

# MULTIPARTY NEGOTIATION SIMULATION

## The Salmon Case:

### GMOs in the Production of Food and Commodity Exports

#### Introduction

The use of genetically modified organisms in food production and the production of food commodities has become a subject of considerable controversy and debate. Questions pertaining to potential impacts on human health and the environment have resulted in the polarization of stake holders including agricultural, fish and livestock producers, environmentalists, food safety regulators, and international trading partners and trade officials.

In 1992, 175 nations signed the Convention on Biological Diversity at the Earth Summit held in Rio de Janeiro, Brazil. The Convention committed the signatory nations to develop an agreement on the safe transfer, handling, and use of genetically modified organisms (GMOs). In February of 1999, the signatory nations reconvened in Cartagena, Colombia to negotiate the Biosafety Protocol which was finalized in January, 2000 in Montreal, Canada and signed by 130 countries (not including the U.S.). The Biosafety Protocol deals with the use of GMOs in commodities that may be used in food production but does not specifically deal with the use of GMOs in food products marketed for direct consumption.

At issue are the apparently competing standards related to the use of GMOs in the production, manufacturing, and export of commodities and food. The use of GMOs in the production of consumable food products is covered by the Sanitary and Phytosanitary Standards (SPS) of the WTO/GATT. The Biosafety Protocol introduces the *precautionary principle* as the acceptable standard for controlling the use of GMOs in commodities to be exported from one country to another. This simulation is designed to introduce negotiations related to the reconciliation of these standards among nations and trading regimes that have articulated different interests in the standards to be employed with respect to GMO labelling.

#### Scenario

For purposes of this simulation exercise, a hypothetical set of facts have been developed involving the use of GMOs or genetic engineering in the production of salmon as both a food (ready for consumption) and as a commodity (for live fish farming and as a byproduct used in fertilizer production.) The scenario will include developed and developing countries and will mirror contemporary negotiations on the appropriate standards, protocols, and labelling procedures to be required with the export of salmon as food and as a commodity in trade. More specific criteria for the simulation and party instructions are set forth, *infra.*, at pps27-29.

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#### BACKGROUND

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"Genetically modified organism," or GMO, means a living organism in which the genetic material has been permanently altered through gene technology in a way that does not occur naturally by multiplication and/or natural recombination.

Since its introduction to the market in 1992, genetically engineered material has become a common ingredient in many types of foods sold and produced in the U.S. Since the growing and marketing of food products that contain or are derived from genetically modified organisms remain largely unregulated in the U.S., most Americans have not been aware of their existence and until recently, there has been little or no opposition to the sale of such products without special labels.

In the EU, on the other hand, public protests against GMOs have been loud, powerful, and sometimes even violent. Since the outbreak of mad cow disease in Britain and the dioxin scandal in Belgium, food safety has become a highly prioritized issue on the EU's agenda. Because not enough scientific tests have been conducted to date, the EU has relied heavily on the "precautionary principle" in its defense against imports of GM material. GMOs are living organisms created through genetic engineering that permits scientists to transplant the genes of

one species to another for the purpose of transferring desirable characteristics. Genetic modification thus entails the permanent alteration of the species' genetic code (DNA) through laboratory methods, which cannot be duplicated by way of natural reproductive means. So far, this process has been applied primarily to agricultural crops to improve their resistance to disease, pesticides, and herbicides, enhance nutritional content, and increase yield. Corn, soybeans, cotton, and potatoes are among the bio-engineered products already on the market. Other research has focused on manipulating the genes of fish in order to obtain varieties with a faster growth rate. More extreme examples of transgenic research include the transfer of certain fish genes into strawberries and tomatoes to make them frost-resistant, and the development of fruits and vegetables able to produce their own pesticides at the appropriate time of the growing process.

Most researchers in the field of biotechnology agree that the recently developed techniques of splicing different strands of DNA represent a major scientific advancement. Other proponents point to the potential of GMOs to revolutionize current methods of food production, and help preserve the world's natural resources. Officials at the United Nations World Food Program have estimated that up to 40% of the world's crops are destroyed as they grow, or before they leave the field.<sup>1</sup> By using GMOs in the development of seeds that are better able to resist disease and can yield larger crops, scientists could unquestionably achieve a much higher percentage of surviving crops.

Those who oppose genetic modification of food generally do so on two grounds: first, the lack of satisfactory testing to determine their safety to human health, and second, their potentially negative effects on the environment. Because so few scientific safety studies have been conducted to date, there is no definite proof that genetically engineered food is safe to consume. Some consumer advocates have also expressed their concerns about the potential for unknown allergens, an increase in natural toxic substances, and a decrease in nutritional value. In addition, some religious groups are worried about the possibility that genes from foods they are forbidden to eat may be spliced into fruits and vegetables. There is also great concern over the ethical ramifications of large-scale bio-engineering, particularly in Europe where the memory of Nazi abuse of science during World War II has left many people terrified of any kind of genetic manipulation – even in plants.<sup>2</sup>

For large biotechnology companies such as U.S.-based Monsanto and Dupont, and Swiss-based Novartis, the rapid increase in the development of GM technology has signaled the beginning of a new and tremendously profitable era. Sales of GM seeds have risen in value from \$75 million in 1995 to \$1.5 billion in 1998, and the crops they produce are by now commonly found in a variety of different foods ranging from chips, beer, and milkshakes to breakfast cereals, muffin mixes, and infant soy formulas.<sup>3</sup> So far, more than 4,500 genetically modified plants have been tested. To date, the U.S. Department of Agriculture (USDA) has approved 50 varieties of crops that have been engineered to resist insects, herbicides, or plant viruses, including 13 kinds of corn, 11 types of tomatoes, and 4 varieties of soybeans.<sup>4</sup> Genetically modified crops account for almost 40% of all corn currently produced in the U.S., 45% of all soybeans, and 50% of all cotton. Together these represent more than three fourths of all genetically modified crops in the world.

Genetic modification of food has been a relatively unquestioned phenomenon in the U.S. and Canada since its introduction to the market in 1992. Since the growing and marketing of food products derived from, or containing, GMOs remain largely unregulated in the U.S., the majority of American consumers have simply not been informed of their existence. The only requirement for a company wishing to grow bio-engineered products is to report its intent to the USDA along with an assurance that the product is safe. Moreover, companies are required to report any problems or negative research results in connection with the production of GM products. Since the U.S. government considers GM components in foods as mere additives, the Food and Drug Administration is not required to approve them prior to sale to consumers. With regards to labelling of genetically altered foods, government policy has long been that food only needs to be labelled if the ingredients change the nutritional content or could cause allergies. Moreover, several large biotechnology companies have long held that under current production methods, segregation of genetically modified and conventional, identity-preserved, crops is almost impossible. Accordingly, the introduction of mandatory labelling schemes would prove very costly, consequently hurting U.S. grain growers.

In the EU, on the other hand, mandatory labelling of foods that contain protein or DNA as a result of genetic modification has been required since the fall of 1998.<sup>5</sup> On October 21, 1999, this requirement was modified by the adoption by the EU Commission of a "1% threshold," meaning that only those foods containing more than 1% genetically modified ingredients need to be labelled as such. In view of the EU's apparently unrelenting position with regards to mandatory labelling of GM products, the attitude of the U.S. government may come to change over the next few months. In a speech on July 13, 1999, U.S. Secretary of Agriculture Dan Glickman told U.S. producers that they may have to consider labelling as a way to ensure access in foreign markets, where consumers require complete disclosure of GM content in food products.<sup>6</sup> Some U.S. companies, concerned that customers may be switching from using products which may be genetically modified (such as corn and soybeans) to products whose genetic code is still unadulterated (such as peas and tapioca), have already changed their policy voluntarily. Archer Daniels Midland Company, for example, has recommended that farmers supplying grain to the company develop ways to segregate conventional crops from modified ones in order to meet increased foreign demand for non-GM products.<sup>7</sup> However, the National Corn Growers Association and other producer

groups have so far strongly criticized ADM's new position, revealing an ever-widening rift between relevant U.S. government agencies, producers of agricultural goods, and leading biotechnology corporations.

In Europe, public opposition to "Frankenstein foods" has been mounting for more than two years, especially in France and Britain. A rash of health scares, including the outbreak of mad cow disease in Britain in 1996 and the discovery of dioxin-polluted chicken in Belgium this year, has provoked widespread fear of food tampering. At the root of both disasters was the same cause: adulterated animal feed. Public protests against genetically modified food and the large multinational corporations promoting them have been both loud and powerful, impelling politicians to proceed with extreme caution. Farmers who have agreed to participate in government-run test planting of GM seeds have seen their fields invaded and destroyed. In some cases, protests against GMOs have taken violent forms, such as in the ransacking and demolition of a McDonald's restaurant in Millau, France, on August 12, 1999. Several major political parties and prominent citizens, including Paul McCartney and Prince Charles, have aligned themselves with environmental advocacy groups that strongly oppose GMOs. Tremendous pressure has been placed on national governments to exercise the "precautionary principle" and await the results of further research studies before allowing GMOs to freely enter EU markets.

