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# Monsanto and the Requirement for Real Risks in GM Food Regulation

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# *Monsanto* and the Requirement for Real Risks in GM Food Regulation

## I. INTRODUCTION

Before beginning any discussion on the legal issues involving genetically modified (“GM”) foods, a brief explanation of the science behind GM foods is in order. You may know from your high school biology class that traits of living organisms are inherited. For example, you may have inherited the color of your eyes from your mother or your height from your father. “Genes” are the key elements in this process of inheritance.<sup>1</sup> When genes are modified, often the physical manifestations of these genes also change.<sup>2</sup> Consequently, the aim of genetic modification is to improve the productivity, quality, or performance of an organism.<sup>3</sup>

Genetic modification occurs from two sources – traditional breeding techniques and genetic engineering.<sup>4</sup> Traditional breeding is based on crossing plants or animals to create a hybrid organism.<sup>5</sup> Genetic engineering, on the other hand, refers to the use of scientific techniques (collectively known as “recombinant technology”<sup>6</sup>) that artificially move functional genes between organisms or between species.<sup>7</sup> These inserted genes are called “transgenes” and the products of these genes (such as proteins) are called “transgenic” products.<sup>8</sup> Consumer concern has mainly

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1. THOMAS BERNAUER, GENES, TRADE, AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY 24 (2003).

2. *See id.* at 23.

3. *Id.*

4. Michael W. Toffel & James E. Heyman, *An Atlantic Divide? European and American Attitudes on Genetically Engineered Foods* 3 (Haas Sch. of Bus., Univ. of California, Working Paper, 2002), [http://faculty.haas.berkeley.edu/toffel/papers/Atlantic\\_Divide\\_Manuscript.pdf](http://faculty.haas.berkeley.edu/toffel/papers/Atlantic_Divide_Manuscript.pdf) (last visited Feb. 22, 2005).

5. *Id.* For example, a mule comes from breeding a donkey and a horse. A mule is a hybrid.

6. AMGEN, RECOMBINANT DNA TECHNOLOGY, <http://www.amgen.com/rnd/RecombinantDNA.html> (last visited Feb. 19, 2005).

7. Toffel & Heyman, *supra* note 4, at 3.

8. DEPT. OF SOIL & CROP SCIENCES AT COLORADO STATE UNIVERSITY,

focused on transgenic foods. This note will refer to these foods simply as "GM foods."

Genetic engineering has two distinct advantages over traditional breeding, namely, the ability to control which genes will be transferred, and the length of time it takes for the desired trait to manifest.<sup>9</sup> Unlike traditional breeding, genetic engineering allows for a more controlled transfer of one or a few specific genes with known functions from one organism to another or even across different species, such as from bacteria to corn.<sup>10</sup> Genetic engineering also allows for faster development of new food products and increases the range of traits available for developing new crop varieties.<sup>11</sup> Therefore, genetic engineering allows growers to produce more nutritional foods in larger quantities and in a shorter period of time.<sup>12</sup>

Accordingly, GM foods from this method have tremendous potential to alleviate hunger throughout the world. As the world population continues to increase while the available space for farming continues to shrink, an increase in food production is absolutely essential.<sup>13</sup> GM foods will allow countries to meet this rising demand. Despite this benefit, however, many people have remained wary of consuming GM foods because of safety concerns. A main health concern is that the transfer of genes from one organism to another may result in the transfer of allergens,<sup>14</sup>

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TRANSGENIC CROPS: AN INTRODUCTION AND RESOURCE GUIDE, <http://www.colostate.edu/programs/lifesciences/TransgenicCrops/what.html> (last visited Feb. 19, 2005).

9. BERNAUER, *supra* note 1, at 23; James Stamps, *Trade in Biotechnology Food Products*, 43 INT'L ECON. REV. 5 (2002), available at [http://hotdocs.usitc.gov/docs/pubs/international\\_economic\\_review/PUB3571.PDF](http://hotdocs.usitc.gov/docs/pubs/international_economic_review/PUB3571.PDF).

10. BERNAUER, *supra* note 1, at 23.

11. Stamps, *supra* note 9, at 5. Traditional breeding, on the other hand, can be time-consuming because it may require breeding several generations to obtain a desired trait and breed out unwanted characteristics. *Id.*

12. See Norman E. Borlaug, *Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry*, 124 PLANT PHYSIOLOGY 487, 489 (1990). This article also illustrates the many advances that genetic engineering has accomplished in the field of agriculture, including increase in arable lands, amelioration of soil degradation problems, reduction in overall herbicide and fertilizer use, and lower production costs.

