Genetically Modified Organisms (GMOs):

A Transatlantic Trade Dispute

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SCENARIO

For the purpose of this project, I assume the role of policy advisor to a fictitious person, Mr. Thomas Hopkins, EU Commissioner for Health and Consumer Protection (Directorate-General 24).

The first portion of the project includes a background section and several short analytical papers that examine the political, commercial, and legal aspects of the U.S.-EU dispute over GM products. The second half of the project provides a recommendation and strategy for addressing the U.S.-EU dispute over trade in GMOs.

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EXECUTIVE SUMMARY

Issue

In June 1999, the EU Council of Ministers decided to impose tougher, highly burdensome risk assessment requirements on all products that contain genetically modified organisms (GMOs)—requirements such as comprehensive labelling, thorough monitoring of products once they have been put on the market, and renewed approvals for all products after they have been on the market for 10 years. The practical effect of the regulations is that of a moratorium on the import of GMOs.

As the world's largest producer and exporter of GMOs, the U.S. is very concerned about the long-term effects of this *de facto* moratorium. The U.S. agricultural industry has argued that the EU's restrictive policy on biotechnology products is nothing but an attempt to protect its own agricultural industry. Already, the EU's ban on GMOs is said to be costing U.S. corn farmers some $200 million annually in lost sales, and the U.S. has threatened to take the EU before the WTO dispute settlement body if the issue is not soon resolved.

Background

A "genetically modified organism," or GMO, is a living organism, the genetic material of which has been permanently altered through gene technology (i.e., altered 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 foods sold and produced in the U.S. However, because growing and marketing GM food products are largely unregulated activities in the U.S., most Americans have not, until recently, been aware of GMOs and, until recently, there has been little or no U.S. 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, and EU officials have responded by imposing strict risk assessment requirements on GM products. However, because not enough scientific tests have been conducted to prove that GMOs are indeed harmful to human, animal and/or environmental health, the EU has relied heavily on the "precautionary principle" to defend these regulations. It is this "safety first" approach to GMO regulation, as well as the EU's failure to establish a transparent and timely regulatory system, that the U.S. has threatened to challenge within the WTO.

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Recommendation & Strategy

Thanks to the Biosafety Protocol to the Convention on Biological Diversity (which was finalized in Montreal earlier this year), issues surrounding the release of GMOs into the environment (e.g., seed plantings) have already found a forum.

In order to ensure that European consumers retain their choice as to whether or not to consume GM food products, however, the European Commission should seek an agreement with the U.S. concerning mandatory labelling requirements and use of the precautionary principle.

INTRODUCTION

High-tech electronic data protection, beef, bananas—the EU and the U.S. have been caught up in a near-record number of trade disputes in recent months. These disputes, however, would likely all fade into triviality if a transatlantic trade war were to erupt over the issue of agricultural products that are derived from or contain genetically modified organisms (GMOs).

Indeed, European consumers have vehemently opposed the unregulated release of GMOs into EU markets, and in response, EU legislators have taken actions that effectively ban the import of goods made with genetically modified ingredients. The result has been a major disruption in U.S.-EU agricultural trade flows that, in June last year, prompted the U.S. government to threaten to challenge the current EU regulations within the WTO. The specific areas of contention include the EU's:

- mandatory labelling requirement for products that contain more than 1% genetically altered ingredients,
- time-limited product authorizations, and
- non-transparent regulations for GM product approvals.

The U.S. biotechnology industry, as well as the U.S. government, has charged that the EU's product approval process for GM products is subjected to delays due to political considerations rather than only legitimate health or safety concerns. In the words of U.S. Trade Representative Charlene Barshefsky, the EU's procedures for approving GMOs involve a "highly politicized, opaque regulatory process" that has fostered "consumer fear about food safety."[1]

EU Concerns Over Food Safety

While the American public's response to GMOs has been relatively subdued, the European response has been extremely emotional. Many Europeans are strongly opposed to any kind of genetic tampering, and a recent survey revealed that only half of all Europeans find it morally acceptable to apply biotechnology to food.[2] Europe's recent string of health scares due to food contaminants (e.g. mad cow disease and dioxin contamination) has only helped further heighten concerns over food safety. And widespread, even violent protests against "Frankenstein Foods" have ensured that the GMO issue gets media and public attention.