Under current legislation, EU member states are required to regulate the release of GMOs into the environment in order to minimize or, preferably, prevent their potentially harmful effects. So far, only 18 GMOs have been authorized for experimental growth in the EU since 1990; however, none was approved in the past two years, although four applications were rejected.<sup>8</sup> Additionally, following a meeting of the EU's environment ministers in Brussels on June 25, 1999, a *de facto* moratorium on new GMO approvals is now in place until 2002 after demands by France, Greece, Austria, Denmark, and Luxembourg to ban GMOs altogether.<sup>9</sup>

Establishing a common stance for the EU on the cultivation and use of GMOs remains a difficult matter. The emotive issue of food safety is one where individual nation-states continue to fiercely guard their right to regulate. In Britain, the government of Prime Minister Tony Blair, a strong proponent of GM foods himself, has had to yield to public pressure to impose regulations on food outlets, by demanding that they identify all food items that may contain traces of GMOs.<sup>10</sup> France is currently being challenged by the EU Commission over its decision to withhold *pro forma* approval of two strains of GM grape seed despite favorable decisions by the Commission in 1997.<sup>11</sup> Because the applications for the grape seeds were originally filed with France authorities, the seeds cannot be put on the market without French approval. Both Austria and Luxembourg have flat-out refused GM trials in their countries. On the issue of ethics and GMOs, Sweden has taken the lead by demanding that ethical considerations be taken into account in issuing licenses for the marketing of GMOs.<sup>12</sup> In addition to supporting Sweden's view on ethics, Denmark, Spain, and Greece have taken a firm stance on GMOs that may cause resistance to medicinal antibiotics, vowing never to approve such products.<sup>13</sup>

With agricultural exports of more than \$50 billion worldwide each year, the U.S. is naturally very concerned about continued restrictions and/or prohibitions on sales of genetically modified products. More and more countries are expressing concerns about the spread of GMOs, particularly with regard to their safety for the environment and human health. The EU has gone the farthest in its protest against GMOs by imposing regulations that involve tougher risk assessments, more comprehensive labelling and monitoring of products once on the market, and a requirement that all GM foods be re-approved for marketing after 10 years.<sup>14</sup> In Japan, the Ministry of Agriculture, Forestry, and Fisheries (MAFF) recently announced a proposal to introduce mandatory labelling of GMOs as of April 2001.<sup>15</sup> The outline of the Japanese proposal currently lists approximately 30 food products derived from genetically modified corn and soybeans, but domestic Japanese consumer groups are actively lobbying the MAFF to add more products to the list.<sup>16</sup> A few days after the Japanese proposal was made public, Australian and New Zealand state and federal health ministers issued a communiqué calling for mandatory labelling of all GM foods in response to increased public anxiety over GMOs.<sup>17</sup>

Although the production of bio-engineered food is currently under debate in many countries around the world, the trade dispute over the use of GMOs is still mainly a U.S.-EU issue. The fundamental differences between the U.S. and EU's attitudes seem almost insurmountable at this point in time, and officials on both sides of the Atlantic are very concerned that the issue of biotechnology may considerably complicate the launch of a future new round of multilateral trade negotiations. U.S. Trade Representative Charlene Barshefsky has long charged that EU's procedures for approving GMOs involves a "highly politicized, opaque regulatory process, leading to consumer fear about food safety."<sup>18</sup> From a trade policy viewpoint, the U.S. administration has therefore focused its efforts on establishing "transparent and timely" global regulatory processes for the approval and marketing of GM products.<sup>19</sup> At the same time, Members of the U.S. Congress have actively lobbied the Administration to push the EU to, at the very least, complete the regulatory process for corn and soy products that have already passed the EU's scientific review process and are due for approval.<sup>20</sup> Representatives of the U.S. agricultural industry want the Administration to go even further and have insisted on promptly resolving the issue based on scientific principles as stipulated by the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). This would mean taking the EU before the WTO Dispute Settlement Body rather than attempting to resolve the problem through bilateral negotiations.

As a result of the many differing objectives and concerns of domestic lawmakers and industry representatives, the Clinton Administration has encountered considerable difficulties in its development of consensus on how to proceed with GMOs and trade with the EU. In late October 1999, the Administration announced its intent to make an interagency decision on a strategy for dealing with biotechnology issues at the WTO Ministerial. One of the main issues to agree on prior to the Ministerial was whether or not to endorse the creation of a working group on biotechnology under the auspices of the WTO as proposed by Canada and Japan.<sup>21</sup> Although U.S. Trade Representative Barshefsky did not officially reject the possibility of creating such a working group, officials at the Office of the USTR did express their concerns that the Canadian proposal was "too broad."<sup>22</sup> Whereas the U.S. would prefer a working group that focused solely on ways to improve transparent and timely regulatory processes for biotechnology products, the Canadian proposal seeks to assess the adequacy of all existing rules for agricultural and pharmaceutical biotechnology products. For the U.S., the potential rewards from this approach could include tighter disciplines on regulatory approval processes for agricultural biotechnology products. However, representatives of the U.S. biotechnology industry have warned that any negotiations seeking to improve regulatory processes could also lead to a reopening of already ratified agreements, such as the SPS Agreement, and the potential weakening of current trade rules. Moreover, U.S. agricultural representatives are afraid that the creation of a WTO working party could be seen as a "tacit admission" that biotechnology is not covered by existing WTO rules.<sup>23</sup> Following this logic, the creation of a working party would likely lead to negotiations of a separate agreement on biotechnology, outside the realm of the SPS Agreement, which could mean that biotechnology products may have to face higher standards than conventional products in the future.

For Canada, as a member of the so-called Miami Group, the establishment of a WTO working party on biotechnology would represent an important step to help move the debate over trade in GMOs out of non-trade arenas. Specifically, Canada believed it could facilitate the successful completion of the negotiations for the proposed Biosafety Protocol to the United Nations Convention on Biological Diversity (CBD), which were resumed in Montreal in late January 2000. Due to an impasse in the Biosafety Protocol negotiations in Cartagena in February 1999, all attempts during that year at forging a global treaty to regulate trade in genetically modified products were futile.

There were three major sticking points in the negotiations for the proposed Biosafety Protocol that prevented the Miami Group from accepting it in Cartagena.<sup>24</sup> The first issue involved the outlined steps a country must take prior to releasing living modified organisms (LMOs) into the environment. The Miami Group was firmly opposed to the definition of LMOs, which they felt went beyond the scope of the Protocol and in their opinion should cover only those organisms that have been proven to pose a direct threat to the environment. The second major point of contention between the Miami Group and the rest of the world pertained to the crucial relationship of the Biosafety Protocol to other international agreements, and specifically, the SPS Agreement. On this issue, the Miami Group has consistently pushed for WTO supremacy over the Convention on Biological Diversity, including the Biosafety Protocol, and the rule of science-based principles over precautionary measures. The third main sticking point in the negotiations was whether the proposed requirement for advance approval by the importing country should apply to genetically altered agricultural commodities meant for eating or further processing, as opposed to planting. The Miami Group, led by the U.S., has argued that commodities intended for consumption or processing, such as corn and soy beans, should not be subjected to advance approval since they do not enter the environment. The EU and most developing countries have taken the stance that all GM commodities should be included because they contain seeds that can be planted. Some developing nations have even gone so far as to demand that the treaty also cover products made from genetic engineering, such as cornflakes made from modified corn, or blue jeans made from genetically altered cotton, though these stipulations were eventually dropped from the final draft of the proposed Protocol in Cartagena.<sup>25</sup>

In spite of the great divide between the Miami Group and the Like-Minded Group, led by the EU, and a tense standoff that ensued for hours, the Biosafety Protocol was finally adopted in Montreal in late January 2000 by delegates from more than 130 nations. The Protocol, officially known as the Cartagena Protocol on Biosafety, is mainly concerned with protecting the environment and does not specifically address the issue of GM food. The key requirement of the treaty is that exporters must obtain permission in advance from the importing country before proceeding with the first shipment of a particular LMO meant for release into the environment (such as seeds, microbes, or fish). However, this requirement does not apply to exports of agricultural commodities intended for consumption or processing. With regards to labelling, the Protocol only stipulates that international shipments of genetically engineered commodities (not products) must be accompanied by a statement that the cargo "may contain GMOs."

For the EU, the most important aspect of the treaty was the inclusion of the "precautionary principle" - a kind of safety first approach that allows nations to protect themselves against unwanted imports. According to the Protocol, countries now have the right to refuse the importation of any GMOs they fear may have the potential to harm the environment, even if there is insufficient scientific evidence to support that belief.