13. U.N. Food and Agric. Org. [FAO], Comm. On Agric., 15th Sess., *Biotechnology: Item 7 of the Provisional Agenda* (1999), [http://www.fao.org/unfao/bodies/COAG/COAG15/x0074e.htm#P143\\_11723](http://www.fao.org/unfao/bodies/COAG/COAG15/x0074e.htm#P143_11723).

14. Marion Nestle, *Allergies to Transgenic Foods – Questions of Policy*, 334 NEW ENG. J. MED. 726 (1996).

rendering allergenic previously non-allergenic foods. The concern is that people susceptible to certain allergens will eat foods that they previously thought were safe for them to eat.

Consumer resistance to GM foods is fierce in Europe, and this is reflected in the laws regulating them.<sup>15</sup> These regulations, for the most part, have eliminated trade in GM foods within the European Union (EU). From 1998 to 2003, no GM products were approved for sale within the EU.<sup>16</sup> Indeed, the EU did not lift the 5-year moratorium on GM foods until after the United States, Canada, and Argentina commenced an action against it in the World Trade Organization.<sup>17</sup> The perceived safety risks associated with GM foods have undermined their trade even as these concerns remain unfounded.<sup>18</sup>

The European Court of Justice's (ECJ) decision in the case of *Monsanto v. Presidenza del Consiglio dei Ministri*<sup>19</sup> is significant because it illustrates a more constructive approach to GMO ("genetically modified organism"<sup>20</sup>) trade than those advocated by people on opposite sides of the GMO debate. By holding that novel foods containing transgenic proteins may still be considered substantially equivalent to existing foods and emphasizing a risk

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15. Elisabeth Rosenthal, *Europe is United: No Bioengineered Food*, INT'L HERALD TRIBUNE, Oct. 6, 2004, available at <http://www.iht.com/bin/print.php?file=542151.html> ("Since the late 1990s the European Union has required that all food containing more than tiny amounts of genetically modified materials be labeled, and that all genetically modified products be submitted for approval before sale in Europe.").

16. *Id.*

17. *Id.* The current WTO dispute revolves around the issue of whether the EU's laws and procedures that discriminate against GM products are unnecessary and thus constitute an unfair barrier to trade. See Request for Consultations by the United States, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/1 (May 20, 2003), available at [http://trade-info.cec.eu.int/doclib/docs/2003/november/tradoc\\_114610.pdf](http://trade-info.cec.eu.int/doclib/docs/2003/november/tradoc_114610.pdf); Request for Consultations by Canada, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/1 (May 20, 2003); Request for Consultations by Argentina, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* WT/DS293/1 (May 21, 2003). Subsequently, the EU adopted the GM Food and Feed Law (Regulation 1829/2003) and GMO Traceability and Labeling Law (Regulation 1830/2003), which came into force on April 18, 2004 and finally made it possible to transform and sell GM foods. *Italy Not Opened to GMO Containing Foods*, ANSA – ENGLISH CORPORATE NEWS SERVICE, Nov. 9, 2004, 2004 WL 98952238.

18. See BERNAUER, *supra* note 1, at 24-25.

19. Case C-236/01, *Monsanto Agricoltura Italian SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. I-8105, available at <http://curia.eu.int>.

20. "Genetically modified organism" refers to either a genetically modified plant or animal. Genetically modified foods come from GMOs.

assessment based on real, perceived risks instead of hypothetical risks,<sup>21</sup> the Court strikes the proper balance between safety and trade concerns. The Court's decision will likely have wide-ranging implications on how novel foods will be regulated in the future. It is also likely that the decision's effects will expand to include all of GM foods, not just a subsection of it. With this decision, the Court signaled to Member States that it is prepared to overturn, if necessary, GM food regulations that are based on mere hypothetical risks to health.

Although the issues presented here apply to all organisms or products involving recombinant technology, this note will focus solely on GM foods. Part II discusses the relevant provisions of Directive 90/220 on the deliberate release of GMOs into the environment and Regulation 258/97 concerning novel foods and novel food ingredients ("Novel Foods Regulation"). Part III recounts the facts of *Monsanto*. Part IV begins with a discussion of the role of risk perception in foods and its effect on GM food regulation. It then analyzes the Court's decision, keeping in mind its impact on future GM food regulation, and how the Court's emphasis on real, perceived risks strikes the proper balance between safety and trade concerns.