[1] "Barshefsky Says Biotech Problems Require Bilateral, WTO Approach." Inside U.S. Trade. Vol. 17, No. 42, October 22, 1999.
[2] Speech by Mr. David Byrne, European Commissioner for Health and Consumer Protection to the Conference on "Biotechnology – Science and Impact," delivered in The Hague on January 21, 2000. http://www.europa.eu.int/comm/dg24/library/speeches/speech36_en.html (January 25, 2000).

The EU's Regulatory Regime for GM Products

Under current EU legislation, a genetically modified food can only be placed on the market after it has been scientifically evaluated in accordance with the latest scientific knowledge and found to be safe for human health and the environment. In cases where the scientific evidence is insufficient, inconclusive, or uncertain, protective measures are adopted on the basis of the "precautionary principle," which is found in Article 5.7 of the WTO Agreement on Sanitary and Phytosanitary Measures.

The EU has also imposed labeling requirements on GM foods—a position that EU Commissioner for Health and Consumer Protection David Byrne recently reaffirmed stating that the right to information is "key… to the development of a civil responsibility."[3] Europeans have consistently called for clear, unambiguous labeling—not so much for safety reasons, but in order to enable consumers to make informed choices.

The EU has also taken action to ensure that international trade rules support their position on GMOs. The European Commission recently issued a communication that seeks to better define the precautionary principle and to clarify the conditions for its use by answering when and how it should be applied to protect the public[4]—a move the U.S. industry fears would reopen and possibly weaken the SPS Agreement. In negotiating the Biosafety Protocol, the EU succeeded in establishing 1) mandatory labelling requirements for all living modified organisms meant for release into the environment and 2) the precautionary principle as a legitimate basis for a country's decision to refuse to accept imports of such organisms.[5]

The Importance of GMO's within the U.S. Economy

With an export value of more than $50 billion yearly, agricultural products represent a crucially important sector of the U.S. economy, and GM crops play a large role within the sector—they currently make up almost 40% of all corn, 45% of all soybeans, and 50% of all cotton produced in the U.S. It has been estimated that U.S. corn producers alone are losing some $200 million/year in corn exports due to the EU's refusal to permit imports of genetically modified corn.[6]

[3] Ibid.
[4] Ibid.
[5] Though this agreement does not cover agricultural products intended for consumption or processing, it does require exporters to obtain pre-shipment permission from the importing country for shipments of living GMOs meant for planting or "commercial use."
[6] Alan Larson, "Biotechnology: Finding a Practical Approach to a Promising Technology." Economic Perspectives. Vol. 4, No. 4, October 1999, p. 6.

BACKGROUND

Genetic modification entails the permanent alteration of a species' genetic code (DNA) through laboratory methods that 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, to enhance nutritional content, and to increase yields. Corn, soybeans, cotton, and potatoes are among the bio-engineered products that are already on the market. More extreme examples of current 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 that are able to produce their own pesticides at the appropriate time of the growing cycle.

So far, more than 4,500 genetically modified plants have been tested, and 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.[7] 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.

Most biotechnology researchers see genetic engineering technologies as a major scientific advancement. They, along with many agricultural producers, point to the potential of GMOs to revolutionize current methods of food production and to 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 by pests or other environmental circumstances prior to harvest.[8] GMOs offer the promise of substantially improving crop yields.