The question about the status and relationship between the various international organizations that deal with food safety and animal and plant health standards is extremely important and will need to be properly addressed in future trade negotiations related to biotechnology products. Within the WTO, biosafety in relation to GMOs and world trade appears to fall chiefly under the SPS Agreement, though there are some implications for GMOs in

standard-setting under the WTO Agreement on Technical Barriers to Trade (TBT Agreement). The SPS Agreement itself does not set the standards for sanitary and phytosanitary measures. Rather, it encourages member countries to use the standards set by the following three international organizations: the FAO-WHO Codex Alimentarius Commission (for food safety), the International Office for Epizootics (for animal health), and the FAO's Secretariat of the International Plant Protection Convention (for plant health). In addition, the SPS Agreement also stipulates that member governments can agree to refer to any other international organizations or agreements (such as the Convention on Biological Diversity and the Biosafety Protocol) whose membership is open to all WTO members.<sup>26</sup>

The current debate between the U.S. and the EU on issues related to food safety, biotechnology, and animal health – including the recent dispute in the WTO over beef hormones – has raised the question of whether the SPS Agreement's preference for scientific evidence goes far enough to protect consumers from possible health risks.<sup>27</sup> A phrase that has emerged in the discussion is the precautionary principle, which is found in Article 5.7 of the SPS Agreement. This principle allows member countries to take a kind of "better safe than sorry" approach when dealing with scientific uncertainties, such as the effects of biotechnology on human health and the environment. In the case of risk assessment of GMOs and biotechnology products, the EU has often referred to the precautionary principle as a way to ensure the protection of consumer health, much to the frustration and dismay of U.S. trade officials. EU Commissioner for Health and Consumer Protection David Byrne has declared that the Commission wishes to "consolidate the WTO framework for the use of the precautionary principle in the area of food safety."<sup>28</sup> Specifically, this would mean working to strengthen individual member countries' rights to establish higher levels of sanitary and phytosanitary protection than that based on international standards, provided they can be scientifically justified in a comprehensive risk assessment. On February 2, 2000, the EU Commission issued a communication on the precautionary principle, that aimed to clarify the issue of when and how to use it, both within the EU and internationally. In response to this paper, the USDA has commented that it is "strikingly vague in some areas and raises questions in others."<sup>29</sup> According to the USDA, the most glaring omission from the paper is any concrete definition of the precautionary principle, which the EU proposes to apply across a wide range of food safety, health, and environmental issues.

Another key phrase that has recently become popular in the transatlantic debate over agriculture and biotechnology is "multifunctionality." As introduced by the EU, multifunctionality refers to the vital role played by agriculture in modern society through its linkage to important policy goals such as sustainable development, preservation of the environment, employment, and food safety. In other words, it represents a step away from the traditional focus on efficiency and productivity that continues to guide U.S. trade policy. During the WTO Ministerial in Seattle, the EU maintained its firm position that further negotiations to reduce export subsidies and improving market access can only resume once the multifunctional role of agriculture has been acknowledged by all trading partners. However, the EU also recognizes that it cannot stand alone on environmental issues, including those related to GMOs, and has therefore agreed to support the creation of a fact-finding WTO working group on biotechnology. After many informal talks in Seattle, the U.S. finally decided to do the same, provided that the working group does not take on any negotiating authority, but remains a solely fact-finding body.

Although the issue of GMOs has remained high on the U.S. Administration's trade agenda, no further steps were taken to confront EU's *de facto* ban on such products in the fall of 1999. Rather than to push the EU into a trade war over biotechnology, the Office of the U.S. Trade Representative chose to focus its energies on creating a positive and productive overall negotiating climate for the WTO Ministerial, which was hosted by the U.S. in Seattle on November 30. Given the main objective of using the Seattle Ministerial as a springboard to successfully launch a new round of multilateral trade negotiations, the Office of the U.S. Trade Representative was mainly concerned about maintaining the support of the EU on key issues related to WTO operations and procedures. However, the issue of biotechnology continues to create conflict between U.S. and EU officials in bilateral trade talks, and the need for mutually acceptable rules and guidelines has become increasingly urgent. Although the current prospects of launching a new multilateral trade round before 2001 seem bleak, it will be necessary for both the EU and the U.S. to continue to negotiate the issue of biotechnology on both bilateral and multilateral levels. If GMOs are not soon brought into the framework of transparent and unambiguous WTO rules and regulations, the present conflict may well erupt into a large-scale agricultural trade war between the EU and the U.S. In the words of U.S. Agriculture Secretary, any escalation of the transatlantic disputes over bioengineered crops "could make beef hormones look like the minor leagues."<sup>30</sup>

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## COMMERCIAL ANALYSIS

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As the world's largest producer and exporter of genetically modified products, the U.S. is very concerned about the long-term effects of the EU's *de facto* moratorium. According to U.S. Trade Representative Charlene

Barshefsky, the delays are already costing U.S. corn farmers some \$200 million annually in lost sales.<sup>31</sup> The U.S. exports more than \$50 billion of agricultural products per year, and an increasing share of the major crops is genetically engineered.<sup>32</sup> Due to the additional costs of sorting, segregating, and handling GM crops away from conventionally grown products, U.S. farmers have vehemently opposed all mandatory labelling schemes that aim at preventing the mingling of conventional and biotech crop varieties. The Food Biotech Communications Initiative, which represents companies such as Monsanto, Coca-Cola, and Nestlé, has argued that segregation is likely to increase food costs by "as much as 150%."<sup>33</sup> In response to the EU's demand for segregation and labelling of GM food, the U.S. government has threatened a "trade war."<sup>34</sup>

The main reasons U.S. farmers have adopted genetically modified crops are higher yields, lower costs, and greater ease of management. Soybean growers have switched to the genetically modified Roundup Ready soybean seed largely due to the simplicity and effectiveness of weed control it brings. Corn and cotton producers have adopted genetically modified Bt corn and Bt cotton varieties because of their pest controlling abilities, which have resulted in greater yields.<sup>35</sup> According to Acting Under-Secretary of State for Economics, Business, and Agricultural Affairs, Alan Larson, biotechnology has the potential to increase crop yields by more than 20%, without any greater use of natural resources.<sup>36</sup> The economic advantages of higher crop yields and less pesticide usage to U.S. farmers are obvious. In a study by Greg Taxler and Jose Falck-Zepeda of Auburn University in Alabama, the reported gains from planting Bt cotton amounted to \$200 million in 1997, of which 42% went to farmers, 35% to Monsanto (which held the gene patent), and 7% to consumers.<sup>37</sup> Overall, the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) has estimated the economic benefits of genetically engineered crops to U.S. and Canadian growers at roughly \$465 million for 1996-97.<sup>38</sup>

From a European viewpoint, the commercial aspect of GMOs is intrinsically linked to the issue of food safety. As pointed out by Commissioner David Byrne in his speech to the conference on "Biotechnology – science and impact" on January 21, 2000, high levels of consumer confidence are necessary in order to boost trade and competitiveness.<sup>39</sup> To compromise on food safety (i.e. allow the sale and use of GMOs prior to sufficient and adequate scientific testing) would be to gamble with the whole agri-food sector. In an industry worth 600 billion euros annually in the EU – approximately 15% of total manufacturing output – and providing about 10 million jobs, even a slight dip in confidence can have significant economic effects. This is not to mention the actual cost of recent food safety related scandals: last year's dioxin pollution in Belgium, where animal feed tainted with polychlorinated biphenyls and furans was sold to 1,700 Belgian farmers and found its way into their chickens, pigs, and cattle, is estimated to have cost that country's farmers \$600 million in sales. In Britain, farmers are still suffering from the effects of mad cow disease, which has reportedly cost over \$5.5 billion in lost exports and culled herds.<sup>40</sup>

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## POLITICAL ANALYSIS (EU)

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On August 12, 1999, a McDonald's restaurant in the French town of Millau became an object of worldwide attention as it was ransacked and demolished by an angry crowd of farmers and ecologists protesting against American "multinationals of foul food."<sup>41</sup> Their leader, José Bové, is a Parisian intellectual turned activist-farmer, who has become the front figure of European opposition to genetically modified organisms (GMOs), commonly referred to as "Frankenstein food," and U.S. "culinary imperialism" in Europe. Backed by international environmental interest groups such as Greenpeace and Friends of the Earth, Bové has staged several attacks on McDonalds, which he sees as a symbol of an American-led globalization that is threatening the culinary sovereignty of EU member states, and the right of European consumers to eat as they see fit.<sup>42</sup>



