http://www.efsa.eu.int/science/gmo/gmo\\_opinions/507\\_en.html](http://www.efsa.eu.int/science/gmo/gmo_opinions/507_en.html); European Food Safety Authority, Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Greek invoke of Article 23 of Directive 2001/18/EC, 2004 E.F.S.A. J. 79, 1-8, [http://www.efsa.eu.int/science/gmo/gmo\\_opinions/506\\_en.html](http://www.efsa.eu.int/science/gmo/gmo_opinions/506_en.html).

















feed produced from GMOs.<sup>179</sup> For products consisting of or containing GMOs, operators must use the words “This product contains genetically modified organisms” or “This product contains genetically modified [name of the organism(s)].” For pre-packaged products, the words must appear on the label; for non-pre-packaged products, on or in connection with the product display. Labeling applies at all stages of placing on the market. Specific requirements in other E.C. legislation continue to apply.<sup>180</sup>

Regulation 1829/2003 has similar labeling requirements for GM foods and feeds.<sup>181</sup> The food labeling provisions apply to foods to be delivered to the final consumer or mass caterers in the Community that either contain or consist of GMOs or are produced from or contain ingredients produced from GMOs. Regulation 1829/2003 is more detailed than Regulation 1830/2003 about the content of the label. For example, if food consists of more than one ingredient, the words “genetically modified” shall appear in parentheses following the ingredient concerned. Moreover, if the ingredient is designated by category, the words “contains genetically modified [name of organism]” shall appear in the list of ingredients. Further, if there is no list of ingredients, “genetically modified” shall appear clearly on the label. Labels must mention characteristics or properties of the food if the food is different from its conventional counterpart in composition, nutritional value or effects, intended use, or health implications, or if the food may raise ethical or religious concerns.<sup>182</sup> Detailed rules for implementation may be adopted.

Labeling rules for feed are similar, though not identical. GMOs for feed use and feed containing or consisting of GMOs must indicate “genetically modified [name of organism]” in parenthesis following the name of the feed. Feed produced from GMOs will instead indicate “produced from genetically modified [name of organism].”<sup>183</sup> The Regulation does not require labeling of products produced with GMOs or products from animals fed with GM feed.<sup>184</sup>

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179. Regulation 1830/2003, arts. 4B, 5, 2003 O.J. (L 268) at 24, 26-27.

180. Regulation 1830/2003, art. 4A(5), 2003 O.J. (L 268) at 26. For an example of requirements that continue to apply *see* Directive 2000/13, as amended by Commission Directive 2001/101, 2001 O.J. (L 310) 19.

181. Council Regulation 1829/2003, arts. 12-14, 24-26, 2003 O.J. (L 268) at 11-12, 16-17.

182. Regulation 1829/2003, art. 13(2), 2003 O.J. (L 268) at 11-12.

183. Regulation 1829/2003, art. 25(2)(b), 2003 O.J. (L 268) at 17.

184. For criticism of this regulatory omission, *see* MacMaoláin, *supra* note 165.



























ment, with its risk assessment, may provide the standard for determining whether measures are necessary.<sup>272</sup>

The E.C. Regulation that governs traceability and labeling may give rise to further claims under the WTO, especially because label requirements apply to imports.<sup>273</sup> The Agreement on Technical Barriers to Trade (TBT Agreement) is intended to ensure that technical regulations made to fulfill a legitimate objective do not create unnecessary obstacles to international trade. Because labeling is a technical regulation, E.C. measures must be compatible with the TBT Agreement. Thus, the measures must fulfill a legitimate objective, which include, e.g., “protection of human health or safety, animal or plant life or health, or the environment.”<sup>274</sup> If challenged under the TBT Agreement, E.C. justifications for labeling (environmental protection, consumer choice) must be found to be a legitimate objective. The TBT Agreement also requires non-discriminatory treatment for like products; discrimination triggers application of GATT Article XX.<sup>275</sup>

The Cartagena Protocol affects trade through its advance informed consent procedure and required labels for imports of LMOs. Its provisions may raise questions under the WTO, especially where Protocol restrictions seem to conflict with WTO goals of free trade. Differences in approach exist; the Protocol, for example, encourages adoption of the precautionary approach in the face of scientific uncertainty,<sup>276</sup> while the SPS Agreement allows only a provisional measure, followed by an objective risk assessment within a reasonable time.<sup>277</sup> Further, some have questioned whether the label requirement (“may contain LMOs”) under the Cartagena Protocol complies with the SPS or TBT, and whether the E.C. might use its obligations under the Protocol to support its own measures in a WTO dispute.<sup>278</sup>

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272. See Norman W. Thorson, *International Trade in Genetically Altered Agricultural Products: Impact of the Biosafety Protocol*, in AGRICULTURE AND INTERNATIONAL TRADE, *supra* note 268, at 239, 257-61.

273. Appleton, *supra* note 262, at 570.

274. The WTO Agreement on Technical Barriers to Trade (GATT Standards Code), art. 2.2, available at [http://www.wto.org/english/tratop\\_e/tbt\\_e/tbtagr.htm](http://www.wto.org/english/tratop_e/tbt_e/tbtagr.htm). For a detailed description see Ostrovsky, *supra* note 266, at 225-31.

275. See Hilson & French, *supra* note 268, at 231-33.

276. Convention on Biological Diversity, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, arts. 10(6), 11(8), 39 I.L.M. 1027, available at <http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>.

277. SPS Agreement, art. 5.7.

278. Hilson & French, *supra* note 268, at 235.



tize GM products and discourage consumption of foods with no known health risks.<sup>281</sup>

Different attitudes in United States and the E.U. toward GMOs on the part of citizens, the agricultural community, and regulatory agencies help to account for differences in regulatory requirements for GM crops and their products. The European approach, based on process and heavily influenced by the precautionary principle, has limited the market for GM varieties, which are a significant percentage of United States agricultural production. It is to be hoped that incompatibilities in the U.S. and E.C. regulatory systems can be resolved without further damage to trade and to U.S.-E.U. relations.

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281. See Mansour & Key, *supra* note 1, at 64-68; Appleton, *supra* note 262.