For large biotechnology companies such as the U.S.-based companies Monsanto and Dupont, and the Swiss-based company 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.[9]

[7] Jeffrey Kluger, "Bad Seeds." Time Magazine. International edition, Vol. 154, No. 12, September 20, 1999.
[8] Michel Specter, "Bucking U.S. Trend, Europe Blocks Gene-Altered Food." The New York Times. International, July 20, 1998.
[9] Kluger.

Nonetheless, because few scientific studies have been conducted, there is not yet proof that genetically engineered foods are either safe or harmful for human consumption, and this has left many consumer groups highly concerned about GM foods' potential to cause harm—either to the environment or to those who consume the foods. There is concern that GM foods could produce unknown allergens, increased levels of naturally occurring toxic substances, or decreased levels of nutrition. Certain religious groups are further worried about the possibility that genes from foods they are forbidden to eat might 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.[10]

U.S. Policy & Opinion on GM Foods

In the United States, growing and marketing GM foods are largely unregulated activities. A company that wants to grow a bio-engineered product need only 1) report its intent to raise a GM crop to the USDA; 2) provide an assurance that the product is safe; and 3) report any problems or negative research results in connection with the product in question. 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. Moreover, labels are not required to indicate whether a food contains GM materials because U.S. policy only requires labels to indicate ingredients that change the nutritional content of a food or could cause allergies.

Several large biotechnology companies have argued that any change in U.S. policy would be extremely costly and harmful to the profitability of U.S. grain growers. Under current production methods, they assert, segregation of genetically modified and conventional, identity-preserved, crops is almost impossible. Accordingly, many within the U.S. agricultural industry have insisted on promptly resolving the U.S.-EU dispute 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.

Other U.S. companies, however, have become concerned that customers may be switching away from products that may contain GMOs (such as corn and soybeans) to products that have not been genetically altered (*e.g.* peas and tapioca), and these companies have voluntarily changed their policies on GMOs. Archer Daniels Midland Company, for example, has recommended that its suppliers develop ways to segregate conventional from modified grains in order to meet increased foreign demand for non-GM products.[11]

While the National Corn Growers Association and other producer groups have strongly criticized ADM's position (and ADM has subsequently softened its stance), recent comments by U.S.

[10] Specter (see note 8) quotes ethicist Arthur Caplan of the University of Pennsylvania as stating 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."

[11] "Japan, EU Demands for Non-GMO Crops Reverberates in U.S." Inside U.S. Trade. Vol 17, No. 37, September 17, 1999.

Secretary of Agriculture Dan Glickman indicate that U.S. policy towards GM foods could be following ADM's lead and bending to consumer pressure. In July 1999, Glickman told U.S. producers that they may have to consider labeling in order to ensure access to foreign markets that require complete disclosure of GM content.[12]

As for Congress, some senators and representatives have actively lobbied the U.S. 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.[13] Other members, however, has introduced mandatory labelling legislation.

EU Policy & Opinion on GM Foods

Establishing a common EU position concerning the cultivation and use of GMOs has been difficult, largely because food safety is an area in which individual nation-states continue to fiercely guard their right to regulate. Nonetheless, public opposition to "Frankenstein foods" has been mounting for more than two years, especially in France and Britain. Farmers who have agreed to participate in government-run test plantings of GM seeds have seen their fields invaded and destroyed, and on August 12, 1999, a McDonald's restaurant in Millau, France, was ransacked. Several major political parties and prominent citizens, including Paul McCartney and Prince Charles, have aligned themselves with environmental advocacy groups that strongly oppose GMOs.