In Europe, public protests against genetically engineered foods have been mounting for more than three years, especially in France and Britain. Prince Charles, one of the most prominent figures in the EU campaign against GMOs, has publicly stated that he would not allow any genetically altered food to ever pass his lips. In his words, the changing of the rules of nature through modern science "takes mankind into realms that belong to God, and to God alone."<sup>43</sup>

Why are Europeans so much more apprehensive about GMOs than Americans? Some experts claim that behind the politico-gastronomic outcry is a hybrid of cultural and economic fears of a new technology that is widely perceived to be completely dominated by American multinational corporations. Alain Duhamel, a French political analyst, believes that at the root of the protests is a widespread rejection of cultural and culinary dispossession. According to this theory, there is an "allergy" in Europe to the amount of American power that has been accumulated since the end of the cold war, and its most virulent expression is culinary sovereignty.<sup>44</sup> Or, in the words of José Bové, what Europeans reject is "the idea that the power of the market place becomes the dominant force in all societies, and that multinationals like McDonald's or Monsanto come to impose the food we eat and the seeds we plant."<sup>45</sup>

In light of the recent public health scares in Europe, such as the outbreak of mad cow disease and dioxin contamination, it is perhaps not surprising that food safety has become a top priority for the EU Commission. Each successive crisis has further eroded consumers' trust in the capacity of the food industry and in the public authorities ostensibly in charge of monitoring and ensuring the highest standards of food safety.<sup>46</sup> In response to public concerns about food safety, the EU Commission recently issued a White Paper on Food Safety, outlining 80 separate actions designed to make EU legislation more coherent, responsive, and flexible. Among the more tangible proposals is the establishment of an independent European Food Authority with particular responsibilities for risk assessment and risk communication. Though there are many similarities between this proposed agency and the U.S. Food and Drug Administration, the European Food Authority will not have any regulatory powers and hence will not get into the area of risk management. Any decision-making with regards to risk management will continue to be the responsibility of the EU Commission, Parliament, and Council of Ministers. Included in the White Paper are also specific action proposals aimed at dealing with issues related to GMOs, such as the application of the precautionary principle in risk management decisions, and the introduction of adequate procedures for food traceability. In addition to food safety, there are many other legitimate factors related to biotechnology that play a significant role for many European consumers. Issues like animal welfare, environmental considerations, sustainable agriculture, and consumers' right to information are highly political and are crucial elements of the EU policy-making process.

Protection of the environment is a particularly strong concern to the European public. In France, the UK, Germany, and the Nordic countries, the Green Parties continue to enjoy significant political leverage, and in the EU Parliament there has been a dramatic increase in the number of Green MPs; from 26 in 1994, to 38 in 1999.<sup>47</sup> Not surprisingly, the Green Parties in Europe have taken a very firm stance against GMOs. Their main argument against biotechnology is that not enough scientific testing has been done to determine their effect on the environment. Moreover, Green Party members have warned that any premature release of GMOs into the environment could result in serious disruption, if not devastation, of the ecosystem. In Sweden, the Green Party along with the Swedish chapter of Friends of the Earth have launched a nationwide campaign calling for a five-year moratorium on the production, sale, and licensing of GMOs.<sup>48</sup> Traditionally, the Green Parties of the Nordic countries, as well as in Spain, Italy, and Greece, have been politically affiliated with the Socialist Parties. However, in light of the tremendous public outcry over GMOs, other parties have also expressed the need to proceed with caution in matters related to biotechnology.

European consumers have consistently demanded that genetically modified food be labelled in order to enable the public to make informed choices about the products they buy. The consumers' right to information is clearly outlined in the Amsterdam Treaty, the legal framework for European integration, and as public awareness of GMOs has increased, so have the demands for complete information on production methods and product labelling. According to a 1998 survey, 86% of Europeans called for mandatory labelling of genetically modified food.<sup>49</sup> EU Commissioner for Health and Consumer Protection, David Byrne, has publicly supported consumers' right to information, and has called on regulators and food producers to make certain that these demands are met.<sup>50</sup> In response to these demands, the EU Commission is currently working on improving legislation on GMO labelling and on the legal framework for a "GMO-free" line of products, to which producers can adhere on a voluntary basis.

Several groups of European distributors have already joined forces in a bid to rid their supermarket shelves of GM products, regardless of what the EU legislation on the issue may stipulate. In March 1999, Sainsbury's, the U.K.'s second leading supermarket chain, announced that it would no longer accept genetically modified ingredients in the production of its brand products. Sainsbury's decision to discontinue the sale of products that contain or are derived from GMOs were subsequently adopted by the other six distribution members of the Sainsbury consortium: Marks and Spencer (U.K.), Carrefour (France), Effelunga (Italy), Migros (Switzerland), Delhaize (Belgium), and Superquinn (Finland).<sup>51</sup>

One of the EU arguments brought up in favor of mandatory labelling is allergenicity. It is a scientific fact that genetic engineering can introduce unknown allergens into food. Virtually every gene transfer in crops results in some protein production, and proteins are what trigger allergic reactions.<sup>52</sup> If someone is at risk for an allergic reaction to a conventional food, he or she can check the food label, which typically identifies all the ingredients, and thus avoid exposing himself/herself to that same allergen. However, if someone has a reaction to a genetically engineered food product, and the label does not disclose the presence of GMOs, it is impossible to

know what specifically caused the reaction, and what to avoid in the future.<sup>53</sup> Another argument in support of mandatory labelling of genetically modified products is ethical and religious considerations. Many Europeans find GMOs objectionable for ethical or religious reasons, and demand the right to know whether the products they buy contain spliced genes from animals or species that are proscribed by certain religions. Labelling would allow these consumers to choose according to their beliefs and conscience.<sup>54</sup>

Among the EU member states, Sweden, Denmark, Spain, and Greece have been the most vocal in their calls for ethical considerations in the approval process for the marketing of new GMOs.<sup>55</sup> In response to these demands, the EU Commission in June 1999 recommended that the European Working Party on Ethics in Science and New Technology should be consulted prior to the marketing of any new products containing GMOs.<sup>56</sup> Some experts suggest that the issue of ethics and biotechnology strikes at the very core of European opposition to GMOs, because it calls into question the very issue of control. As American professor Joan Gussow has stated: "Someone is going to produce and subsequently manipulate the materials out of which each of us is made. Are we really prepared to trust that responsibility to Phillip Morris?"<sup>57</sup>

Some critics have suggested that the real reason for the heated debate in Europe is nothing less than agricultural protectionism. According to this theory, Europeans resent the fact that most of the patents on genetically modified high-yielding seeds belong to large American corporations such as Monsanto, DuPont and Dow.<sup>58</sup> However, from a European viewpoint, it seems only natural that many consumers are suspicious of who controls a technology that promises to revolutionize agriculture. Biotechnology allows agricultural production to become more vertically integrated, consolidated, and centralized – all in the hands of multinational corporations. The truth is that the many benefits that biotechnology can provide to mankind are not always so obvious to the consumer. In a nutshell, while consumers have been promised foods that taste better, are more nutritious, and will help "feed the world," the applications of biotechnology to date have failed miserably in delivering any noticeable consumer benefits. For example, the introduction of BGH/BST, a genetically engineered drug that makes cows produce more milk, has not translated into lower prices for consumers.<sup>59</sup> In a recent speech to The Hague Conference on Biotechnology, Commissioner David Byrne conceded that most of the GMOs currently on the market are not targeted to deliver benefits to the consumer, but rather to provide profits for the producers.<sup>60</sup> The public attitude towards GMOs in Europe is not likely to change until the biotechnology industry successfully manages to inform consumers of the merits of this new technology.

One recent initiative to address public concerns about biotechnology was the three-day Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods, organized by the OECD at the request of the Group of Eight (G8) industrialized countries, in late February 2000. The purpose of the conference was to provide more information about the science behind GM food and whether or not it is safe to eat. The likely outcome of the meeting, which was attended by four hundred scientists, regulators, environmental and consumer activists, is the creation of an international panel on food safety to inform policymakers about GM issues. According to Sir Robert May, Britain's chief scientific adviser, the panel could be similar to the IPCC, the Intergovernmental Panel on Climate Change, which was set up to tackle the challenges of global warming.<sup>61</sup> Moreover, Sir May suggested that the panel should consist of scientists who are both supporters and critics of biotechnology, so that a broader range of expertise would be represented.