## II. LEGAL BACKGROUND

### A. Council Directive 90/220/EEC

Council Directive 90/220/EEC ("Directive 90/220")<sup>22</sup> on the deliberate release of GMOs into the environment forms "the framework by which the member states of the EU approach their cooperative system of food biotechnology regulation."<sup>23</sup> Article 11(5) provides that a GM product may not be released into the environment without the written consent of the competent

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21. *Monsanto*, 2003 E.C.R. I-8105 ¶ 84.

22. Council Directive 90/220/EEC On the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. (L 117) 15, available at [http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0220&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0220&model=guichett).

23. Jeffrey K. Francker, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 278 (2000).

authority of the State where it is first released.<sup>24</sup> It also provides for a “case-by-case environmental risk assessment” prior to the release of any GM product.<sup>25</sup> Directive 90/220 was amended in 2001 and renamed Directive 2001/18/EC,<sup>26</sup> but the relevant provisions pertaining to the case at hand remain unchanged.<sup>27</sup>

### B. The Novel Foods Regulation

Regulation 258/97/EC, also known as the Novel Foods Regulation, specifically deals with placing novel foods or novel food ingredients on the market.<sup>28</sup> Article 1(2) defines novel foods or novel foods ingredients (“novel foods”) as those containing or consisting of GMOs as defined in Directive 90/220, or, those produced from, but not containing, GMOs.<sup>29</sup>

The Novel Foods Regulation subjects novel foods to a safety, or risk, assessment before they are placed on the market.<sup>30</sup> One way for novel foods to be placed on the market is through the “simplified procedure.”<sup>31</sup> The simplified procedure requires a company proposing to release novel foods into the Community market to notify the Commission of its intent.<sup>32</sup> This notice is accompanied by a written consent from a Member State’s competent authority, and a report regarding the food’s composition, nutritional value, metabolism, intended use, and level of undesirable substances.<sup>33</sup> The Commission then forwards a copy of the notification to Member States within sixty days and if a Member State so requests, a copy of the report.<sup>34</sup> Additional

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24. Council Directive 90/220, *supra* note 22, art. 11(5).

25. *Id.* pmb. l.

26. Council Directive 2001/18, On the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) 1 (EC).

27. The requirement of article 11(5) of Directive 90/220 for a written consent from the competent authority of the Member State can be found in article 13(1) of Directive 2001/18/EC. The requirement for a case-by-case assessment can be found in preamble (19) of Directive 2001/18/EC.

28. Council Regulation 258/97, Concerning Novel Foods and Novel Food Ingredients, preamble (2), 1997 O.J. (L 43) 1.

29. *Id.* art. 1(2).

30. *Id.* pmb. l. (2).

31. *Id.* art. 5.

32. *Id.*

33. *Id.*

34. *Id.*

specific labeling requirements ensure that the consumer is informed of the novel foods' characteristics.<sup>35</sup>

To be marketed under the simplified procedure, novel foods must be "substantially equivalent" to existing foods.<sup>36</sup> According to article 3(4), the novel foods are substantially equivalent to existing foods if they are similar in composition, nutritional value, metabolism, intended use, and the level of undesirable substances.<sup>37</sup> Recommendation 97/618/EC has broadened this definition by stating that novel foods are substantially equivalent to existing foods regardless of the difference in composition as long as it has no effect on public health.<sup>38</sup> If the novel foods are substantially equivalent to existing foods, they may be inspected using the same safety standards as existing foods – no more, no less.<sup>39</sup> Consequently, a comprehensive risk assessment is not required.<sup>40</sup> If the novel foods are not substantially equivalent to existing foods, however, then the simplified procedure may not be used to market the products, and a more comprehensive risk assessment is required.<sup>41</sup>

Under article 12, a Member State objecting to the classification of the novel food as "substantially equivalent" to existing foods has the power to enact measures temporarily restricting or suspending the trade in and use of the novel food.<sup>42</sup> To do so, it must show the Commission and other Member States that it has detailed grounds for considering the use of the novel food as dangerous to human health or the environment.<sup>43</sup>

### III. FACTS OF MONSANTO

In the present case, French and United Kingdom authorities approved the marketing of certain novel foods within their

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35. *Id.* art. 8.

36. *Id.* pmb. (2).

37. *Id.* art. 3(4).

38. See Commission Recommendation 97/618, sec. 3.3, 1997 O.J. (L 253) 1, 6 (EC), available at [http://www.fsai.ie/legislation/food/eu\\_docs/Novel\\_Foods\\_and\\_Ingredients/Recomm97.618.pdf](http://www.fsai.ie/legislation/food/eu_docs/Novel_Foods_and_Ingredients/Recomm97.618.pdf) (last visited Feb. 22, 2005).

