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## The European Union's Efforts to Sidestep the WTO through its Ban on GMOs: A Response to Sarah Lively's Paper, "The ABCs and NTBS of GMOs"

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# COMMENTS

## The European Union's Efforts to Sidestep the WTO through its Ban on GMOs: A Response to Sarah Lively's Paper, "The ABCs and NTBs of GMOs"

*Johannes S.A. Claus III\**

### I. INTRODUCTION

In the past few years, the European Union has passed a number of Regulations and Council Directives that have restricted the "release into the environment" and "placing on the market" of Genetically-Modified Organisms, or GMOs.<sup>1</sup> The European Union has also mandated that any product containing GMOs or derivatives of GMOs be labeled as such.<sup>2</sup> These policies have greatly restricted the importation of agricultural and foodstuff products into the European Community ("EC") from the United States.

In an article recently published in this *Journal*, Ms. Lively details her belief that these E.U. policies, which have been challenged by the United

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<sup>1</sup> Council Directive 2001/18/EC, 2001 O.J. (L 106) 1.

<sup>2</sup> Council Regulation 258/97, 1997 O.J. (L 43) 1; Council Regulation 1139/98, 1998 O.J. (L 159) 4.

States, would withstand scrutiny by a World Trade Organization dispute settlement body.<sup>3</sup> Specifically, Ms. Lively maintains that the Regulations and Directives passed by the European Union are in harmony with the Agreement on the Application of Sanitary and Phytosanitary Measures<sup>4</sup> ("SPS") and the Agreement on Technical Barriers to Trade<sup>5</sup> ("TBT"), ancillary agreements to the Marrakesh Agreement, which created the World Trade Organization ("WTO").

The purpose of this paper is to refute Ms. Lively's article, detailing the reasons why the E.U. legislation is not in harmony with the WTO agreements. This paper will argue that if a WTO dispute settlement body were to decide upon the validity of the current European GMO regime, it would strike down the regulation as contrary to the WTO agreements signed by the European Union and the United States. The European Union's four year moratorium on GMOs continues to be one of the most hotly-contested trade issues facing it and the United States. Officially, U.S. patience with the E.U. refusal to process applications for biotechnology imports is "growing very thin."<sup>6</sup> Currently, the U.S. Trade Representative is considering filing a case against the European Union in the WTO.<sup>7</sup> Given the diametrically opposed positions of the United States and the European Union on this issue, the debate over GMO regulation will most likely be resolved before an international dispute settlement body, not through bilateral agreement of the parties. The premise of this article is that if the WTO resolves this dispute, it will decide in favor of the United States<sup>8</sup>

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<sup>3</sup> Sarah Lively, Comment, *The ABCs of NTBs and GMOs: The Great EU v. US Trade Debate—Do European Restrictions on the Trade of Genetically Modified Organisms Violate International Trade Law?*, 23 NW. J. INT'L L. & BUS. 239 (2002).

<sup>4</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 495, 496 [hereinafter SPS Agreement], available at [http://www.wto.org/english/docs\\_e/legal\\_e/15-sps.pdf](http://www.wto.org/english/docs_e/legal_e/15-sps.pdf) (last visited Nov. 10, 2003).

<sup>5</sup> Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120 [hereinafter TBT Agreement], available at [http://www.wto.org/english/docs\\_e/legal\\_e/17-tbt.pdf](http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf) (last visited Nov. 10, 2003).

<sup>6</sup> Kathryn McConnell, *Veneman Says U.S. Patience with EU Growing Thin*, U.S. Department of State, available at <http://usinfo.state.gov/xarchives/display.html?p=washfile-english&y=2003&m=February&x=20030220171300azwaniecki@pd.state.gov0.704632&t=xarchives/xarchitem.html&PHPSESSID=c7eec3bc9c939c4d5b2bf9dcca719bfd> (Feb. 20, 2003).

<sup>7</sup> Ann Veneman, *U.S. Considering Action Against EU on Biotech Imports*, U.S. Department of State, Feb. 20 2003, available at <http://usinfo.state.gov/topical/global/biotech/03022101.htm> (last visited July 21, 2003).

<sup>8</sup> Since I began writing this article in September of 2002, the debate over genetically-modified organisms has intensified to the point that the United States government, with the support of Australia and Canada, announced in June 2003 that it will file suit with the WTO against the European Union's moratorium on importing or planting GMOs in the European Union. Since billions of dollars and farmers' livelihoods are at stake on either side of the Atlantic, not to mention the implications of GMO use on the environment and on the very lives

Part II of this paper will briefly review the nature of the debate between the United States and the European Union regarding the use and regulation of GMOs. Part III will explain why this issue is one that could affect the lives of millions around the world, particularly in developing nations. Part IV will detail the provisions of the E.U. legislation that regulate the import and distribution of GMOs within the EC. Part V will provide a legal analysis showing how the European regulatory regime on GMOs fails to comply with the WTO agreements, including influential WTO dispute settlement decisions that may help determine the direction a WTO dispute settlement body may take on the GMO issue. Part VI will then attempt to refute the exaggerated claims of the risk posed by GMOs that Ms. Lively uses to defend the European Union's regulation of GMOs. Part VII will conclude that the E.U. regime would fail WTO scrutiny.

## II. THE DEBATE SURROUNDING GENETICALLY-MODIFIED ORGANISMS

In the last decade, scientists and agronomists (partly in the United States and Canada, but significantly in Europe and elsewhere as well) have unleashed advances in the production of crops<sup>9</sup> that have not been seen since the Green Revolution of the 20th Century.<sup>10</sup> Through the use of new gene transfer technology, crops can now be created that are resistant to herbicides, resistant to pests, are generally sturdier, more durable, and more nutritious.<sup>11</sup> These crops have increased yields and reduced costs for farmers, as less pesticide has to be used in the production of these crops.<sup>12</sup> There are also environmental benefits, as fewer toxins will be used in the production of crops.<sup>13</sup> Third World nations would most benefit from the increased yields and nutritional benefits of crops such as "Golden Rice" (fortified with Vitamin A) and other foodstuffs that have been infused with vitamins

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of many Third World citizens, this is a struggle that will not subside in the near future. It is the author's hope that this article will shed some light on this bitter debate as well as provide a road map for some of the arguments that will be made before the WTO dispute resolution body.

<sup>9</sup> I will not attempt to explain the science of GMO technology or give a history of its development in this article. For an informative discussion on the technology of GMOs, see Sophia Kolehmainen, *Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 VA. ENVTL. L.J. 267, 269 (2001).

<sup>10</sup> Judy Aita, *Developing Countries Should Adopt Biotech, UN Panelists Urge; They say the technology can improve yields, yield more nutrition*. WASH. FILE, U.S. Dept. of State, Sep. 24, 2002, available at <http://usinfo.state.gov/topical/pol/usandun/02092422.htm>.

<sup>11</sup> Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 263 (2000).

<sup>12</sup> Aita, *supra* note 10. C.S. Prakash, Director of Plant Molecular Genetics at Tuskegee University, stated in this article that GMO crops have reduced pesticide use in cotton and maize by 46 million pounds, and simultaneously offered increased yields and reduced production costs.

<sup>13</sup> Stanley H. Abrahamson & J. Thomas Carrato, *Crop Technology: The Case for Product Stewardship*, 20 VA. ENVTL. L.J. 241, 243 (2001).

or other nutrients through genetic engineering.<sup>14</sup> Therefore, while the developed nations of the world "have the freedom to debate the pros and cons of their development and consumption of GMOs, it would be wrong for such debate to impede basic research" that could truly benefit the living standard of the developing world.<sup>15</sup>

Europe has, for the most part, been a staunch detractor of these new technologies from the 1990s to the present.<sup>16</sup> As a result of the pressure from interest groups within Europe<sup>17</sup> and an increasingly skeptical public, the European Union has enacted a series of measures designed to stop the import of GMOs as well as the domestic production of these products until they can be scientifically proven safe.<sup>18</sup> The European Union has also created strict guidelines for the labeling of food products that contain or consist of GMOs,<sup>19</sup> which has made export of crops to the European Union difficult given that there is no system in the United States for dividing bulk agricultural goods into GMO and GMO-free shipments.<sup>20</sup>

### III. THIS DEBATE HAS FAR-REACHING CONSEQUENCES FOR THE DEVELOPING WORLD

The success or failure of GMOs will have tangible and immediate impact on a developing world struggling with famine, crop disease, and chronic food shortages. For instance, a cotton farmer in India sells his kidney to help pay off his debts, rendering him unable to work, even though cotton seed is available that is resistant to the pests that destroyed his crop.<sup>21</sup> Zambia rejects food aid shipments from the United States, although the nation is suffering from a region-wide famine that threatens the lives of 15

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<sup>14</sup> Ronald Cantrell, *Rice Essential for Global Security, Stability*, ECONOMIC PERSPECTIVES, May 9, 2002, available at <http://usinfo.state.gov/regional/nea/sasia/text/0509rice.htm> (last visited Sept. 6, 2003).