In short, national governments in the EU have come under tremendous pressure to impose tight restrictions on GM products, and accordingly, the EU began in 1998 to require foods to be labelled if they contain protein or DNA as a result of genetic modification.[14] EU member states are also required to regulate the release of GMOs into the environment in order to minimize their potentially harmful effects. (So far, only 18 GMOs have been authorized for experimental growth in the EU since 1990, and in the past two years, each of the four new applications were rejected.[15]) Moreover, in response to demands by France, Greece, Austria, Denmark, and Luxembourg, the EU recently established what amounts to a *de facto* moratorium on new GMO approvals until 2002;[16] the EU has imposed regulations that involve tougher risk assessments, more comprehensive labelling and monitoring of products once they are on the market, and re-approval of GM foods after they have been on the market for 10 years.[17]

Individual EU countries have also taken action to contain GMOs. In Britain, Prime Minister Tony Blair, a strong proponent of GM foods himself, has yielded to public pressure, and food

[12] Anita Manning, "Altered Food Might Mutate Trade." USA Today. July 14, 1999.
[13] "Congress Weighs in With Issues for Visit by EU Commission." Inside U.S. Trade. Vol. 17, No. 43, October 29, 1999.
[14] The 1998 labeling requirement is found in Regulation (EC) No 258/97 (Novel Foods Regulation) and Regulation (EC) No 1139/98. On October 21, 1999, this requirement was modified so that only foods containing more than 1% genetically modified ingredients now need to be labeled as such.
[15] Stephen Bates, "Tougher EU Controls Mean Moratorium on GM Crops." The Guardian, June 26, 1999, p. 8.
[16] Ibid. The *de facto* ban was established following a meeting of the EU's environment ministers in Brussels on June 25, 1999.
[17] Ibid, p. 8.

outlets are now required to identify all food items that may contain traces of GMOs.[18] Both Austria and Luxembourg have flat-out refused GM trials in their countries, and France is currently being challenged by the EU Commission over its decision to withhold pro forma approval of two strains of GM rapeseed—strains that were approved by the Commission in 1997.[19]

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.[20] Denmark, Spain, and Greece have supported Sweden's stand on ethics and, further, have vowed never to approve products that may cause resistance to medicinal antibiotics.[21]

Other Countries' Policies & Opinions on GM Foods

Although the EU countries have gone the farthest in their protest against GMOs, other countries have also begun to tightly regulate GM products. In Japan, the Ministry of Agriculture, Forestry, and Fisheries (MAFF) recently announced a proposal to introduce mandatory labelling of some 30 food products derived from genetically modified corn and soybeans (beginning in April 2001), and Japanese consumer groups are actively lobbying MAFF to add more products to the list.[22]

A few days after the Japanese proposal was made public, Australian and New Zealand state and federal health ministers responded to increased public anxiety over GMOs with a communiqué that called for mandatory labelling of all GM foods.[23]

WTO Efforts to Address GMOs

Within the WTO, the standard-setting rules under the WTO Agreement on Technical Barriers to Trade (TBT Agreement) have some implications for the GMO issue. More relevant is the WTO's SPS Agreement. However 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.[24]

[18] Warren Hoge, "Britons Skirmish Over Genetically Modified Crops." The New York Times, August 23, 1999.
[19] Because the applications for the rapeseeds were originally filed in France, the seeds cannot be put on the market without French approval. "EU Moves to Take France to European Court of Justice Over GMOs." Inside US Trade, Vol. 17, No. 29, July 23, 1999.
[20] "Ethical Concerns at Heart of Discussions on GMO Directive." European Report. June 19, 1999.
[21] "Finnish Environment Minister Urges Caution on GMO Legislation." Nordic Business Report, June 14, 1999.
[22] "Japan Announces GMO Labelling in the Face of U.S. Opposition." Inside U.S. Trade. Vol. 17, No. 33, August 20, 1999.
[23] Fiona Carruthers, "Cooking with Genes." Time Magazine. International edition. Vol. 154, No. 7, August 16, 1999.
[24] Press Pack, WTO 3rd Ministerial Conference, Seattle, p.20.