In spite of the efforts, however, many environmental groups such as Greenpeace and Friends of the Earth, criticized the conference as doing nothing to solve the uncertainties surrounding biotechnology. Greenpeace, in particular, accused the OECD of sidelining critics and failing to include more farmers and other concerned advocacy groups in the meeting. To demonstrate their opposition to the continued trade in GMOs, Greenpeace activists on February 25, 2000, intercepted a vessel thought to be carrying up to 60,000 tonnes of genetically modified soya from U.S. agribusiness giant Cargill off the coast of Anglesey, north Wales. Jim Thomas, GM campaigner at Greenpeace was quoted as saying: "This ship is carrying a cargo that nobody wants and most people would like to see sent home. There is no demand for GM crops and it's pointless bringing in thousands of tonnes of stuff only to contaminate the food chain. Cargill have already proven that they can get GM free soya and could easily shift the balance towards a GM free Britain."<sup>62</sup>

One effect of the OECD conference in Edinburgh was the apparent softening of British Prime Minister Tony Blair's previous staunch support of GM food. Writing in the Independent on February 29, 2000, Blair admitted that there is cause for legitimate public concern: "There is no doubt that there is potential for harm, both in terms of human safety and in the diversity of our environment, but there is no doubt either, that this new technology could bring benefits for mankind."<sup>63</sup> Though Blair went to great lengths stressing his government was neither pro- nor anti-GMOs, environmentalists such as Friends of the Earth hailed the new tone of Blair's message, calling it "a

fantastic leap forward" and a sign that the British government has finally begun to pay attention to public demands for a more robust regulatory approach to biotechnology.<sup>64</sup> A few days later, the EU moved to extend its temporary moratorium on new GMO approvals by postponing a decision on the sale and marketing of three new GM crops until the summer. According to EU sources, the decision to postpone the approvals was made based on "insufficient information" for the two new GM varieties of rapeseed and one variety of fodder beet.<sup>65</sup> All three varieties had been produced by European biotechnology companies: AgrEvo, Danisco, Hoechst AG, and Shering AG.

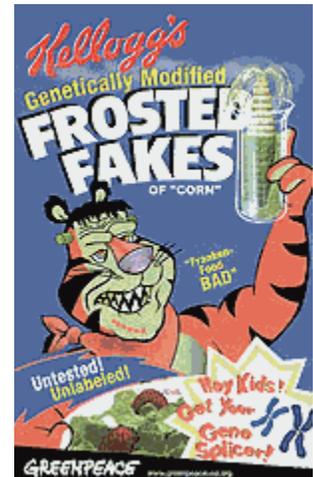
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## POLITICAL ANALYSIS (U.S.)

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Whereas the debate over GMOs in Europe has been widely characterized by public protests and a high level of consumer activism, the American public has been considerably slower to react to this new technology. Unlike the British, for instance, whose concerns about food safety have been on the rise since the outbreak of mad cow disease in 1996, Americans have seemed largely indifferent to genetically modified foods. An important reason for this is that only very few Americans have been aware of the introduction of GMOs into the food chain of mainstream America. Since the U.S. government has classified GMOs as mere additives in food, the Food and Drug Administration (FDA) is not required to approve them prior to sale and marketing to consumers. Nor is there a labelling requirement for genetically engineered products: in accordance with FDA regulations, only those foods whose ingredients are proven to change the nutritional content or can cause allergies are subject to mandatory labelling practices.

However, thanks to international non-governmental public advocacy groups such as Greenpeace and Friends of the Earth, long-simmering European anxieties over GMOs now appear to have spread to the U.S. public at large as well. In late fall of 1999, Greenpeace invaded cereal maker Kellogg's headquarters in Battle Creek, Michigan, to protest against the company's use of genetically engineered grains. One of the activists even dressed up as Kellogg's trademark Tony the Tiger, or "Franken Tony", as he is better known among GM opponents. Although many U.S. environmentalist and consumer activist groups have since launched their own campaigns against GMOs, Greenpeace remains one of the most vocal organizations against GM food in the U.S. Through its True Food Network, Greenpeace has been instrumental in pressuring companies such as Heinz and Gerber into dropping genetically altered soybeans and corn from their baby formulas, and in Europe, Kellogg's has already begun to phase out their GM products in response to Greenpeace's demands.<sup>66</sup>



In addition to its highly publicized activist campaigns, Greenpeace has also turned to the law in its efforts to protect the environment from the advances of biotechnology. In late February 1999, sixty-five plaintiffs, including Greenpeace, the Sierra Club, and the International Federation of Organic Agricultural Movements, filed a lawsuit in the district court of Washington D.C. against the U.S. Environmental Protection Agency (EPA), on grounds that it had acted unlawfully in its approvals of crops engineered to produce Bt toxin, a gene-modified insecticide produced by the soil bacterium *Bacillus thuringiensis*.<sup>67</sup> The suit demands that the EPA immediately withdraws its approval of all Bt plants and refrains from making any new approvals until a complete scientific assessment has been carried out with regards to their impact on the environment. While the EPA has rejected all accusations that it may have approved any biotechnology products without due regard to their potentially harmful effects on the environment, some scientist groups, such as the Union of Concerned Scientists, have confirmed that the EPA's current approval process for biotech crops is inadequate.<sup>68</sup> In response to rising demands for improved testing and monitoring of genetically engineered crops, the Scientific Advisory Panel, which makes recommendations to

the EPA, announced in February 2000, that it would advise the EPA to test crops on a wider variety of insects than the four species currently done, and to require more data from the seed companies on the impact of the crops in the field.<sup>69</sup>

The concern over the safety of genetically engineered products has also begun to infiltrate U.S. politics. In November 1999, Representative Dennis Kucinich (D-Ohio) introduced bill HR 3377 - the Genetically Engineered Food Right to Know Act, which would require all foods that contain or are produced with GM material to bear this label:

### **GENETICALLY ENGINEERED**

Followed by this subtext:

**UNITED STATES GOVERNMENT NOTICE: THIS PRODUCT CONTAINS GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL.**

The bill has garnered the support of fifty co-sponsors, and is currently awaiting review in the House Subcommittee on Health and the Environment. Meanwhile, on March 9, 2000, Representative Kucinich introduced bill HR 3883 - the Genetically Engineered Food Safety Act, which would require all GM foods to be examined for allergenicity, unintended effects, toxicity, functional characteristics, and nutrient levels, in addition to passing FDA's process for food additives. Moreover, the bill would require the FDA to conduct a public comment period of at least thirty days once the completed safety application is available to the public, and to disclose all studies performed by the applicant to the public. Bill HR 3883 has the support of nine co-sponsors, and was referred to the House Subcommittee on Health and the Environment on March 21.

Whereas many scientists have embraced the idea of greater public disclosure about genetically modified food in order to gain consumers' trust on the issue, food industry leaders fear that labels identifying products containing GM ingredients would scare consumers away. With regards to the proposed label that would be required under bill HR 3377, Gene Grobowski, spokesman for Grocery Manufacturers of America, has stated: "It looks like the surgeon general's warning on cigarettes."<sup>70</sup> Another opponent to mandatory labelling is the Farm Bureau, which sees the labelling issue as part of the "general hysteria that Europeans have drummed up to keep U.S. produce from reaching their grocers' shelves".<sup>71</sup> In a letter to President Clinton dated November 12, 1999, thirty-eight organizations representing a cross-section of the U.S. agri-food industry urged the Administration to support the science-based labelling policies of the FDA as they relate to the labelling of genetically engineered foods.<sup>72</sup> Specifically, these organizations expressed their concerns that if the FDA were to require labelling for biotech products, such labelling could have the effect of misleading consumers into believing that biotech foods are either "different" from conventional foods or represent a potential health risk. Moreover, by changing the current policy to require special labelling, the FDA would run the risk of undermining its own credibility.

This view is shared by several U.S. senators. On January 26, 2000, Senator Christopher Bond (R-Missouri) testified before the U.S. Senate on the benefits and politics of biotechnology, accusing "some elements of the European Union....to provide short-term protection to their farmers....[and] limit the productivity of foreign farmers" by exploiting public fears of genetically engineered foods.<sup>73</sup> Along with Senators Kerry, Durbin, Hagel, Craig, Frist, Conrad, Lugar, Gorton, Grassley, Ashcroft, Robb, Burns, Grams, Gordon Smith, Baucus, Helms, Hutchinson, Roberts, Bayh, Brownback, Crapo, and Coverdell, Senator Bond urged the Administration be firm in its negotiations on biotechnology products, and not yield from its insistence on science-based, rather than politically influenced, risk assessments. Senator Bond also criticized "opportunistic" food companies such as ADM and Novartis for "knowingly undermining our scientists and trade negotiators to placate the Luddites and protectionists."