<sup>15</sup> *Id.* Ronald Cantrell is the Director General of the International Rice Research Institute in the Philippines. His views are shared by the Bush Administration and Agriculture Secretary, Ann Veneman. See Ann Veneman, *Remarks by Secretary of Agriculture Ann M. Veneman at the 79th Agricultural Outlook Forum*, available at <http://usinfo.state.gov/xarchives/display.html?p=washfile-english&y=2003&m=February&x=20030221141755odessey@pd.state.gov0.704632&t=xarchives/xarchitem.html&PHPSESSID=c7eec3bc9c939c4d5b2bf9dcca719bfd> (Feb. 20, 2003).

<sup>16</sup> Nigel Williams, *Agricultural Biotech Faces Backlash in Europe*, 281 SCI. 768 (Aug. 7, 1998).

<sup>17</sup> Farmers, environmental groups like Greenpeace, and even factions of the Catholic Church have been involved in pushing for regulations or moratoria on GMOs within Europe. See generally Francer, *supra* note 11.

<sup>18</sup> Council Directive 2001/18/EC, *supra* note 1.

<sup>19</sup> Council Regulation 258/97, *supra* note 2; Council Regulation 1139/98, *supra* note 2.

<sup>20</sup> Ved Nanda, *Genetically Modified Food and International Law—The Biosafety Protocol and Regulations in Europe*, 28 DENV. J. INT'L. L. & POL'Y 235, 262 (2000).

<sup>21</sup> John Biewen, *Engineering Crops in a Needy World*, Amer. Radio Works, available at [http://americanradioworks.org/features/gmos\\_india/story/](http://americanradioworks.org/features/gmos_india/story/) (last visited Sept. 6, 2003).

million people.<sup>22</sup> The Philippines debates whether or not to allow research on a type of rice that is resistant to blight, although this rice would boost yield at a lower cost in this poor and growing nation.<sup>23</sup>

What do all of these scenarios have in common? They have all resulted, to a certain extent, from countries' fears that the use of genetically-modified ("GM") crops in their countries would render their exports inadmissible to the European Union's market.<sup>24</sup> Some African scientists have recently agreed with U.S. charges that the European Union indirectly pressures African officials to reject GM food aid.<sup>25</sup> The scientists stated that E.U.-funded groups such as Oxfam and Save the Children "have frightened African governments"<sup>26</sup> into rejecting food aid containing GMOs. These fears have also kept many developing nations from allowing new GM crop seeds to enter their countries. This is in spite of the fact that these crops could boost production, using less pesticide, increasing nutrition, or growing on less-productive land.<sup>27</sup>

It is estimated that in the next two to three decades, two billion people will be added to the ranks of the human race,<sup>28</sup> and all of these people will need to eat. The GM foods that have been designed have tremendous possibility to increase yield per acre, decrease the use of costly and environmentally damaging pesticide, allow planting in previously fallow soil, and even increase the nutritional value of the crops.<sup>29</sup> These crops could be a real asset to a poor or developing country struggling to feed its population or boost its export revenue.<sup>30</sup> But recent actions by the European Parliament and other legislative bodies, including the Japanese Parliament, could effectively strangle these possibilities by increasing the cost of exporting crops to these nations, hampering gains from international trade. Even worse, these restrictions by the European Union could decrease incentives to research new strains of crops, killing any future gains from this promis-

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<sup>22</sup> David Gollust, *Africa Raises Questions on 'Biotech' Food Aid*, VOA NEWS, Aug. 21, 2002, available at <http://greennature.com/article1607.html>.

<sup>23</sup> Environmental News Services, *Genetically Modified Rice Tests Alarm Philippine Farmers*, available at <http://www.thecampaign.org/newsupdates/aug00i.htm> (Aug. 17, 2002).

<sup>24</sup> Gollust, *supra* note 22.

<sup>25</sup> Briefly: BRUSSELS, WALL ST. J., Jan. 30, 2003, at A12.

<sup>26</sup> *Id.*

<sup>27</sup> Kurt Buechle, *The Great Global Promise of Genetically Modified Organisms: Overcoming Fear, Misconceptions, and the Cartagena Protocol on Biosafety*, 9 IND. J. GLOBAL LEGAL STUD. 283, 290 (2001).

<sup>28</sup> Julie Teel, *Rapporteur's Summary of the Deliberative Forum: Have NGOs Distorted or Illuminated the Benefits and Hazards of Genetically Modified Organisms?*, 13 COLO. J. INT'L ENVTL. L. & POL'Y 137, 147 (2002).

<sup>29</sup> Buechle, *supra* note 27.

<sup>30</sup> For example, a new type of cotton was tested in India that yielded 40% more per acre and required 7% less pesticide spraying. The use of this product would greatly enhance the export potential of India, let alone the income gains to farmers in that country. Francer, *supra* note 11, at 264 n.40.

ing area of technology. An example of how this hesitance to conduct research could be costly to Third World citizens is the current possibility that a banana and plantain blight could extinguish the Cavendish banana, a staple to half a billion people in Africa and Asia.<sup>31</sup> Research into a GM version of the banana that would be resistant to the blight has been hampered by concerns that GM bananas could “put off consumers with GM concerns” in the European Union.<sup>32</sup> The current situation is considered by some to be comparable to the Great Potato Blight which devastated Ireland in the 19th Century.<sup>33</sup>

There are possible drawbacks to the use of biotechnology in crop production, including claims of cross-pollination of neighboring crops, damage to non-pest native fauna, and a reduction of the usefulness of these crops as pests grow resistant to the bacteria found in these GM crops.<sup>34</sup> No scientific evidence has been produced, not even hypothetically, that these crops are harmful to consumers in the short or the long term.<sup>35</sup> However, a deeper sense of mistrust of the corporate interests involved,<sup>36</sup> and nostalgia for a simpler time when food was grown at the local farm underlie the worries voiced by the “grassroots” detractors of this new technology.<sup>37</sup>

#### IV. AN EXPLANATION OF THE CURRENT EUROPEAN UNION REGULATORY REGIME CONCERNING GMOs

In response to adverse public opinion and pressure from interest groups within Europe, the European Council and Parliament has delivered a number of Directives and Regulations in recent years that greatly curtail the growth, distribution, or marketing of GMO-containing foodstuffs within the European Union. The two most important regulations are Council Directive 90/220 (Replaced by 2001/18/EC) and Council Regulations 258/97 and 1139/98. Council Directive 2001/18/EC is designed to prohibit the “deliberate release” of GMOs into the E.U. environment or the “placing [of GMOs] on the market” without prior approval from the Member States.<sup>38</sup> The prior approval process is lengthy and based on the subjective conclusion of each Member State of the safety of the GMO.

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<sup>31</sup> *Bananas could split for good*, BBC NEWS, WORLD EDITION, SCI. & TECH., Jan. 16, 2003, available at <http://news.bbc.co.uk/2/hi/science/nature/2664373.stm>.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> See discussion *infra* Section VI.

<sup>35</sup> U.S. GEN. ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTERS, GENETICALLY MODIFIED FOODS at 9, May 23, 2002, available at <http://www.gao.gov/new.items/d02566.pdf> (last searched Sept. 6, 2003) [hereinafter *G.A.O. Report*].

<sup>36</sup> Williams, *supra* note 16.

<sup>37</sup> *Id.* at 769.

<sup>38</sup> Council Directive 2001/18/EC, *supra* note 1, at pmbl. ¶ 25.

The requirements for "deliberate release" into the environment<sup>39</sup> or "placing on the market"<sup>40</sup> are distinct but similar. The person attempting to introduce the GMO must file a notification with the competent agency in the country targeted for introduction.<sup>41</sup> The notification must contain the information listed in Annex III and IV of the Directive.<sup>42</sup> The list of information needed is exhaustive; it obviously must be in order to cover all possible risks of releasing GMOs into the environment. It includes items such as "[p]otential interactions with the abiotic environment"<sup>43</sup> and "[i]nformation on how the genetically-modified plant differs from the recipient plant"<sup>44</sup> as well as a "[d]escription of the release site ecosystem, including climate, flora and fauna."<sup>45</sup> Some of these items have the flavor of an interrogatory: taking one line to ask, but possibly taking two hundred pages to adequately answer. Thereafter, the competent agency has 90 days to review the application.<sup>46</sup> Importantly, the Member State's competent authority can extend this period indefinitely by asking for further information.<sup>47</sup> Then, if the competent authority finds that the GMO is safe for placement on the market, it must prepare an assessment of the application and send it to the (European) Commission, who then sends it to all the other Member States.<sup>48</sup> At this point, the Commission and the Member States have 105 days to discuss the application and arrive at an agreement as to whether the GMO should be placed on the market.<sup>49</sup> However, if the Member States take any additional time to ask questions of the applicant, that time is not counted toward the 105 days.<sup>50</sup> If a Member State does object to the application, then an additional 120 days will be added so that a decision

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<sup>39</sup> *Id.* at art. 2, ¶ 3. "Deliberate Release" into the environment is defined as "any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment." Presumably, this means the planting of GMO crops for research or commercial purposes.