39. *Id.*

40. Case C-236/01, *Monsanto Agricoltura Italiana SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. I-8105, ¶ 128, available at <http://curia.eu.int>.

41. *Id.* ¶ 129.

42. Council Regulation 258/97, *supra* note 28, art. 12.

43. *Monsanto*, 2003 E.C.R. I-8105 ¶ 11.

respective territories.<sup>44</sup> These foods were derived from genetically modified maize with increased tolerance to herbicide and were resistant to insects.<sup>45</sup> The finished food products no longer contain GMOs, but did contain transgenic proteins.<sup>46</sup> Monsanto and other biotechnology companies subsequently notified the Commission and other Member States of their intent to market the novel foods throughout the Community.<sup>47</sup> The notifications were accompanied by opinions from the competent UK authority stating that the novel foods were “substantially equivalent to products derived from conventional maize and were safe for use in food.”<sup>48</sup>

The Italian Health Ministry lodged a complaint to the Commission, objecting to the use of the simplified procedure and stating that protective measures must be taken to ensure that the novel foods were indeed safe and their potential health risks rigorously assessed before they were placed on the market.<sup>49</sup> The Commission replied that the condition of substantial equivalence was satisfied and that the use of the simplified procedure was therefore appropriate.<sup>50</sup> In response, the Italian government subsequently adopted the Decree of August 4, 2000 (“Decree”), suspending the trade in and use of the novel foods.<sup>51</sup> The Italian government justified the Decree by stating that the absence of detailed information and the referral to the Scientific Committee for Food for the purpose of reassessing the effects of GMOs on consumer health and on the environment constituted a sufficient basis for the suspension of the marketing of the novel foods.<sup>52</sup>

Monsanto, along with other biotechnology companies, filed an action against the Italian government before the Italian regional administrative court, called the Tribunale amministrativo regionale del Lazio (“Tribunale”), seeking the repeal of the Decree and full compensation for damages suffered while the Decree was in effect.<sup>53</sup> The Tribunale stayed the proceedings and

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44. *Id.* ¶ 17.

45. *Id.*

46. *Id.* ¶ 21.

47. *Id.* ¶¶ 18, 20.

48. *Id.* ¶ 19.

49. *Id.* ¶ 24.

50. *Id.* ¶ 25.

51. *Id.* ¶¶ 16, 31.

52. *Id.* ¶ 32.

53. *Id.* ¶ 40.



submitted several questions regarding the proper interpretation of the Novel Foods Regulation to the ECJ for a preliminary ruling.<sup>54</sup>

Prior to the Court's decision but after Monsanto submitted the notifications under the simplified procedure to the Commission, the Commission and Member States agreed to no longer apply the simplified procedure to novel foods derived from GMOs containing transgenic protein, effective beginning in 1998.<sup>55</sup> Nevertheless, the Court held that the mere presence of transgenic protein in novel foods did not preclude those foods from being considered substantially equivalent to existing foods, and consequently, from being marketed using the simplified procedure at the time.<sup>56</sup> If a Member State objects to the classification, it may adopt measures preventing the marketing of novel foods within its jurisdiction as long as the State, pursuant to Directive 90/220, first carries out a safety assessment "which is as complete as possible given the particular circumstances of the individual case."<sup>57</sup> In addition, it must be apparent from the safety assessment that the protective measures are necessary in order to ensure that the novel foods are safe for consumption.<sup>58</sup> In reaching this conclusion, the Court reasoned:

If the twofold objective of [the Novel Foods Regulation], namely ensuring the functioning of the internal market in novel foods and protecting public health against the risks to which those foods may give rise, is not to be adversely affected, protective measures . . . may not properly be based on a purely hypothetical approach to risk, founded on mere suppositions which are not yet scientifically verified.<sup>59</sup>

#### IV. ANALYSIS

##### *A. The Role of Risk Perception in Foods on GM Food Regulation*

As this article will show, GM food regulation is heavily influenced by how the public perceives risks in foods. In assessing risk, the key issue is to determine whether a product's attendant

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54. *Id.* ¶ 48.

55. *Id.* ¶ 21.

56. *Id.* ¶ 84.

57. *Id.* ¶ 114.