As early as February 1997, the giant Swiss agribusiness, chemicals, and drug company Novartis announced its intent to advocate that all genetically engineered crops and foods be clearly labelled.<sup>74</sup> The head of Novartis' agribusiness unit, Wolfgang Samo, explained the move by stating: "There is no need from a scientific and safety standpoint, but if we believe in the consumers' right to choose, the industry cannot reasonably argue against labels facilitating this choice."<sup>75</sup> The new policy immediately provoked criticism from farm and industry groups, causing a rift within the biotechnology industry. On August 31 1999, Archer Daniels Midland Company (ADM) issued a recommendation that farmers selling to the company segregate non-genetically enhanced crops to preserve their identity.<sup>76</sup> Although ADM denied that they would pay a premium for non-GM crops, the announcement was reportedly causing instability in the U.S. agricultural markets, with the result that the National Corn Growers Association vowed it would help farmers recoup any harvesting or handling losses due to the ADM announcement. However, in February 2000, ADM changed its stance after its chairman G. Allen Andreas told the Chicago Tribune that the "pendulum is beginning to turn back" on the controversy surrounding GMOs, by issuing a statement that it would not turn away genetically modified grains.<sup>77</sup>

In response to mounting public demands, several U.S. and Canadian companies have recently announced their intent to discontinue their use of genetically modified products and ingredients. In February 2000, Seagram announced that it will not accept GMO corn in the fall for its distilleries.<sup>78</sup> McCain Foods Ltd will not accept genetically modified potatoes, and Frito-Lay, a division of Pepsico Inc., has confirmed that it will not buy GM corn for use in its chips. Whole Foods Market Inc., which has 103 stores nationwide, has announced that it will be banning genetically engineered foods from its store brands. Until the biotechnology industry and its researchers become fully engaged participants in the public debate over GMOs and their implications on safety, the environment, and ethics, the U.S. consumers are likely to continue down the same path as their European counterparts, and reject unlabelled genetically modified products.

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### **POLITICAL ANALYSIS: DEVELOPING COUNTRIES**

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While much of the reported dispute related to GMOs involves the EU and the United States, there are varying positions and interests involving the alignment of developing and least developed countries. Among the "Miami Group" are the countries of the US, Canada, Argentina, Uruguay, and Australia who control the world market in biotechnology. For those developing and least developed countries that have not developed their biotechnology capacity, they view the advent of GMOs and GE products as potentially impacting their nations adversely, OR as creating niche markets in the EU and Japan for the export of non-GMO produced agricultural, fish, and livestock products.

As importing countries, the DCs and LDCs often lack the technical capacity to test, inspect, or study the safety of imported products and therefore are unable to exercise their potential range of options related to the WTO/GATT SPS Agreement. As countries dependent on imports of food products and of materials necessary for agricultural, fish, and livestock production, the DCs and LDCs face a dilemma of reliance on foreign exports and legitimate concern for potential adverse impacts on health and environment.

Depending on their export crops and products, DCs and LDCs may either attempt to exploit the niche of market access to nations and consumers who prefer non-GE products or may themselves seek to condition the importation of GE products to protect ecosystems from the unknown consequences of GMOs on plants, waterways, and consumers.

As parties to multilateral negotiations on GMOs, labelling, and safety issues, the DCs and LDCs will seek to obtain increased market access for their products and technical assistance in the monitoring of imports and/or the development of their own GE capacity.

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## LEGAL ANALYSIS

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The main EU legislation on the deliberate release into the environment of GMOs is Council Directive 90/220/EEC, which was adopted on April 23, 1990. This measure has subsequently been amended by Commission Directive 94/15/EC of April 15, 1994, and Commission Directive 97/35/EC of June 18, 1997. Under this legislation, Member States are required to regulate the release of GMOs into the environment so as to "minimize their potential negative effects on human health and the environment, since living organisms released in the environment for experimental purposes or as commercial products may cross national frontiers and affect other Member States by virtue of their irreversible effects on the environment."<sup>79</sup> In accordance with Directive 90/220/EEC, any person seeking to release GMOs into the environment (plant seeds, for example) must submit a notification of intent to the competent authority in the Member State where the release will take place. Along with the notification, a full dossier of information including a full risk assessment, appropriate safety and emergency response measures, and in the case of products, precise instructions and conditions for use, plus a proposal for labelling and packaging.<sup>80</sup>

As a complement to Directive 90/220/EEC, which primarily governs the environmental release and the animal feed safety assessment of GMOs, the EU has also adopted Regulation (EC) No. 258/97 (Novel Foods Regulation), and Regulation (EC) No. 1139/98 (labelling of foodstuffs containing or derived from Monsanto's RR soy and Novartis' Bt-Corn) to ensure the mandatory labelling of any food products that contain protein or DNA resulting from genetic modification.<sup>81</sup>

Critics of these regulations, however, such as the U.S. biotechnology industry, have complained about the lack of a fully transparent legal framework for labelling requirements within the EU. In particular, producers of genetically engineered goods have called for greater streamlining of GMO regulations between the EU and the individual EU Member States.<sup>82</sup>

In response to this criticism, the EU Commission in October 1999 presented a proposal (IP/99/783) with the aim of completing the current labelling rules and providing greater legal certainty for both operators and consumers. Specifically, this proposal introduced (1) a *de minimis* labelling threshold of 1% for the accidental content of genetically modified material of individually considered ingredients, and (2) new rules for making foods containing GMO-derived additives and flavorings subject to the same labelling rules as those of the Novel Foods Regulation.<sup>83</sup> By introducing a threshold level of 1%, the Commission sought to solve the problem faced by producers who have tried to avoid GMOs but who due to "accidental contamination" still find themselves with a low amount of GM material in their products. It is important to note that the proposed threshold only applies to goods already authorized for human consumption in the EU. Furthermore, it is subject to the following conditions:

- The origin of the GM material has to be accidental. In other words, producers have to submit evidence that they have avoided GM source materials.
- The proportion of GM material accidentally present must not be higher than 1% of each ingredient individually considered. For example, in the case of a processed product containing maize starch, the percentage of allowed GM material is not 1% of the product itself, but rather 1% of the starch.

Proposal IP/99/783 also seeks to ensure that foodstuffs that contain GMO-derived additives and/or flavorings are labelled in the same way as those GM foodstuffs that are subject to the Novel Foods Regulation, i.e.:

- Those products that have additives or flavorings that are, contain, or consist of GMOs;
- Those that raise a particular safety (e.g. allergies) or ethical concern;
- Those that are not equivalent to their conventionally produced counterparts (i.e. that contain protein or DNA resulting from genetic modification).

On June 25, 1999, at the EU Council of Ministers meeting in Luxembourg, the European environment ministers agreed to put a hold on the authorization of new GMOs until a new Directive comes into operation in 2002, and a new framework of rules on labelling and monitoring has been established. Although the vote was not unanimous (Spain, Portugal, and the U.K. declined to sign the agreement due to fears that its wording might be legally challenged by the biotechnology industry), all fifteen Member States will have to abide by the new regulations. Among its provisions are tighter risk assessments of all GMO releases, a post-market monitoring regime on all releases, a more comprehensive labelling scheme, and the phasing out of antibiotic marker genes.<sup>84</sup> Moreover, the Council decided to replace the former open-ended granting of consents to GM products with authorizations limited to a maximum of 10 years. Although a blanket moratorium on new approvals would have been illegal under EU law, the effect of these new regulations is the same: a complete ban on the importation of non-approved genetically altered goods until 2002.

Not surprisingly, the U.S. is deeply concerned about the long-term effects of the EU's *de facto* moratorium, and has threatened to bring its complaints before the WTO Dispute Settlement Body. However, so far all efforts to build a solid legal basis for a formal challenge against the EU have come up short.<sup>85</sup> Since the EU has not explicitly rejected more GMO approvals, but merely postponed further action until a new Directive is in place, there may in fact not be enough legal grounds for the U.S. to pursue a case against the EU. Absent a clear rejection of GMOs, the next best legal argument would likely be to charge the EU with "undue delay" as set out in Annex C of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), although this provision is not legally defined in the agreement.

On the other hand, the EU could dispute the applicability of the SPS Agreement in relation to GMOs under the argument that biotechnology products do not fit under either of the four categories of risk factors as laid out by the SPS Agreement: additives, toxins, contaminants, and disease-causing organisms.<sup>86</sup> The challenge for WTO negotiators will then become what to do with the SPS Agreement. Currently, there are three possible options:

- Leaving it in its present form;
- Open it for renegotiations;
- Negotiating an understanding of the interpretation of its specific provisions.

However, the U.S. Administration, strongly lobbied by domestic agricultural groups, has so far opposed re-opening the SPS Agreement, and has been hesitant to endorse clarification of its provisions out of fear that any tinkering with the agreement could lead to a weakening of existing provisions.<sup>87</sup>

There are two other WTO agreements that potentially could be applied in favor of the U.S. position: the Agreement on Technical Barriers to Trade (TBT Agreement), and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). According to the least trade restrictive rule of the TBT Agreement, governments are required to minimize the negative impacts on trade when setting domestic product standards. This rule could possibly be used to challenge EU's labelling requirements of all products that contain or are derived from GMOs. Similarly, the TRIPS Agreement could provide another avenue for the U.S. in formalizing its opposition to EU's ban on GMOs. If genetically engineered agricultural products are patented, new commercial

rights could come into play that diminish the ability of individual Member governments to restrict the release and sale of GMOs in their markets.