<sup>40</sup> *Id.* at art. 2, ¶ 4. "Placing on the market" means making available to third parties, whether in return for payment or free of charge. This would include the sale of bulk grains or packaged food items which contain GMOs.

<sup>41</sup> *Id.* at art. 6, ¶ 1 (for release into the environment of a GMO); art. 13 ¶ 1 (for placing in the market of a GMO).

<sup>42</sup> *Id.* at art. 13, ¶ 2(a).

<sup>43</sup> *Id.* at annex III B (D)11.

<sup>44</sup> *Id.* at annex III B (D)4.

<sup>45</sup> *Id.* at annex III B (E)2.

<sup>46</sup> *Id.* at art. 6, ¶ 5 (for release into the environment of a GMO); art. 14 ¶ 2 (for placing in the market of a GMO).

<sup>47</sup> *Id.* at art. 6, ¶ 6(a) (for release into the environment of a GMO); art. 14 ¶ 4 (for placing in the market of a GMO).

<sup>48</sup> *Id.* at art. 14, ¶ 2.

<sup>49</sup> *Id.* at art. 15, ¶ 1.

<sup>50</sup> *Id.*



can be reached.<sup>51</sup> Any time spent awaiting further information requested of the applicant will not accrue to those 120 days.<sup>52</sup>

Possibly the most troublesome part of Directive 2001/18 is that it allows for a Member State to "take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products."<sup>53</sup> Although this sounds like rhetorical gibberish, it is likely taken very seriously. None other than the Prince of Wales has said: "The use of these techniques raises, it seems to me, crucial ethical and practical considerations. I happen to believe that this kind of genetic modification takes mankind into realms that belong to God, and to God alone."<sup>54</sup>

There is no telling how European politicians could restrain the import of GMOs based on "ethical considerations." No matter what the facial requirements for introducing new GMOs into the European market, the reality is that the European Union has refused to allow any new GMOs into the region since 1998, and fourteen applications are still awaiting approval.<sup>55</sup> E.U. ministers have indicated that they will block any new registrations of GMOs.<sup>56</sup> This appears to be a moratorium without an end in sight.<sup>57</sup>

Council Regulation 258/97 mandates the labeling of food and food ingredients that *may* contain GMOs.<sup>58</sup> In a later regulation, the European Union added GM soya and maize to the list of items that have to be labeled as containing GMOs.<sup>59</sup> These two products had previously been spared labeling since the European Union had approved of their distribution within. These Regulations present a dilemma to U.S. exporters, since the U.S. agri-

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<sup>51</sup> *Id.* at art. 18, ¶ 1.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.* at pmb., ¶ 9.

<sup>54</sup> The Prince of Wales, *Seeds of Disaster*, THE DAILY TELEGRAPH, June 8, 1998, available at [http://www.princeofwales.gov.uk/speeches/agriculture\\_08061998.html](http://www.princeofwales.gov.uk/speeches/agriculture_08061998.html).

<sup>55</sup> Nanda, *supra* note 20, at 262. This number of shelved applications is as of 2000. Since this moratorium has not been lifted, it is to be expected that there are more than 14 applications to introduce GMOs that have not been approved by the European Union.

<sup>56</sup> Francer, *supra* note 11, at 289.

<sup>57</sup> *Id.* See also G.A.O. Report, *supra* note 35, which notes that the European Union has not approved any new GM foods in several years.

<sup>58</sup> Compare Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (2d Cir. 1996) with Council Regulation 258/97, *supra* note 2. The difference between U.S. and European views on labeling could not be starker. A Second Circuit ruling decided that a Vermont statute mandating labeling of dairy products from cows treated with bovine growth hormone was unconstitutional because it violated the dairy manufacturers First Amendment right not to speak. In doing so, the court noted that since there was no proof that the growth hormone was potentially harmful, "strong consumer interest and the public's 'right to know'" were "insufficient to justify compromising protected constitutional rights." See also Oregon ballot initiative election results, available at <http://www.cnn.com/ELECTION/2002/pages/ballot/index.html> (last visited Sept. 6, 2003). A 2002 ballot initiative in Oregon, one of the most progressive in the United States, would have required mandatory labeling of all GMO products entering the state. It failed in a statewide vote by a margin of 71% to 29% after a vigorous statewide debate of the pros and cons of labeling.

<sup>59</sup> Council Regulation 1139/98, *supra* note 2.

cultural system does not allow for the separation of bulk goods into categories of "GMO" and "GMO-free" shipments of grain.<sup>60</sup> Therefore, the United States would have to label any shipments to the European Union, since the shipment "may" contain GMOs.<sup>61</sup> This requirement has led to large losses in U.S. exports, as many E.U. grain buyers are unwilling to purchase GMO-containing products.<sup>62</sup>

To clarify what quantity of GMOs would constitute the need for labeling, the European Union decided on a level of one percent as the *de minimus* threshold for products that would require labeling.<sup>63</sup> This seems to be an arbitrary limit, without a policy or safety justification cited by the Regulation.<sup>64</sup> It may be difficult for the European Union to justify the rationale for this particular limit before the WTO or any other adjudicating body.<sup>65</sup>

#### V. THE E.U. LEGISLATION IS NOT COMPLIANT WITH THE WORLD TRADE ORGANIZATION'S MANDATES

In her article, Ms. Lively contends that these restrictions are not in violation of the Sanitary and Phytosanitary Measures ("SPS") or the Agreement on Technical Barriers to Trade ("TBT") that were signed by the European Union during the Uruguay Round of the General Agreement on Tariffs and Trade. Her thesis is that "considering the real and potentially dangerous health and environmental risks posed by GMOs," the EC's restrictions do not amount to illegal Non-Trade Barriers ("NTBs") "under current international trade law."<sup>66</sup>

Ms. Lively rests heavily on the view that since there is substantial evidence that GMOs pose a threat to health and the environment, regulation is necessary and appropriate. These supposed threats, however, have not necessarily been proven, as will be demonstrated in Section VII. Her article

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<sup>60</sup> Nanda, *supra* note 20, at 276.

<sup>61</sup> Francer, *supra* note 11, at 287-88.

<sup>62</sup> Presumably, this was the effect the interest groups were hoping for: a regulatory mandate that effectively blocks competition from cheaper price exporters. The original Council Regulation 258/97 and Council Directive 90/220 did not provide effective means for keeping out competition of bulk grains, so the regime was tightened by Council Regulation 1139/98. Since the European Union agrees that there is no foreseeable harm that is posed by the soya and maize (the European Union has cleared these products for entry and consumption in Europe) the only reason for the labeling requirements is concern regarding competition, not public safety concern.

<sup>63</sup> Commission Regulation 49/2000, art. 1, 2000 O.J. (L 6) 13; See CORN CAPSULES, *EU Biotech Moratorium Still in Place Despite New Directive*, Nov. 4, 2002, at <http://www.corn.org/web/cc1102.htm>. It is important to note that the European Parliament has been in favor of an even stricter threshold, 0.5%, for labeling.

<sup>64</sup> Commission Regulation 49/2000, *supra* note 63, at art. 8. This Regulation notes that 1% "remains low," yet takes feasibility into account. There is no discussion of why 1% may be significant in affecting health or safety.

<sup>65</sup> Francer, *supra* note 11, at 289.

<sup>66</sup> Lively, *supra* note 3, at 241.

also states that this legislation by the EC is not discriminatory against U.S. exporters. However, she fails to address the fact that the inordinate negative effect this legislation has had on U.S. exporters may be construed by the WTO as a de facto trade barrier. Ms. Lively also uses the Rio Declaration on Environment and Development ("Rio Declaration"), which both the United States and the European Union signed, to purport that the "Precautionary Principle" used by the European Union can justify this legislation.<sup>67</sup> However, the Precautionary Principle has been rejected by the WTO appellate body that invalidated the recent E.U. ban on North American beef.<sup>68</sup> For these reasons and others that will be examined below, the current E.U. regulatory regime on GMOs is out of step with the WTO and its ancillary agreements.

One of the reasons this legislation was necessary at the E.U. level was that some E.U. Member States had already begun individually regulating, and in some cases proscribing, GMOs in a conflicting manner, necessitating a unified, Union-wide policy.<sup>69</sup> One of the reasons that the European Union wrote these regulations was to bring a united European answer to this perceived threat from GMOs that would satisfy the international agreements that the European Union had signed.<sup>70</sup> Nonetheless, in an understandable effort to appease their more stridently GMO-opposing Member States, the E.U. legislation continues to be outside the limit of acceptable restrictions on trade under the WTO agreements.