58. *Id.*

59. *Id.* ¶ 106.

risks are judged to be acceptable.<sup>60</sup> Among many European consumers, the attendant risks of GM foods are simply unacceptable.<sup>61</sup> However, this was not always the case. In 1996, Safeway and Sainsbury's, the United Kingdom's two largest supermarket chains, began selling tomato puree made from genetically engineered tomatoes.<sup>62</sup> These modified tomatoes required less heat and concentration before canning, thus costing less to produce.<sup>63</sup> The clearly-labeled product flew off the shelves; by late 1997 Safeway's stores had sold 750,000 cans.<sup>64</sup> By July 1999, however, both Safeway and Sainsbury's had withdrawn the product, mainly because of pressure from consumer groups.<sup>65</sup> Public opposition against genetically engineered food became so fierce, not just in the UK but throughout Europe, that some politicians won elections by vowing to keep "Frankenfoods" at bay.<sup>66</sup>

Several factors contribute to the perception that the risks presented by GM foods are simply unacceptable. First, food is "high culture, if not religion" in Europe.<sup>67</sup> Europeans tend to be more attached to national culinary traditions and are more likely to expect food products to be fresh and natural compared to their American counterparts.<sup>68</sup> Thus, they view foods produced through

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60. E.I.L. VOS, OVERCOMING THE CRISIS OF CONFIDENCE: RISK REGULATION IN AN ENLARGED EUROPEAN UNION 8, at <http://www.unimaas.nl/bestand.asp?id=2066> (January 23, 2004).

61. See Rosenthal, *supra* note 15.

62. BERNAUER, *supra* note 1, at 24.

63. *Id.*

64. *Id.*

65. *Id.*

66. Lizette Alvarez, *Consumers in Europe Resist Gene-Altered Foods*, N.Y. TIMES 3, Feb. 11, 2003 (describing how some politicians in Austria won their seats by opposing GM foods). A recent survey in Italy showed that only 13% of Italians were willing buy foodstuffs containing GMOs and only at discount prices. *Italy Not Opened to GMO Containing Foods*, *supra* note 17.

67. Rosenthal, *supra* note 15. One author, reflecting the views of pro-trade groups, suggests that the strong anti-GM stance in Europe is based on more than just "cultural preferences" and mistrust of food safety regulators but is instead simply based on classical trade economics. Lawrence A. Kogan, *Ducking the Truth about Europe's GMO Policy Trade Protectionism*, INT'L HERALD TRIBUNE, Nov. 27, 2004, available at [http://www.iht.com/bin/print\\_ipub.php?file=/articles/2004/11/26/opinion/edkogan.html](http://www.iht.com/bin/print_ipub.php?file=/articles/2004/11/26/opinion/edkogan.html). See Lawrence A. Kogan, *Exporting Europe's Protectionism*, THE NATIONAL INTEREST, Oct. 1, 2004, 2004 WL 76694309, for an in-depth critique of EU's stringent GM regulations.

68. Paulette Kurzer, *European Citizens against Globalization: Public Health and Risk Perceptions* 20, (Martindale Ctr., Coll. Of Bus. & Econ., Lehigh Univ., Working Paper,

genetic engineering with deep suspicion. Second, there is a general mistrust of EU regulatory and public health agencies, most likely because of their perceived failure in preventing a string of food scandals, most notably the outbreak of bovine spongiform encephalopathy ("BSE", or mad-cow disease) and its human equivalent Creutzfeldt-Jacob disease ("CJD") in 1996.<sup>69</sup> EU and Member State authorities at that time reassured anxious consumers that BSE was not transmissible from ruminants to humans, a claim that ended up being both unwarranted and untrue.<sup>70</sup> This incident, and others, such as the 1999 contamination of Coca-Cola products in Belgium and France,<sup>71</sup> shook the public's trust in the judgment of government officials and experts in the field of consumer protection.<sup>72</sup> Third, the horrific manner of death resulting from CJD heightened public concern over what they were eating.<sup>73</sup> Although concern over GM foods were present prior to the outbreak of BSE, the outbreak created a backlash against GM foods, and whatever inroads they have made in the European market by 1996 quickly disappeared. The combination of these factors contributed to the consumer perception that the risk to public health will greatly increase if GM foods were freely released in the market.