One of the most salient points of contention between the U.S. and the EU on the issue of GMOs is labelling. In accordance with the Novel Foods Regulation, all foodstuffs that contain or are derived from GMOs must be labelled as such. In order to gain exemption from this labelling requirement, producers have to show that each of the ingredients contains less than 1% of altered DNA, or traces thereof. The U.S. has consistently opposed all mandatory labelling schemes to indicate GMO content since there is no legal basis for such requirements under U.S. law. The current policy of the Food and Drug Administration (FDA) only requires labelling of food in cases where ingredients change the nutritional content of the food, or may cause allergies. However, there is no formal opposition on the part of the FDA to voluntary labelling, as long as the labelling is "truthful." Interestingly, the FDA would consider any labelling that implies that conventional products are better, or safer, than the bio-engineered variety, "misleading."<sup>88</sup> Moreover, in light of current U.S. farming and harvesting practices, many experts claim that the cost involved in separating conventionally grown grains from genetically modified crops for purposes of labelling would be extremely high, and is likely to negatively impact U.S. grain trade.<sup>89</sup>

The tensions between the EU and the U.S. on the legal aspects of biotechnology are not solely revealed in bilateral negotiation sessions, but also on a multilateral level, such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which was recently concluded in Montreal. Ironically, the U.S. – the world's by far largest exporter of GMOs – was not allowed to fully participate in these negotiations, since it is not yet a signatory to the Convention on Biological Diversity (although President Clinton did sign the Convention in 1993, Senator Jesse Helms has refused to allow a Senate vote to ratify it). Hence, U.S. trade negotiators did not have a formal vote and could not take the microphone in full plenary sessions. However, the U.S. was able to participate "on the sidelines" through its linkage to the so-called Miami Group, which consists of six major food-exporting nations: the U.S., Canada, Australia, Uruguay, Argentina, and Chile.

The chief legal instrument of the Biosafety Protocol is the *Advance Informed Agreement (AIA)*, a process which provides importing countries the right to refuse shipments of particular living modified organisms intended for release into the environment, like seeds, microbes, or fish. Also included in the AIA is the requirement that exporters obtain permission from the importing country prior to exporting the first shipment of a certain living organism. According to the treaty, when a GM crop is approved for commercial use in one country, that country must issue information about it to a central clearinghouse, so that others can decide whether or not to prohibit the importation of that product. However, advance notice and permission will not be required for agricultural commodities intended for consumption or further processing – the AIA is solely designed to regulate the release of living GMOs into the environment.

For the EU, the most significant outcome of the Biosafety Protocol is the legal recognition and inclusion in the treaty of the *precautionary principle*.<sup>90</sup> The basic idea of this concept is a "safety first" approach that allows countries to take action to protect themselves against the importation of potentially hazardous goods even if there is a lack of scientific evidence to validate these concerns. In the case of risk assessment of GMOs and other biotechnology products, the EU has often referred to this principle as a way to legally defend its policies, much to the frustration and dismay of U.S. trade officials who insist on the use of "sound scientific data." The EC Treaty, incorporating provisions already introduced by the Maastricht Treaty of 1992, specifically Article 174 thereof, states:

"Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay...."

Although the principle is not explicitly defined in the WTO SPS Agreement, Article 5, paragraph 7 recognizes its basic relevance to trade measures taken by Members:

"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available scientific information, including that from the relevant international organizations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

However, the issue of when and how to apply this principle remains highly controversial, not only on the international level, but also within the EU itself. In order to provide some structural guidelines on the appropriate use of the precautionary principle, the EU Commission on February 2, 2000 issued a communication with the fourfold aim of:

- Outlining the Commission's approach to using the precautionary principle,
- Establishing Commission guidelines for applying it,
- Building a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully, and
- Avoiding unwarranted recourse to the precautionary principle, as a disguised form of protectionism.

While the communication is specifically directed to the Community, it also seeks to provide an input to the ongoing international debate over the proper application of this principle. As a result of the explicit inclusion of the precautionary principle in the Biosafety Protocol, the Miami Group, led by the U.S., has pushed for WTO legal supremacy over the Biosafety Protocol. In contrast, the so-called Like-Minded Group, which consists of over one hundred developing nations, along with the EU, wants the Biosafety Protocol to be co-equal to the WTO.

At the OECD Conference on the Scientific and Health Aspects of Genetically Modified Food, which was held in Edinburgh in late February 2000, another important scientific concept – "substantial equivalence" – was discussed in legal terms. Introduced by the OECD in 1993, the concept of substantial equivalence means that if a GM food can be characterized as being chemically similar to its natural counterpart, it can be assumed to pose no new health risks. The concept was endorsed by the United Nations Food and Agriculture Organization (FAO), and the World Health Organization (WHO) three years later and has been employed ever since.<sup>91</sup> However, as a result of the OECD Conference, this approval system is likely to be re-evaluated in upcoming international meetings on GMO safety standards, such as the Codex Alimentarius meeting in Tokyo in March 2000. The Codex task force on GM food standards aims at developing global legal standards on how to evaluate the safety of GM foods by 2003.

## **The Use of GMOs in the Cultivation , Production, and Marketing of**

### **Salmon As Food and Commodity Products.**

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The use of GMOs in the production of fish and livestock is perhaps most advanced in the cultivation of salmon fish or as they have been called "super salmon". These are fish that grow from zero to 10 pounds in just 14 months, or one-half the normal time.

The farmed salmon will look and taste similar to other farmed salmon, but the difference will be in the invisible genetic code and in the increased profit margins that will benefit the salmon fish farms.

Proponents of the new technology call this the "blue revolution", a triumph of genetic engineering that promises to help feed the world while reducing pressure on depleted fish populations.

Critics warn against what they call "Frankenfish", a biological disaster comparable to nuclear energy or toxic waste dumping.

Supersalmon genetics were discovered somewhat by accident about 20 years ago, when a researcher in Newfoundland froze a tank full of flounder. To his amazement, the fish survived. Further research led to discovery of a protein that prevents flounder and other fish from freezing, a genetic adaptation to the icy waters off of Canada.

As gene-splicing techniques were developed, Canadian scientists located the "antifreeze" gene. They attempted to introduce the gene into Atlantic salmon in hopes that salmon farms could be developed in colder waters.

The antifreeze splicing was not perfected, but the scientists discovered the same gene can be used to control growth. The genetic material is injected into salmon eggs, a process that occurs under a microscope. It alters the way the fish's growth hormones work, enabling those hormones to be produced by the liver as well as the pituitary gland. That change greatly accelerates growth—by up to 600 hundred percent in the early months 200 hundred percent overall.

For genetic engineers, fish have several advantages over mammals or other animals. A spawning female Atlantic salmon will produce 5,000 to 15,000 eggs. And because fish eggs don't have to be carried by a mother, the task of implanting and cultivating fish in captivity is greatly simplified. The implant will be successful in only a small proportion of the fish—perhaps 20 to 30 of 10,000. But those fish become "progenitors". The normal genetics take over and several generations later a new strain of fish has been created. The economic implications are huge.

Currently, the wholesale prices of farmed salmon have dropped dramatically. Costs have escalated and dozens of salmon farms have gone bankrupt from Maine to Puget Sound to Norway. By switching to the fast-growing supersalmon, fish farmers can double their production while greatly reducing their feed costs per pound of fish produced.

Critics complain that there has been virtually no testing on the potential adverse impacts to consumers and the environment. Fish farming can place local ecosystems (rivers and oceans) at risk of transgenic fish stocks. Critics also complain that the fish farming produces high concentrations of waste, disease, and antibiotics. The greatest fear is that genetically-altered, farmed fish will escape their floating pens and breed with wild fish or prey upon them.

### **Common Facts and Assumptions of the Simulation**

For purposes of this simulation, assume the following to be true:

1. Companies in the United States are cultivating supersalmon (genetically engineered) in tanks and are prepared to export to foreign markets for consumption as a food product;
2. Companies in the United Kingdom (U.K.) are also working to perfect the techniques of salmon farming using genetically engineered fish stock purchased as a commodity from U.S.-based companies;
3. Companies in the United States that are producing GE salmon for export as a commodity to stock fish farms are selling the by-product of dead fish and overproduction to fertilizer manufacturers who include the GE fish in fertilizer products for sale domestically and internationally;
4. Developing Country (DC) of "Calero" produces farmed salmon for domestic sales and for export. These salmon farms do NOT use GMOs or any other form of genetic engineering in their production. Recent crops have suffered from disease and production costs have increased. The Calero non-GMO, salmon exports are popular in the EU and Japan.