#### A. The E.U. Legislation is in Conflict with the SPS and TBT Agreements of the WTO.

The European Union's Directive 2001/18 on the deliberate release into the environment of GMOs ("Directive on the Release of GMOs") states that an environmental risk assessment should be performed prior to the release of the GMOs into the environment.<sup>71</sup> This Directive is an amendment to, and repeals, Directive 90/220/EEC on the deliberate release into the environment of GMOs, which is discussed in Ms. Lively's article.<sup>72</sup> The Direc-

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<sup>67</sup> See discussion of precautionary principle *infra* Section V(B).

<sup>68</sup> World Trade Organization, *Report of the Appellate Body: EC Measures Concerning Meat and Meat Products (Hormones)*, Jan. 16, 1998, WT/DS48/AB/R, *WTO Dispute Settlement Decisions*, 4 Bernan's Ann. Rptr. 275 (1998) [hereinafter *WTO Hormone Decision*], available at [http://www.worldtradelaw.net/reports/wtoab/ec-hormones\(ab\).pdf](http://www.worldtradelaw.net/reports/wtoab/ec-hormones(ab).pdf) (last visited Nov. 10, 2003).

<sup>69</sup> Council Directive 2001/18, *supra* note 1, at pmbl., ¶ 18. I believe Denmark and Austria had completely banned GMO or GMO-containing imports, which is obviously contrary to the agreements ancillary to the WTO.

<sup>70</sup> *Id.* at pmbl., ¶ 13. Interestingly, the preamble notes that this Directive should comply with "trade agreements," not mentioning the WTO, but mentioning the Cartagena Protocol on Biosafety. It is clear that this Directive was aimed more at satisfying the requirements of the latter.

<sup>71</sup> *Id.* at pmbl., ¶ 19.

<sup>72</sup> See Lively, *supra* note 3.

tive on the Release of GMOs is in clear contradiction to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) signed by the European Union. The SPS Agreement states, at art. 5, ¶1 that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."<sup>73</sup>

The European Union has essentially reversed the process. The Directive on the Release of GMOs has called for a sanitary measure that is essentially a moratorium on the release of GMOs, until a risk assessment has been carried out.<sup>74</sup> However, the SPS agreement states that any measure should be based on a risk assessment. The European Union is thus precluded from enacting a moratorium, until an assessment shows that there is a risk to human, animal or plant life or health.

There is a potential caveat to the analysis found at art. 5, ¶ 7 of the SPS, which states that "in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information."<sup>75</sup> This question then becomes a virtual Rorschach ink blot test. On the one hand, one could believe that there is no scientific evidence unequivocally proving the safety of GMO use, and therefore, this uncertainty allows the current E.U. regulation. On the other hand, one could believe that since decades of research have not shown sufficient proof that these crops pose a risk, a risk assessment should be done before placing protective measures against their use.

Detractors of biotechnology and GMOs frequently cite the "novelty" of the science.<sup>76</sup> However, merely stating that a technology is new does not make it so. European consumer angst over the use of GMOs may be new, but the use of these products is not. Anti-pest GMOs such as the Bt crops have been in place for over fifteen years<sup>77</sup> and are planted on an area twice the size of Great Britain.<sup>78</sup> Modern biotechnology has been used for over twenty-five years, with "periodic scrutiny and risk evaluation" without evidence of harm as a result.<sup>79</sup> The ability to extract genes and transplant them into different organisms came about in the 1970s.<sup>80</sup> This technology was not invented yesterday, and there is no grounds for a claim that the "rele-

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<sup>73</sup> SPS Agreement, 1867 U.N.T.S. 495, at art. 5, ¶ 1 (emphasis added).

<sup>74</sup> Council Directive 2001/18, *supra* note 1, at pmbl., ¶ 19.

<sup>75</sup> SPS Agreement, *supra* note 4, at art. 5, ¶ 7.

<sup>76</sup> Lively, *supra* note 3, at 243.

<sup>77</sup> Buechle, *supra* note 27, at 289.

<sup>78</sup> *Id.* at 283.

<sup>79</sup> *Id.*; See also, Julian Kinderlerer, *Genetically Modified Organisms: A European Scientist's View*, 8 N.Y.U. ENVTL. L.J. 556, 561 (2000).

<sup>80</sup> G.A.O. Report, *supra* note 35, at 4.

vant scientific information is insufficient" so as to preclude the need for a risk assessment before regulation under SPS Art. 5 ¶ 7.<sup>81</sup>

It is interesting to note that Art 5, ¶ 7 does state that members should base their measures on available pertinent information, including that of relevant international organizations.<sup>82</sup> The United Nations, after a review of the information regarding GMOs, has recommended the expanded use of GMOs to improve yield and nutrition.<sup>83</sup> Such a finding would not be helpful to the European Union in a potential case before the WTO.

Another clause by which the Directive on the Release of GMOs could be struck down by the WTO is art. 4, ¶ 1 of the SPS.<sup>84</sup> This is the equivalence clause of the SPS, and it states that Members shall accept the sanitary or phytosanitary measures of other states if the exporting Member can "objectively demonstrate[] to the importing Member that its measures achieve the importing Member's" level of protection.<sup>85</sup> This is applicable even if the measures of the exporting Member are different from the measures in the importing country.<sup>86</sup> If this portion of the SPS is to be construed literally, the United States should be able to prove to the WTO that the measures the U.S. system takes ensure that GMO products which are marketed and consumed are safe for the environment and/or human consumption. It should not be very difficult to show that the European Union and the United States have equivalent levels of protection for their citizens and environment, since the United States Government has no less than three regulatory bodies—the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Agriculture ("USDA") and the Environmental Protection Agency ("EPA")—that monitor and assure the safety of GM foods.<sup>87</sup> The coordinator of the FDA's food and biotechnology policy, James Maryanski, stated during a recent U.N. panel that there are 50 varieties of GM crops in the U.S. market that are "as safe as other foods on the market."<sup>88</sup> Each of the 50 GM crops that have been approved by the FDA have undergone rigorous testing to pass the scrutiny of the FDA under a policy that started monitoring these crops in 1992.<sup>89</sup>

These controls include the review of necessary data to assess the safety of the crop, the evaluation of the data by teams of diversely qualified FDA agents who can request additional data from the company looking to market the crop, and the tailoring of specific investigations to fit the "novelty" of

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<sup>81</sup> SPS Agreement, *supra* note 4, at art. 5, ¶ 7.

<sup>82</sup> *Id.*

<sup>83</sup> Aita, *supra* note 10.

<sup>84</sup> SPS Agreement, *supra* note 4, at art. 4, ¶ 1.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> Francer, *supra* note 11, at 265-75. Discussion of the regulatory framework concerning GMOs in the U.S., with an emphasis on the FDA's procedures and guidelines.

<sup>88</sup> Aita, *supra* note 10.

<sup>89</sup> G.A.O. Report, *supra* note 35, at 3.

the application, thereby assuring that the FDA has adequate time to study the application.<sup>90</sup> The consultation process between the FDA and the companies has historically been voluntary, but the FDA in 2001 proposed rules which would make this process mandatory, with the companies giving notice to the FDA 120 days before their intended marketing of the product.<sup>91</sup> The proposed rules will not significantly alter current practice, however, as companies now come to the FDA in the early stages of development to streamline the process in a "consultation" that lasts anywhere from 18 months to 3 years.<sup>92</sup> Under the 1992 policy, this includes several risk assessment "decision trees" that provide a "step by step" testing structure.<sup>93</sup> This sounds very similar to the Directive on the Release of GMOs, which states that "the introduction of GMOs into the environment should be carried out according to the 'step by step' principle."<sup>94</sup> The scale of release is increased gradually, but only when prior tests indicate that the next step can be taken.<sup>95</sup> During a recent General Accounting Office survey of the effectiveness of the FDA safety process, the European Union, along with other bodies and organizations, stated that the tests were "good" or "very good" and were adequate to ensure safety of GM products for public consumption.<sup>96</sup>

The USDA and EPA have a stronger role in ensuring the environmental viability of GMOs. For any grower to field test a pest or herbicide-resistant GMO on more than 10 acres, the grower must be reviewed by the EPA and receive a grant.<sup>97</sup> Prior to the commercialization of the crop, the EPA reviews the application, receives comments from the public, and possibly requests the counsel of independent scientific experts.<sup>98</sup>

All of this evidence leads to the conclusion that the United States can "objectively demonstrate" that its measures provide the same level of protection as the E.U. measures. The European Union, therefore, has no alternative under Art 4 ¶ 1 of the SPS but to allow GMOs that had passed U.S. inspection to enter the European Union, particularly after stating in the G.A.O. Report that the FDA measures ensure public safety, and that the FDA regimen of tests provides the "weight of evidence needed for scientists to make an accurate assessment of risk."<sup>99</sup>

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<sup>90</sup> *Id.*

<sup>91</sup> Raymond Formanek, *Proposed Rules Issued for Bioengineered Foods*, FDA CONSUMER, No. 2, Vol. 35, at 9, Mar. 1, 2001, available at [http://www.fda.gov/fdac/features/2001/201\\_food.html](http://www.fda.gov/fdac/features/2001/201_food.html).