The EU's broad legislative framework regulating GM foods reflects the public's concerns regarding them. Indeed, the BSE crisis forced the European Community to take firm action to reform the European food safety system.<sup>74</sup> In the aftermath of the BSE crisis, the EU adopted the Treaty of Amsterdam, which

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2004), available at <http://www.lehigh.edu/martindale/publications/kurzer.pdf>. See also Toby A. Ten Eyck, George Gaskell & Jonathan Jackson, *Seeds, food and trade wars: Public opinion and policy responses in the USA and Europe*, 10 JOURNAL OF COMMERCIAL BIOTECHNOLOGY 258, 258 (2004) ("In the minds of at least some countries, food is in a different category from other traded products. It is part of national and regional identity; the imposition of novel foods that challenge deeply held cultural values is likely to be resisted.").

69. Stamps, *supra* note 9, at 9.

70. Kurzer, *supra* note 68, at 17.

71. Stamps, *supra* note 9, at 9.

72. Kurzer, *supra* note 68, at 17.

73. Aynsley Kellow, *Risk Assessment and Decision-making for Genetically Modified Foods*, 13 RISK 115, 134 (2002).

74. Karolina Szawlowska, *Risk Assessment in the European Food Safety Regulation: Who is to Decide Whose Science is Better? Commission v. France and Beyond*, 5 GERMAN L.J. 1259, 1262-63 (2004).

required that all Community policies and action ensure a high level of protection to human health and environment.<sup>75</sup> There is a concern, however, that too much regulation will stifle the free movement of goods within the EU, which is guaranteed by the Treaty Establishing the European Community (“EC Treaty”).<sup>76</sup> Too much regulation also has the effect of stifling scientific progress in food biotechnology in the EU,<sup>77</sup> considering that no studies have shown that consuming GM foods is detrimental to one’s health.<sup>78</sup> On the other hand, the EC Treaty and the Treaty of Amsterdam do guarantee the protection of human health and the environment.<sup>79</sup> The *Monsanto* case perfectly illustrates the tension between the free movement of goods, GM foods in particular, and the protection of human health.

### B. Risk Assessment Based on Real Risks

The Court’s emphasis on a risk assessment based on real and perceived risks instead of hypothetical risks is an eminently sensible approach to novel foods and could lead to a shift in the way the Member States approach GM food regulation. Instead of relying on mere suppositions that are not yet scientifically verified,<sup>80</sup> the Court held that a Member State must have detailed grounds for considering the use of novel foods as endangering human health.<sup>81</sup> This requirement ensures that Member States do

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75. *Id.*; Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities and Certain Related Acts, Oct. 2, 1997, O.J. (C 340) 1 [hereinafter Treaty of Amsterdam].

76. Treaty Establishing the European Community, Nov. 10, 1997, 1997 O.J. (C 340) 3, arts. 3(1)(c), 14(2) [hereinafter EC Treaty].

77. According to the European Commission, “[t]he lack of progress on the authorizations of new GMOs is having a direct impact on research activities on GMOS and GMO field trials in Europe.” Life Sciences and Biotechnology – A Strategy for Europe: Progress Report and Future Orientations, Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee, COM(03)96 final at 17, [http://europa.eu.int/comm/biotechnology/pdf/com2003-96\\_en.pdf](http://europa.eu.int/comm/biotechnology/pdf/com2003-96_en.pdf) (last visited Jan. 15, 2005). A survey of biotechnology companies and research institutes showed that 39% have cancelled research and development projects on GMOs over the last four years, blaming the unclear regulatory framework and uncertain market situation. *Id.* at 18.

78. See BERNAUER, *supra* note 1, at 24-25.

79. EC Treaty, *supra* note 76, art. 174(1).

80. Case C-236/01, *Monsanto Agricoltura Italian SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. I-8105, ¶ 106, available at <http://curia.eu.int>.

81. *Id.* ¶ 108.

not misuse their regulatory powers<sup>82</sup> by impeding the trade in novel foods without adequate proof that the foods endanger human health. In addition, the holding opens the door for a similar framework if broadened to apply not just to novel foods, but also to GM foods in general. This approach will go a long way towards other nations' acceptance of GM foods, especially nations sorely in need of GM foods to meet their populations' food and nutritional requirements.