5. The Least Developed Country of "Sudero" is dependent upon the import of fertilizer products from the United States, the EU, and Japan for the cultivation of its primary export crops of cotton and sugar (cane). Sudero lacks the infrastructure and technical capacity to monitor food and commodity imports for biosafety and other potential hazards to human health and the environment. Sudero fears that exports of its cotton and sugar products may be blocked by countries that fear potential (but as yet unproven) adverse impacts on the environment or health because of Sudero's of fertilizers containing GE salmon by-product.
6. Assume that there is currently no labelling of the fertilizer exports from the United States that contain GE salmon byproduct.
7. Assume that the U.S. supersalmon farmers seek to export whole salmon and fillets as food products to the EU, Japan, and to emerging markets in Calero and Sudero. The US producers do not want to label their product as containing GMOs. They have lobbied the USTR to break down barriers to the importation of their products in the EU and Japan.
8. Assume that the countries of Calero and Sudero are signatories to the Biosafety Protocol and are members of the WTO;
9. Japan and the EU are signatories to the Biosafety Protocol and the United States is NOT.

### **Parties to the Negotiations**

The following parties are present at the negotiations:

1. The United States Trade Representative's Office (USTR) representing the U.S. Administration.
2. The Director General of the European Union (EU) with responsibility for transatlantic negotiations on trade;
3. The Ministry of Foreign Affairs (MOFA) of the Government of Japan (GOJ);
4. The Ministry of Trade of the developing country of Calero;
5. The Ministry of Trade and Commerce of the country of Sudero (LDC).

### **Instructions to the Parties**

Each party to the negotiation will receive separate and confidential negotiating instructions. To facilitate the negotiations, assume the following to be fact:

1. The country representatives to the negotiations have full authority to explore any and all options and proposals that might result in a negotiated agreement;
2. The negotiators will all be encouraged to develop proposals for consideration by their counterparts to address some or all of the trade-related issues presented;
3. Country team members will have an opportunity to meet with each other to develop a negotiating strategy and to assign various roles or responsibilities in the negotiations;
4. A series of short bilateral negotiations/conferences will be scheduled to address issues between the parties prior to a multilateral session is conducted on the parameters of a WTO Agreement on GMOs;
5. The multilateral session may be facilitated by a non-interested party.
6. Country representatives may divulge factual information or instructions to counterparts if it is determined that such representations might advance the interest of the party divulging said information.

### **Goals of the Simulation Exercise**

The goals of the simulation exercise are to:

1. Develop analytical and negotiation strategy skills;
2. Work within a team to build consensus around preferred outcomes and a common negotiating strategy;
3. Analyze the proposals of counterparts and develop counterproposals based on interest identification and generation of multiple options;
4. Practice negotiation skills and techniques in bilateral and multilateral settings;
5. Analyze the negotiation process including techniques and outcomes.

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**Footnotes:**

<sup>1</sup> Specter, Michael. "Bucking U.S. Trend, Europe Blocks Gene-Altered Food." The New York Times. International

<sup>2</sup> July 20, 1998.

Ibid. Ethicist Arthur Caplan of the University of Pennsylvania states in this article that "the shadow of the Holocaust is dense and incredibly powerful still. It leaves Europe terrified about the abuse of genetics. To them the potential to abuse genetics is no theory. It is a historical fact."

<sup>3</sup> Kluger, Jeffrey. "Bad Seeds." Time Magazine. International edition, Vol. 154, No. 12, September 20, 1999.

<sup>4</sup> Ibid.

<sup>5</sup> Under current EU legislation, foods and food ingredients produced from GMOs have to be labelled according to Regulation (EC) No 258/97 (Novel Foods Regulation) and Regulation (EC) No 1139/98.

<sup>6</sup> Manning, Anita. "Altered Food Might Mutate Trade." USA Today. July 14, 1999.

<sup>7</sup> "Japan, EU Demands for Non-GMO Crops Reverberates in U.S." Inside U.S. Trade. Vol 17, No. 37, September 17, 1999.

<sup>8</sup> Bates, Stephen. "Tougher EU Controls Mean Moratorium on GM Crops." The Guardian. June 26, 1999, p. 8.

<sup>9</sup> Ibid.

<sup>10</sup> Hoge, Warren. "Britons Skirmish Over Genetically Modified Crops." The New York Times. August 23, 1999.

<sup>11</sup> "EU Moves to Take France to European Court of Justice Over GMOs." Inside US Trade. Vol. 17, No. 29, July 23, 1999.

<sup>12</sup> "Ethical Concerns at Heart of Discussions on GMO Directive." European Report. June 19, 1999.

<sup>13</sup> "Finnish Environment Minister Urges Caution on GMO Legislation." Nordic Business Report. June 14, 1999.

<sup>14</sup> Bates, p. 8.

<sup>15</sup> "Japan Announces GMO Labelling in the Face of U.S. Opposition." Inside U.S. Trade. Vol. 17, No. 33, August 20, 1999.

<sup>16</sup> Ibid.

<sup>17</sup> Carruthers, Fiona. "Cooking with Genes." Time Magazine. International edition. Vol. 154, No. 7, August 16, 1999.

<sup>18</sup> "Barshefsky Says Biotech Problems Require Bilateral, WTO Approach." Inside U.S. Trade. Vol. 17, No. 42, October 22, 1999.

<sup>19</sup> Ibid.

<sup>20</sup> "Congress Weighs in With Issues for Visit by EU Commission." Inside U.S. Trade. Vol. 17, No. 43, October 29, 1999.

<sup>21</sup> Proposal submitted from Canada in document WT/GC/W/359, and from Japan in WT/GC/W/365.

<sup>22</sup> "Barshefsky Says Biotech Problems Require Bilateral, WTO Approach." Inside U.S. Trade. Vol. 17, No. 42, October 22, 1999.

<sup>23</sup> "U.S., Ag Interests Split on How to Tackle Biotech in WTO Round." Inside U.S. Trade. Vol. 17, No 38, September 24, 1999.

<sup>24</sup> The Miami Group consists of Canada, Australia, Uruguay, Argentina, Chile, and the U.S. (it is noteworthy that although the U.S. has not ratified the Convention on Biological Diversity, it is able to participate in the negotiations through its linkage to the Miami Group).

<sup>25</sup> Pollack, Andrew. "U.S. and Allies Block Treaty on Genetically Altered Goods." The New York Times. February 25, 1999.

<sup>26</sup> The legal aspects of international agreements on biosafety and GMOs will be further discussed in the "Legal Analysis" chapter of this paper.

<sup>27</sup> Press Pack, WTO 3<sup>rd</sup> Ministerial Conference, Seattle, p.20.

<sup>28</sup> Speaking Note for Commissioner Byrne, Arthur Cox Conference on Food Law, 5 November, 1999.

<sup>29</sup> Palmer, Doug. "U.S. Sees Faults in EU Precautionary Principle Paper." Reuters. March 22, 2000.

<sup>30</sup> Quoted in St. Louis Post-Dispatch, May 25, 1999.

<sup>31</sup> "Europe Clamps Down on GMOs." Chemistry & Industry Magazine. <http://ci.mond.org/current/991304.htm>, July 5, 1999 (retrieved February 23, 2000).

<sup>32</sup> Pollack, Andrew. "Setting Rules on Biotechnology Trade." The New York Times. February 15, 1999.

<sup>33</sup> MacKenzie, Debora. "How to Price What We Put on Our Plate." New Scientist. February 27, 1999.

<sup>34</sup> Ibid.

<sup>35</sup> Carpenter, Janet, and Gianessi, Leonard. "Why U.S. Farmers are Adopting Genetically Modified Crops." Economic Perspectives. Vol. 4, No. 4, October 1999, p. 22.

<sup>36</sup> Larson, Alan. "Biotechnology: Finding a Practical Approach to a Promising Technology." Economic Perspectives. Vol. 4, No. 4, October 1999, p. 6.

<sup>37</sup> El Feki, Shereen. "Growing Pains: Agriculture and Technology." The Economist. March 25, 2000.

<sup>38</sup> "Modern Food Biotechnology: Facts and Figures." The Alliance for Better Foods Fact Sheet. September 23, 1999.

<sup>39</sup> Speech by Mr. David Byrne, European Commissioner for Health and Consumer Protection to the conference on "Biotechnology – science and impact," The Hague, January 21, 2000.

<sup>40</sup> El Feki, Shereen. "Growing Pains: Agriculture and Technology." The Economist. March 25, 2000

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- <sup>46</sup> Speech by Mr. David Byrne, European Commissioner for Health and Consumer Protection to the Conference on "Biotechnology – Science and Impact." The Hague, January 21, 2000.
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- <sup>48</sup> <http://www.mjv.se/mat/upprop2.html> (February 13, 2000).
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