<sup>92</sup> G.A.O. Report, *supra* note 35, at 19.

<sup>93</sup> *Id.*

<sup>94</sup> Council Directive 2001/18, *supra* note 1, at pmbl. ¶ 24.

<sup>95</sup> *Id.*

<sup>96</sup> G.A.O. Report, *supra* note 35, at 16.

<sup>97</sup> *Id.* at 7.

<sup>98</sup> *Id.*

<sup>99</sup> *Id.* at 16.

B. The European Union cannot rely on the use of the "Precautionary Principle" to prevent GMOs from entering the European Union

The European Union has explicitly based its regulation of the release of GMOs into the environment and placing of GMOs on the market on the "Precautionary Principle."<sup>100</sup> In fact, one of the reasons the Directive on the Release of GMOs was enacted, replacing Directive 90/220, was to make more explicit reference to the Precautionary Principle as a justification for the regulation.<sup>101</sup>

Title XIX ("the Environment title") of the Treaty Establishing the European Community ("EC Treaty") upholds as two of its objectives "protecting and improving the quality of the environment" and "protecting human health."<sup>102</sup> To this end, EC policy concerning "the environment shall aim at a high level of protection" and "shall be based on the precautionary principle."<sup>103</sup> Although only the Environment title of the E.U. treaty states a use of the precautionary principle as policy, subsequent European Commission Communications have expanded the European Union's understanding of the precautionary principle to include human health as well.<sup>104</sup>

The precautionary principle is a relatively new term in the lexicon of environmental regulation. The German Green Party introduced the term,<sup>105</sup> and it only "acquired currency" in the 1990s.<sup>106</sup>

The definition of the precautionary principle is not given in the E.U. Treaty, or in the Directives that regulate the production and distribution within the European Union of GMOs. That lack of definition is intended, presumably, to allow the European Union the leeway to carry out whatever measures it feels are necessary to "maintain a high level of protection."<sup>107</sup>

The Rio Declaration on Development and the Environment explained a precautionary principle cited in the document as "lack of full scientific certainty shall not be used as a reason for postponing cost effective measures

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<sup>100</sup> Council Directive 2001/18, *supra* note 1, at pmb1., ¶¶ 6, 8.

<sup>101</sup> Ruth MacKenzie & Sylvia Francescon, *The Regulation of Genetically Modified Foods in the European Union: an Overview*, 8 N.Y.U. ENVTL. L.J. 530, 541 (2000).

<sup>102</sup> CONSOLIDATED VERSION OF THE TREATY ESTABLISHING THE EUROPEAN COMMUNITY, Dec. 24, 2002, tit. XIX, art 174, O.J. (C 325) 107 (2002) [hereinafter EC TREATY].

<sup>103</sup> *Id.* at 117.

<sup>104</sup> MacKenzie, Francescon, *supra* note 101, at 533. *See also* Council Directive 2001/18, *supra*, note 1, at pt. A, art. 1.

<sup>105</sup> JOHN BRAITHWAITE & PETER DRAHOS, *GLOBAL BUSINESS REGULATION* 284 (Cambridge U. Press 2000).

<sup>106</sup> *Id.* at 525.

<sup>107</sup> EC TREATY, *supra* note 102, at 117. *See also* Council Directive 2001/18, *supra* note 1. The lack of a definition of this term is especially frustrating in the Directives, since there is a section on definitions that is intended to guide the different states in the implementation of the E.U. legislation. It is the author's contention that this ambiguity is designed to allow any measures taken by the Member States to be qualified a "precautionary principles" taken to protect their markets.

to prevent environmental degradation.”<sup>108</sup> However, there is no consensus as to the meaning of precautionary principle, leading to uncertainty about its application.<sup>109</sup> This uncertainty lessens the practical utility of the precautionary principle as a means of regulating these new agricultural biotechnologies and will continue to do so until its meaning is interpreted with authority.<sup>110</sup> Because of its abstract nature, the “precautionary principle tends to lose in rhetorical battles with the principle of deregulation.”<sup>111</sup>

### C. Previous WTO Rulings Undermine the Ability of the European Union to apply the Precautionary Principle

Although the precautionary principle is embedded in the E.U. Treaty, it is questionable whether it applies to human health or environmental standards that have international applications. In an important 1998 decision, a WTO Appellate Body heard arguments from the United States, Canada, and the European Union concerning the use of natural and synthetic growth hormones in North American cattle<sup>112</sup> (“WTO Hormone Decision”). Although strictly speaking, WTO Appellate Body rulings apply only to the facts and parties at hand, the Appellate Body “has recognized that prior decisions are important, since the precedents create legitimate expectations among WTO members.”<sup>113</sup> Therefore, the WTO Hormone Decision is instructive as to how the WTO may rule in a similar case.

The WTO Hormone Decision arose out of a complaint from the United States and Canada concerning a series of E.U. Directives prohibiting the import of bovine meat and meat products where the cattle had been given either natural or synthetic hormones for growth purposes.<sup>114</sup> The United States and Canada claimed that these Directives were in violation of the SPS Agreement ancillary to the WTO.<sup>115</sup> The WTO Appellate Body concluded that the EC had violated the SPS Agreement and requested that the EC bring their SPS measures (the Meat Products regulations) into conformity with their obligations under the WTO Agreements.<sup>116</sup>

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<sup>108</sup> Rio Declaration on Environment and Development, June 13, 1992, U.N. Conference on Environment and Development, Annex 1, princ. 15, A/CONF.151/26 (Vol. I), 31 I.L.M. 874, 879 (1992), available at <http://www.un.org/documents/ga/conf151/> (last visited Nov. 28, 2003).

<sup>109</sup> Dorothy Nelkin, Philippe Sands & Richard B. Stewart, *The International Challenge of Genetically Modified Organism Regulation*, 8 N.Y.U. ENVTL. L. J. 523, 526 (2000).

<sup>110</sup> *Id.*

<sup>111</sup> BRAITHWAITE & DRAHOS, *supra* note 105, at 284.

<sup>112</sup> WTO Hormone Decision, *supra* note 68.

<sup>113</sup> John S. Fredland, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically-Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183, 196 (2000).

<sup>114</sup> WTO Hormone Decision, *supra* note 68, at 285.

<sup>115</sup> *Id.* at 296.

<sup>116</sup> *Id.* at 352.



In their arguments before the Appellate Body, the European Union argued that it could override Articles 5.1 and 5.2 of the SPS by using the precautionary principle.<sup>117</sup> Articles 5.1 and 5.2 state that any sanitary or phytosanitary measures must be based on an appropriate assessment of the "risks to human animal or plant life or health"<sup>118</sup> and this risk assessment should take into account available scientific evidence, etc.<sup>119</sup>

In the Beef Hormone decision, the WTO body claimed that "the precautionary principle ... still awaits authoritative formulation."<sup>120</sup> The Appellate Body concludes that even if the precautionary principle were to be considered a "general customary rule of international law," it does not, by itself, relieve the Appellate Body from reading the provisions of the SPS agreement, and therefore the Appellate Body agreed with the Panel (first instance body) "that the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the SPS Agreement."<sup>121</sup>

Furthermore, the European Court of Justice has decided a string of cases that could invalidate the current E.U. moratorium, based on its own application of the precautionary principle. These include *Kellogg v. Norwegian Food Control Agency* and *Monsanto v. Council of the European Union*.<sup>122</sup> In these cases, the European Court of Justice rejected appeals to the precautionary principle by various governments looking to keep imports out of their territory. The court did not decide in favor of the E.U. Member States (e.g. Denmark) due to the fact that there was no risk assessment performed on the part of the E.U. Member States.<sup>123</sup>

It is plausible that the European Court of Justice would strike down these anti-GMO Regulations based on the European Union's own understanding of the Precautionary Principle. A Communication from the European Commission on the on the Precautionary Principle stated these five guidelines:

1. Measures ... must not be disproportionate to the desired level of protection and must not aim at zero risk.
2. Comparable situations should not be treated differently, and ... different situations should not be treated in the same way, unless there are objective grounds for doing so.
3. Measures ... should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.

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<sup>117</sup> *Id.*

<sup>118</sup> SPS Agreement, *supra* note 4, at 496.

<sup>119</sup> *Id.*

<sup>120</sup> WTO Hormone Decision, cited by Linda O'Neil Coleman, *The European Union: An Appropriate Model for a Precautionary Approach?*, 25 SEATTLE U. L. REV. 609, 631 (2000).