### 1. Substantial Equivalence

The Court's decision may seem to be less protective of human health given the uncertainty of the effects of transgenic proteins present in novel food. In the case at hand, Italy believed that the use of substantial equivalence was not sufficient to ensure a high level of protection to human health and environment.<sup>83</sup> Substantial equivalence, however, is not the beginning and the end of a safety assessment, but a precondition to determine whether the novel food will be marketed under a simplified procedure.<sup>84</sup> According to the Court, if the analysis for substantial equivalence identifies hazards, then the food in question is subject to a full scientific risk assessment.<sup>85</sup> As the Court pointed out, substantial equivalence is but one approach to comparing the novel food with its conventional counterpart in determining whether it should be subject to a risk assessment.<sup>86</sup>

### 2. The Simplified Procedure Does Not Change the Risk Assessment Process

The Court also pointed out that the simplified procedure should not be considered as relaxing the safety requirements with

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82. Member States may adopt measures restricting the free movement of goods in their respective territories to protect public health, but these prohibitions must neither be arbitrary nor merely a disguised restriction on trade between Member States. Julien Cazala, *Food Safety and the Precautionary Principle: the Legitimate Moderation of Community Courts*, 10 EUR. L. J. 539, 550 (2004); EC Treaty, *supra* note 76, art. 30 (ex art. 36).

83. See *Monsanto*, 2003 E.C.R. I-8105 ¶¶ 23-24.

84. Patrycja Dabrowska, *GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the Day in the Recent Judgment of the European Court of Justice?*, 5 GERMAN L.J. 151, 156 (2004).

85. *Monsanto*, 2003 E.C.R. I-8105 ¶ 79.

86. *Id.* ¶ 77.

respect to novel foods.<sup>87</sup> Other steps are involved to ensure a high level of protection to public health. For example, the status of a GMO-derived product may be re-assessed by the Commission.<sup>88</sup> Additionally, labeling requirements inform consumers of the GM content of a product.<sup>89</sup> Finally, article 12 of the Novel Foods Regulation explicitly provides that a Member State may take protective measures, if it has “detailed grounds” for considering that the novel foods endanger human health or the environment. In the present case, Italy’s reasons for adopting the Decree – the mere observations of its competent authority of the presence of transgenic proteins<sup>90</sup> – quite obviously lacked the specificity that the Novel Foods Regulation requires.

Although the Member States and the Commission agreed to no longer use the simplified procedure, it does not lessen the impact of the decision on the regulation of novel foods and how it will affect GM food regulation in general. Even in the absence of a simplified procedure, there still must be detailed grounds before any Member State adopts protective measures.<sup>91</sup> That is, the absence of a simplified procedure does not change the requirement for a risk assessment based on real, perceived risks in regulating novel foods.

### 3. Court’s Decision is Consistent with the Precautionary Principle

The Court’s approach is also perfectly consistent with the precautionary principle, which EU GM food regulations strongly emphasize.<sup>92</sup> The principle allows the adoption of measures to prevent health and environmental harms even if scientific uncertainty still exists.<sup>93</sup> To supporters of stricter food safety regulation, this means “when in doubt, refrain.”<sup>94</sup> That is, the

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87. *Id.* ¶ 80.

88. Dabrowska, *supra* note 84, at 158.

89. *See* Council Regulation 1830/2003, 2003 O.J. (L 268) 24.

90. Monsanto, 2003 E.C.R. I-8105 ¶ 55.

91. According to the Court, “The applicability of Article 12 is not affected by the type of procedure which was followed prior to the placing on the market of the novel foods - namely the simplified procedure or the normal procedure - or, in principle, by the validity of the procedure which was followed.” *Id.* ¶ 104.

92. BERNAUER, *supra* note 1, at 45. E.C. Treaty art. 174 explicitly provides that measures to protect the environment should be based on the precautionary principle.

93. DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 406 (2d ed. 2002).

94. Cazala, *supra* note 82, at 542.

principle obliges competent authorities to ban an activity or product “from the moment when the scientific community raises the specter of possible risks for human health or the environment.”<sup>95</sup> The Court takes a more level-headed approach, applying the principle only where preliminary risk assessment indicates that there are “reasonable grounds for concern” of potentially dangerous effects on the environment, human, animal or plant health.<sup>96</sup> Under the precautionary principle espoused by those who favor stricter regulations, the idea of some vague risk that *may* come with consuming GM foods in the distant future would allow for the ban of these products. Under the Court’s interpretation of the precautionary principle, however, more than mere supposition is needed.