<sup>121</sup> WTO Hormone Decision, *supra* note 68, at 315.

<sup>122</sup> Coleman, *supra* note 120, at 622-23.

<sup>123</sup> *Id.*

4. This examination should include an economic cost/benefit analysis when this is appropriate and feasible. However, other analysis methods ... may also be relevant.
5. The measures must be of a provisional nature pending the availability of more reliable scientific data... Scientific research shall be continued with a view to obtaining more complete data.<sup>124</sup>

The European Union, in carrying out this five-year moratorium, has not followed these guidelines. The moratorium itself, by definition, is based on a "zero risk" strategy.<sup>125</sup> The length of the moratorium proves that it is not of a "provisional nature,"<sup>126</sup> nor does it seem that the European Union has been actively continuing "scientific research"<sup>127</sup> to gain more complete data during the last five years. If these concerns were brought before the European Court of Justice, that judicial body could rule against the European Union in this regard.

Therefore, the European Union cannot state that they have enacted these matters as a protective measure under the precautionary principle; there needs to be a risk assessment performed to establish that there is a risk to human, animal or plant life of health, even under the European Union's own definition of the term.

#### D. The European Union has not Performed a Risk Assessment Regarding the Safety of GMOs

There is one striking difference between the Beef Hormone situation and the current situation: the European Union has not conducted any studies to determine the potential risks to human health or the environment from the release into the environment or placing on the market of GMOs. In the Beef Hormone situation, the European Union had conducted or participated in several studies, including the *1982 Report of the EC Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the basis of the Report of the Scientific Group on Anabolic Agents in Animal Production ("Lamming Report")*.<sup>128</sup> That is not the case in the GMO scenario. What the European Union can point to is a "hysterical ... media reaction"<sup>129</sup> and "adverse public opinion"<sup>130</sup> based

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<sup>124</sup> Communication from the Commission on the Precautionary Principle, European Union Preparatory Acts, COM (00) 1 final, cited in Coleman, *supra* note 120, at 624.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> WTO Hormone Decision, *supra* note 68, at 336. This is only one of six scientific studies that were reportedly included by the European Union in the decision to ban North American beef products. However, as the Appellate Body pointed out, each one of these studies proved the meat products to be safe, and therefore did not rationally support the EC import prohibition.

<sup>129</sup> Kinderlerer, *supra* note 79, at 557.

<sup>130</sup> *Id.* at 563.

mainly from fears generated by other food crises such as BSE (mad cow disease), salmonella, E. coli, and other failings of the European regulatory system.<sup>131</sup> It seems that the European government leaders have abdicated their duty to educate their citizens (or failed to educate themselves) about the benefits and risks of GMOs, rather than regulating in reaction to “unwarranted public hysteria.”<sup>132</sup> Unfortunately for the European Union, the factors of public and media hysteria cannot be considered as an argument before the WTO.<sup>133</sup> So, what has the European Union done to show that it has scientific proof of a threat from GMOs?

Ms. Lively’s article cites the opinion from the 1998 “Beef Hormone” decision of the WTO Appellate Body that stated that if there is not a “known harmful effect on human health or the environment, then the regulations in question cannot be considered ‘effective’ for achieving their protective goal and therefore, are not necessary.”<sup>134</sup> In other words, without a risk assessment demonstrating a harmful effect on health or the environment, the regulation will not stand, since it cannot rest solely on the “precautionary principle” embedded in the E.U. Treaties.<sup>135</sup> Ms. Lively agrees that “[n]o existing scientific evidence shows that GMOs positively pose serious threats to human or environmental health.”<sup>136</sup> Therefore, even under her own analysis, the WTO would have to strike down the E.U. legislation, because restrictive trade practices cannot be based on simple intuition that a product is dangerous; there must be a risk assessment that points to that conclusion. Otherwise, the legislation is purely arbitrary and therefore discriminatory.

#### E. The Cartagena Protocol On Biosafety

Furthermore, Ms. Lively does not take note of the Cartagena Protocol on Biosafety, another treaty signed by both the United States and the European Union.<sup>137</sup> This document enumerates safety measures that can be taken by Member States to protect their environments from “the consequences of genetic engineering.”<sup>138</sup> One of its provisions is that a state can prohibit the import of GMOs even if there “is a lack of scientific certainty” that the product is dangerous.<sup>139</sup> However, this ability to prohibit GMOs

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<sup>131</sup> *Id.* at 556.

<sup>132</sup> Francer, *supra* note 11, at 313.

<sup>133</sup> Kinderlerer, *supra* note 79, at 563.

<sup>134</sup> Lively, *supra* note 3, at 254.

<sup>135</sup> See WTO Hormone Decision, *supra* note 68.

<sup>136</sup> Lively, *supra* note 3, at 253.

<sup>137</sup> *Id.*

<sup>138</sup> Coleman, *supra* note 120, at 631 n.62.

<sup>139</sup> Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (2000) (entered into force Sept. 11, 2003), available at <http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf> (last visited Nov. 28, 2003) [hereinafter Cartagena Protocol].

only applies to living organisms, since no advance notice or permission is required "for exports of agricultural commodities meant for eating or processing."<sup>140</sup> The Cartagena Protocol's scope is limited to "living modified organisms"<sup>141</sup> which are defined as a "biological entity capable of transferring or replicating genetic material."<sup>142</sup> Once the "LMO" has been processed, it no longer is able to transfer genetic material, and is therefore not subject to pre-approval upon importation.<sup>143</sup> Therefore, under the Cartagena Protocol, the United States would have the ability to strike out the portions of the E.U. legislation that attach testing periods for products that are designed for eating or processing.<sup>144</sup>

## F. Conclusion

Therefore, the United States could invalidate this policy not only under the Appellate Body of the WTO, but also under the Cartagena Protocol, or even the European Union's own court system. The U.S. Trade Representative was correct when he said that the current E.U. moratorium is contrary to European and international law.<sup>145</sup>

## VI. AN EXAMINATION OF THE EVIDENCE THAT SUPPORTS A CLAIM OF THE DANGERS OF GMOS.

Ms. Lively refers to three instances that support the belief that GMOs are potentially harmful to health and the environment. They are the Brazil nut case,<sup>146</sup> the Monarch butterfly case,<sup>147</sup> and the Arpad Pusztai experiment that "proved" that rats which were fed GM potatoes experienced health problems.<sup>148</sup> However, while each of these examples has been used time and again by the detractors of GMO technology, each bears little weight.

### A. The Brazil Nut

In the Brazil nut case, researchers had inserted a gene from the Brazil nut into a strain of soybeans, with the hope of enhancing the protein content of the soybean.<sup>149</sup> They succeeded in this attempt, making the soybean in question more nutritionally rich, without any detriment to the yield or quality of the crop.<sup>150</sup> However, the trait of the Brazil nut gene that causes an

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<sup>140</sup> Cartagena Protocol, *cited by* Coleman, *supra* note 120, at 632.

<sup>141</sup> Buechle, *supra* note 27, at 285.

<sup>142</sup> Cartagena Protocol, *supra* note 139, at art. 3(h).

<sup>143</sup> Buechle, *supra* note 27, at 286.

<sup>144</sup> See generally Cartagena Protocol, *supra* note 139.

<sup>145</sup> CORN CAPSULES, *supra* note 63.

<sup>146</sup> Lively, *supra* note 3, at 244.

<sup>147</sup> *Id.*

<sup>148</sup> *Id.* at 16.

<sup>149</sup> Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*,

344 NEW ENG. J. MED. 688, 688 (1996).

<sup>150</sup> *Id.*

allergic reaction in some people was also transferred to the soybean, so that people who ate the soybean would have the same reaction that they had to the nut.<sup>151</sup> There are two reasons why this situation does not prove the dangers of GMOs. First, the researchers tested the soybean for any allergic reactions before the soybean was produced commercially; there were safety checks in place to assure the product's safety before market placement.<sup>152</sup> Second, there are thousands of products that contain possible allergens, and the FDA allows them to go to market once they have a label to describe the allergen that the product contains.<sup>153</sup> Had the company gone ahead with production and distribution, it is possible that all that would be needed to guarantee the safety of products made from the soybean would be a label.<sup>154</sup> This case is the only known case of an allergen being transmitted to a GMO, and it was discovered before it ever reached the market.<sup>155</sup>

### B. The Monarch Butterfly

The second example of a harm committed by the use of GMOs is the toxicity of Bt corn (maize) to the Monarch butterfly. This corn contains a pesticide that is lethal to the European corn borer, an insect that destroys "thousands of acres of crops each year."<sup>156</sup> What is interesting in this debate is that "organic" growers have been spraying the Bt protein on their crops since the 1960s, but they are dead set against the "Frankenstein Food" containing the Bt protein.<sup>157</sup> A study conducted by Cornell University caused shockwaves when it reported that the Bt contained in GMO corn pollen was toxic to Monarch butterfly larvae.<sup>158</sup> However, this research was done in a lab, not in the field.<sup>159</sup> Later testing, conducted on behalf of the EPA, disputed the findings of the Cornell study.<sup>160</sup> This study, published in the *Proceedings of the National Academy of Science* (PNAS) in September,

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<sup>151</sup> See generally *id.*

<sup>152</sup> *Id.* The opening paragraph of the Nordlee article states that the reason for this study is a FDA-mandated test for developers of new plant varieties. See also Buechle, *supra* note 27, at 293. The bean was never produced commercially, as researchers discovered the problem before any beans were sold.

<sup>153</sup> FOOD & DRUG ADMIN., DEP'T HEALTH & HUMAN SERVICES, FED. REGISTER, VOL. 57, NO. 104, STATEMENT OF POLICY: FOODS DERIVED FROM NEW PLANT VARIETIES 22984-23005 (1992). Cited in Nordlee et al., *supra* note 149.

<sup>154</sup> Nordlee et al., *supra* note 149, at 691. In fact, this is the prescribed remedy: if the product goes to market, there should be a label alerting consumers of the possible allergenic properties of the food.

<sup>155</sup> G.A.O. Report, *supra* note 35, at 16.

<sup>156</sup> Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 59 (2001), cited in Lively, *supra* note 3, at 245.

<sup>157</sup> Kolehmainen, *supra* note 9, at 273.

<sup>158</sup> CNN.com, *Researchers Find Bio-engineered Corn Harms Butterflies*, May 20, 1999, at <http://www.cnn.com/NATURE/9905/20/butterfly.killers/> (last visited Sept. 6, 2003).

<sup>159</sup> *Id.*

<sup>160</sup> GEO-PIE, *Impact of Bt-corn on Monarch Butterflies*, Sept. 2001, available at <http://www.comm.cornell.edu/gmo/issues/monarchs.html> (last visited Sept. 6, 2003).

2001, studied the amounts of Bt-corn pollen residue on milkweed plants (the Monarch larvae's only food source) close to corn fields. The researchers then fed those amounts to the Monarch butterfly larvae.<sup>161</sup> The researchers, who included scientists from activist groups and the EPA, as well as the Cornell researcher who conducted the laboratory study, found the effects on the butterfly larvae to be negligible, even if the entire corn market were saturated with Bt corn.<sup>162</sup> Only one strain of Bt corn was shown to have a negative effect on the butterflies, and that strain, *Event 167*, has since been discontinued.<sup>163</sup> The researchers also came to the conclusion that the use of traditional pesticides would have a greater negative impact on the butterflies.<sup>164</sup> Therefore, the use of GM corn, at first thought to be harmful to Monarch butterflies and other "showcase" fauna, may, on second reflection, be a positive alternative to traditional crops that need to be sprayed with pesticide.

Finally, it must also be pointed out that Europe does not have a natural population of Monarch butterflies, and therefore this particular risk to the environment cannot be cited by E.U. regulators.<sup>165</sup>

### C. The Arpad Pusztai Study

The third example of the potential danger of GMOs which received considerable press is the study performed in Scotland by Arpad Pusztai in 1998, which reported that rats who consumed transgenic potatoes (containing a gene encoding a lectin, a protein that can deter pest insects) for a period of ten days<sup>166</sup> suffered stunted growth and weakened immune systems.<sup>167</sup> It must be noted that crops containing this particular lectin, GNA, are still experimental and "haven't made it to the market yet."<sup>168</sup> However, two days after the press release of these findings, the director of the Rowett Institute, where the work was carried out, stated that "Pusztai's

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<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

<sup>165</sup> Monarch Butterfly, at <http://www.gpnc.org/monarch.htm> (last visited Sept. 6, 2003). Several websites devoted to the preservation of the Monarch butterfly noted that the destruction of Mexican forests, where the butterflies winter, is problematic to the survival of the Monarch, but not one mentioned the use of Bt corn as a factor.

<sup>166</sup> There is a discrepancy here. An article in the first *Science* journal, Martin Enserink, *Preliminary Data Touch off Genetic Food Fight*, 283 SCI. 1094 (Feb. 19, 1999), claimed that the study had been performed over a period of 110 days. An article in the second *Science* journal, Martin Enserink, *The Lancet Scolded over Pusztai Paper*, 286 SCI. 656 (1999), quoted ten days. However, upon review of Pusztai's published article in *The Lancet*, the duration of testing was confirmed as ten days. Stanley W. B. Ewen & Arpad Pusztai, *Effect of Diets Containing Genetically Modified Potatoes Expressing Galanthus Nivalis Lectin on Rat Small Intestine*, 354 THE LANCET 1353 (Oct. 16, 1999).

<sup>167</sup> Williams, *supra* note 16, at 768.

<sup>168</sup> Enserink, *The Lancet Scolded over Pusztai Paper*, *supra* note 166, at 656.

data turned out to be ‘a total muddle’” since the “conclusions were based on experiments with non-transgenic potatoes spiked with a lectin.”<sup>169</sup> Later, a committee audited Pusztai’s work and concluded that the evidence did not suggest the potatoes affected the “growth, organ development, or immune function” of the rats.<sup>170</sup> Obviously, this row has only led to more anxiety in an “already confused and worried public” in the European Union and especially the United Kingdom.<sup>171</sup>

A year later, on October 16th, 1999, *The Lancet*, a “prestigious journal” in the United Kingdom, published Pusztai’s paper detailing his experiment with rats and transgenic potatoes.<sup>172</sup> The Royal Society, among others, criticized *The Lancet*, contending that the raw data was “deeply flawed” and that the journal was exploiting the paper for its own publicity.<sup>173</sup> The editor in chief of *The New England Journal of Medicine* was quoted as saying, “[w]hen was the last time [*The Lancet*] published a rat study that was uninterpretable? This really was dropping the bar.”<sup>174</sup> John Pickett, one of the experts who was asked to review the article before publication, recommended that the journal reject the paper. He told the BBC in an interview that had it been a student’s study, “the student would have failed whatever examination” to which he was contributing.<sup>175</sup>

In its published version, Pusztai’s earlier claims of stunted growth or suppressed immune systems were not raised. Instead, the paper focuses on the thickening of the mucosal lining in the intestinal tracks of rats who had eaten transgenic potatoes.<sup>176</sup> Even these findings do not go uncontested. In the same issue of *The Lancet*, a comment on the study by three Dutch researchers details the flaws of Pusztai’s paper: the differences in the rats could be based on nutritional differences between the potatoes, the small number of specimens (only 6 rats in each group), and the rats, protein starved from their all-potato diet, were poor candidates to assess the toxicity of the lectin.<sup>177</sup>

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<sup>169</sup> Enserink, *Preliminary Data Touch off Genetic Food Fight*, *supra* note 166, at 1094.

<sup>170</sup> *Id.* at 1095.

<sup>171</sup> *Id.*

<sup>172</sup> Ewen & Pusztai, *supra* note 166, at 1353.

<sup>173</sup> Enserink, *The Lancet Scolded over Pusztai Paper*, *supra* note 166, at 656.

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> Ewen & Pusztai, *supra* note 166, at 1353.

<sup>177</sup> Harry A. Kuiper et al., *Adequacy of the Methods for Testing the Safety of Genetically Modified Foods*, 354 THE LANCET 1315-16 (Oct. 16, 1999). Incidentally, in another recent edition of *The Lancet*, a different article punctured holes in the common wisdom that organic produce is safer and healthier than conventional mass-produced crops. Apparently, at the same time the original Pusztai findings were splashed on tabloid presses around the world, another study showed a link between a popular “natural” insecticide and Parkinson’s disease. However, as the authors of this article note, Greenpeace didn’t come out and condemn all organic farmers using this pesticide or demand that all 680 products on grocery shelves that use the “natural” insecticide be removed. Shane Morris & Doug Powell, *Rats and risk*, 357 THE LANCET, Jan. 27, 2001, at 309-10. Call it what you will, I’ll call it selective paranoia.