The Italian government’s decision to adopt the Decree is clearly based on mere suppositions of risk. Italy’s real objection about the products is not about the risks they might pose, but about the use of the simplified procedure and substantial equivalence.<sup>97</sup> Italy temporarily banned the novel foods months before the Italian Health Institute first noted the presence of transgenic protein in the foods.<sup>98</sup> Indeed, the Institute noted its presence just weeks before the Decree was enacted.<sup>99</sup> In addition, the risk assessment reports the government relied on stated that the consumption of the novel foods at issue *does not* present any danger to human and animal health.<sup>100</sup> The Italian government’s argument, therefore, was not that the foods were unsafe, but that there should have been another layer of analysis before permitting the foods into the market, regardless of how substantially equivalent they were to conventional foods.<sup>101</sup> This approach clearly cannot be considered reasonable in light of the EC Treaty’s

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95. *Id.*

96. HUNTER, *supra* note 93, at 407.

97. THIJS ETTY & HAN SOMSEN, CASE C-236/01 - MONSANTO, at <http://www.jur.uva.nl/cvm/object.cfm/objectID=BC8AFBBD-89D7-4A16-832E5C96D3E63AD1> (last visited Jan. 13, 2005).

98. *Id.*

99. *Id.*

100. Case C-236/01, *Monsanto Agricoltura Italian SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. I-8105, ¶ 30, *available at* <http://curia.eu.int>.

101. *See* Opinion of Advocate General Alber, *Monsanto Agricoltura Italian SpA v. Presidenza del Consiglio dei Ministri*, Case C-236/01, 2003 E.C.R. I-8105, ¶ 46 [hereinafter A.G. Opinion], *available at* <http://curia.eu.int>.

purpose of promoting the free movement of goods.<sup>102</sup>

#### 4. Court's Decision Strikes the Proper Balance between Public Health and Trade Concerns

The problem with the Italian Decree is that it unnecessarily impedes trade in GM foods. Giving Member States unfettered authority to adopt measures based on mere hypothetical risks to health would only lead to confusion among consumers and business groups. It would also only serve to undermine the purpose of a common market, which is to promote the free movement of goods within the EU. In addition, Italy and the EU have certain obligations under the WTO to ensure the free movement of goods, with certain exceptions.<sup>103</sup> Even these exceptions, however, require more certainty than mere suppositions.<sup>104</sup>

The Court's decision also has the effect of encouraging other nations to look upon GM foods with less suspicion. The EU's position as one of the largest markets in the world gives it considerable sway on what kind of items other nations view as tradable commodities. The EU's unfavorable position regarding GM foods led other nations to refuse to grow them because doing so would have limited their agricultural exports to the EU market.<sup>105</sup> The Court's decision requiring real risks instead of hypothetical risks, in addition to recently enacted law,<sup>106</sup> should encourage other nations, especially poor nations, to grow GM foods and allow them the opportunity to meet the food and health

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102. See EC Treaty, tit. I.

103. The General Agreement on Tariffs and Trade ("GATT"), which States must accept in order to become part of the WTO, requires, among other things, the removal of restrictions that would limit the quantity of imports permitted. HUNTER, *supra* note 93, at 1147.

104. Article XX of GATT provides a health exception to GATT obligations, allowing Member States to adopt measures "necessary" to protect human life or health. *Id.* at 1163. In addition, art. 2.2 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") requires Member States to "ensure that any sanitary and phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health." *Id.* at 1165. GATT panels have consistently favored a narrow interpretation of "necessary." *Id.*

105. For example, Zambia, Zimbabwe, Mozambique, and Malawi sought to prevent imported GM food products from contaminating their domestic crops and jeopardizing exports to the EU. Stamps, *supra* note 9, at 14. See also Rosenthal, *supra* note 15.

106. See Rosenthal, *supra* note 15.



requirements of their growing populations.

#### V. CONCLUSION

The Court, in holding that mere presence of transgenic proteins in novel foods does not necessarily preclude them from being considered substantially equivalent to existing foods, strikes the proper balance between public health concerns and trade concerns. The Court was careful to emphasize that the decision does not amount to a relaxation of the safety requirements that must be met by novel foods.<sup>107</sup> Public health is safeguarded by risk assessment, re-assessment of the novel foods by Member States and at the Community level, and labeling requirements.<sup>108</sup> Trade will be permitted only if the risk assessment does not yield reasonable grounds for concern.<sup>109</sup> This decision, with the emphasis on risk assessment based on real, perceived risks, opens the door for a more balanced approach on regulation not just of novel foods, but also of GM foods in general. Considering their enormous potential, European laws that focus on real, perceived risks of GM foods will go a long way towards removing the stigma currently associated with GM foods and perhaps finally begin to fulfill its potential of alleviating hunger all over the world.

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107. See Case C-236/01, *Monsanto Agricoltura Italian SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. I-8105, ¶ 80, available at <http://curia.eu.int>.

108. *Id.* ¶ 81.

109. *Id.* pmb1. (2).

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