The study's poor reception from the scientific community questions its strength as an example of GMO's negative health effects. Not a single marketed GMO has been shown to harm or threaten human health.<sup>178</sup> It is not possible for the European Union to contend that a risk assessment has been performed that would call for the restriction on imports of GMOs, since no reliable studies conclude that consumption of GMOs currently on the market poses a health risk.<sup>179</sup>

#### D. Fears of Cross-Pollination

Another fear mentioned by Ms. Lively in her article is that these GMOs can transfer their DNA to non-transgenic plants, creating "super-weeds" that would be resistant to herbicide or increase the resistance of insects to pesticide.<sup>180</sup>

This does not seem to be a fear amongst the scientists who have made long-term studies of this problem. In a ten year study conducted by the Imperial College in London, transgenic plants were shown to be no more likely to survive or spread than their traditional counterparts. All four GMO crop samples died out after having been left unattended for four years.<sup>181</sup> Other studies have shown that it is unlikely that weeds will inherit tolerances from GMOs<sup>182</sup> and also that steps can be taken to prevent this transfer from occurring.<sup>183</sup>

#### E. Fears of Antibiotic Resistance

Lastly, Ms. Lively cites the fear that the antibiotic-resistant marker genes, which scientists use to track seeds that have inherited the transplanted trait, implanted in GMOs may transfer to humans through consumption.<sup>184</sup> This would lead to people becoming resistant to antibiotic treatment, increasing the difficulty in fighting disease.<sup>185</sup>

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<sup>178</sup> Editorial, *Biotech Panderers*, WASH. POST, Aug. 5, 2001, at B6.

<sup>179</sup> G.A.O. Report, *supra* note 35, at 2. Every one of the 50 GMOs that have been approved by the U.S. regulatory regime were deemed safe by the independent audit conducted by the U.S.G.A.O. in consultation with the National Academy of Sciences.

<sup>180</sup> Lively, *supra* note 3, at 245.

<sup>181</sup> M. J. Crawley et al., *Transgenic Crops in Natural Habitats*, 409 NATURE 682 (Feb. 8, 2001). See also, John Whitfield, *GM Plants Make Weedy Weeds*, Nature.com, (Feb. 8, 2001), available at <http://www.nature.com/nsu/010208/010208-9.html>. Whitfield's article clarifies that all the GM crops had died during the first four years, and that this study should "allay fears that GM plants will be super-weeds, either in their own right or by breeding with unmodified plants."

<sup>182</sup> See Cliff D. Weston, *Chilling of the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law and the Cartagena Protocol*, 4 J. SMALL & EMERGING BUS. L. 377, 403 (2000).

<sup>183</sup> See Norman Borland, *We Need Biotech to Feed the World*, WALL. ST. J., Dec. 6, 2000, at A22.

<sup>184</sup> Lively, *supra* note 3, at 244-5.

<sup>185</sup> *Id.*



This fear is without support for several reasons. First, the antibiotics tracked by the marker genes are highly toxic and rarely, if ever, used clinically to fight disease.<sup>186</sup> Second, the marker gene appears in trace amounts too small to be able to degrade antibiotics.<sup>187</sup> Third, no naturally occurring mechanism exists that allows the transfer of genes from plant DNA to a microbe.<sup>188</sup>

#### F. Conclusion of Risks Posed by GMOs

In conclusion, there is no substantiated study or proof that GMOs pose a threat to human health, animal health, or the environment. Without an assessment showing a risk to "human, animal or plant life or health," the European Union cannot proscribe sanitary measures against GMO import or use under the SPS agreement.<sup>189</sup>

### VII. CONCLUSION: THE EUROPEAN UNION HAS VIOLATED INTERNATIONAL LAW WITH ITS MORATORIUM ON THE INTRODUCTION OF GMOs

The European Union has violated the SPS and TBT Agreements to the Marrakesh Agreement creating the WTO by enacting the Directive on the Release of GMOs. A WTO Dispute Settlement Panel would find the European Union in violation because it bases its restrictions on the precautionary principle, rather than the risk assessment requirements of SPS Agreement Articles 5.1 and 5.2. A WTO Dispute Settlement Panel would further find that the European Union has not performed a risk assessment to ascertain whether these restricted GMOs are dangerous to human health or the environment. This same body would find that SPS Art. 4.1, the Equivalence Article, precludes the European Union from regulating these GMOs, since they are already subject to equivalent regulation in the United States. Finally, if a Dispute Settlement Panel were to consult scientific experts about the level of risk inherent in GMOs, the experts would indicate a low level of risk and thus undermine support of the E.U. regulation.

#### A. The European Union Incorrectly Used the Precautionary Principle

In the WTO Hormone Decision, the Appellate Body found that the European Union could not use the precautionary principle as a method of circumventing the need to perform a risk assessment under the SPS Agreement Articles 5.1 and 5.2 before enforcing restrictions on imports.<sup>190</sup> Here, in the matter of GMOs, the European Union has made the same error, referring to the precautionary principle in the Directive as a source of authoriza-

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<sup>186</sup> Francer, *supra* note 11, at 294.

<sup>187</sup> *Id.*

<sup>188</sup> See generally *id.*

<sup>189</sup> SPS Agreement, *supra* note 4, at 5, ¶ 1.

<sup>190</sup> WTO Hormone Decision, *supra* note 68, at 351.

tion, rather than the SPS Agreement.<sup>191</sup> A Dispute Settlement Panel should have clear grounds to strike down the EC's use of the precautionary principle to authorize the regulations.

B. The European Union Failed to Perform a Risk Assessment under SPS Articles 5.1 and 5.2 before enacting the Moratorium

The European Union has not performed the necessary risk assessments under the SPS to raise concerns about GMOs. In the WTO Hormone Decision, the European Union cited six studies on the effects of growth hormones, some of which it had organized, to comply with the requirements of the SPS.<sup>192</sup> Although the Panel and the Appellate Body found these studies to show that hormones did not pose an identifiable risk, it was noted that studies were performed under the auspices of the European Union.<sup>193</sup> In the present case, the European Union has not performed systematic and independent research on the matter. Directive 2001/18/EC requests the Member states and the Council to conduct such tests and ensure that adequate funds are provided to conduct such research.<sup>194</sup> However, this is clearly in contrast to the requirements of the SPS, where a sanitary measure is to be "based on an assessment . . . of the risks to human, animal or plant life or health."<sup>195</sup> The Beef Hormone Decision supports this analysis.<sup>196</sup>

C. The European Union Cannot Use SPS Art 5.7 as a Means to Circumvent the Need for a Risk Assessment

The European Union will undoubtedly counter that this situation falls under the category of SPS Art. 5.7, and, therefore, a risk assessment is not necessary. However, although the media frenzy in Europe may only be a few years old, the technology is not. Scientists have been improving and testing these technologies for over two decades now, without evidence of harm as a result.<sup>197</sup> Therefore, no ground exists for a claim that the "relevant scientific information is insufficient" to preclude the need for a risk assessment before regulation.<sup>198</sup>

D. The United States has an Equivalent Regulatory Framework in Place, and this Precludes the Need for E.U. Regulation

SPS 4.1 clearly states that a member shall accept the sanitary measures of other members as equivalent, even if those measures differ from their

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<sup>191</sup> Council Directive 2001/18, *supra* note 1, ¶ 8.

<sup>192</sup> WTO Hormone Decision, *supra* note 68, at 336.

<sup>193</sup> *Id.*

<sup>194</sup> Council Directive 2001/18, *supra* note 1, ¶ 21.

<sup>195</sup> SPS Agreement, *supra* note 4, at 496.

<sup>196</sup> WTO Hormone Decision, *supra* note 68, at 335.

<sup>197</sup> Kinderlerer, *supra* note 79, at 561.

<sup>198</sup> SPS Agreement, *supra* note 4, at 496.

own, where the exporting member can objectively demonstrate the appropriate level of sanitary protection.<sup>199</sup> The United States has one of the most stringent regulatory systems in the world, and since 1986 there have been safety measures in place from the Food and Drug Administration, the U.S. Department of Agriculture, and the Environmental Protection Agency that monitor and require testing of any new product introduced to the market or released into the environment.<sup>200</sup>

E. Evidence does not Predict Health or Environmental Damage from the Continued Use of GMOs

When placed under serious scientific scrutiny, GMOs come away as safe, or safer, than traditional crops that require spraying with insecticide or other noxious chemicals.<sup>201</sup> All that remain are over-cited animal studies, vague concerns about the possibility of resistance to antibiotics, and ill-founded concerns about pollen transfer creating "superweeds." The fact remains that food borne illness is generally a product of under-cooking and poor handling and storage, not "Frankenstein Food."<sup>202</sup>

For all of these reasons, the World Trade Organization Dispute Settlement Panel will find the European Union to have improperly restricted the import and distribution of Genetically-Modified Organisms if and when it hears the case.

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<sup>199</sup> *Id.* at 495.

<sup>200</sup> See generally G.A.O. Report, *supra* note 35. Overview of the different agencies' roles in monitoring GMOs.

<sup>201</sup> See discussion *supra* Section VI.

<sup>202</sup> Jim Richardson, *Food: How Safe, How Altered*, NATIONALGEOGRAPHIC.COM, at [http://magma.nationalgeographic.com/ngm/0205/sights\\_n\\_sounds/media2.html](http://magma.nationalgeographic.com/ngm/0205/sights_n_sounds/media2.html) (last visited July 21, 2003). After spending a year touring the world in search of the "problem" of high tech food production, Richardson came home, bought a thermometer for his refrigerator, and started washing his hands before eating.