Indeed, the EU would like to strengthen countries' rights to establish higher levels of sanitary and phytosanitary protection than those stipulated by international standards,[25] provided they can be scientifically justified in a comprehensive risk assessment.[26] The EU has also taken the position that countries should be able to rely on the SPS Agreement's "precautionary principle" (found in Article 5.7) when dealing with scientific uncertainties, such as the effects of biotechnology on human health and the environment.[27]

In order to resolve these issues, the US and the EU have agreed to support the creation of a fact-finding WTO working group on biotechnology.[28] However the U.S. has insisted that the group remain solely a fact-finding body without any negotiating authority. Representatives of the U.S. biotechnology industry have warned that any negotiations that seek to improve regulatory processes could lead to a reopening of already ratified agreements, such as the SPS Agreement, and this, in turn, could result in a weakening of current trade rules. The U.S. agriculture industry is also 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.[29] Following this logic, the creation of a working party would likely lead to negotiation 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.

OECD Efforts to Address Biotechnology Issues

In February 2000, the OECD held a three-day Conference on the Scientific and Health Aspects of Genetically Modified Foods at the request of the Group of Eight (G8) industrialized countries. Convened in Edinburgh, the conference was intended to explore the science on whether or not GM foods are safe to eat.

The conference was attended by four hundred scientists, regulators, and environmental and consumer activists. Its likely outcome is the creation of an international panel on food safety that will be tasked with informing policymakers about GM issues. Sir Robert May, Britain's chief scientific adviser, has suggested that the panel could be similar to the IPCC, the Intergovernmental Panel on Climate Change, which was established to tackle the challenges of global warming.[30] Sir May has also suggested that the panel should consist of scientists who are

[25] 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 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 Agreement 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), the membership of which is open to all WTO members.
[26] Speaking Note for Commissioner Byrne, Arthur Cox Conference on Food Law, 5 November, 1999.
[27] The legal aspects of international agreements on biosafety and GMOs are further discussed in the "Legal Analysis" section of this paper.
[28] Proposal submitted from Canada in document WT/GC/W/359, and from Japan in WT/GC/W/365.
[29] "U.S., Ag Interests Split on How to Tackle Biotech in WTO Round." Inside U.S. Trade. Vol. 17, No 38, September 24, 1999.
[30] Patricia Reaney, "Adviser Calls for International GM Foods Panel." Reuters. February 29, 2000.

both supporters and critics of biotechnology so that a broad range of expertise would be represented.

Many environmental groups such as Greenpeace and Friends of the Earth, have criticized the conference as doing nothing to solve the uncertainties surrounding biotechnology. Greenpeace, in particular, has accused the OECD of sidelining critics and failing to include more farmers and other concerned advocacy groups in the meeting.

The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety is a supplemental agreement to the United Nations Convention on Biological Diversity. There were three major sticking points in the negotiation of the Protocol. The first involved the steps a country would be required to take prior to releasing living modified organisms (LMOs) into the environment. The Miami Group[31] was firmly opposed to the proposed definition of LMOs, which it felt went beyond the scope of the Protocol. The Miami Group held that the Protocol 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 for reliance on science-based evidence instead of the safety first approach embodied in the precautionary principle.

The third main sticking point concerned 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 only those meant for planting. The Miami Group, led by the U.S., 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 even went so far as to demand that the treaty also cover products made from GM ingredients—products 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.[32]

In spite of the great divide between the Miami Group and the EU-led Like-Minded Group, the Biosafety Protocol was finally adopted in Montreal in late January 2000 by more than 130

[31] Ironically, the U.S.—by far the world's largest exporter of GMOs—was not allowed to take the microphone or vote in the Biosafety Protocol negotiations because it is not yet a signatory to the Convention on Biological Diversity. The U.S. was, however, able to participate "on the sidelines" through its linkage to the so-called Miami Group, which consists of Canada, Australia, Uruguay, Argentina, Chile, and the U.S. (President Clinton signed Convention in 1993, but Senator Jesse Helms has refused to allow a Senate vote to ratify it.)

[32] Andrew Pollack, "U.S. and Allies Block Treaty on Genetically Altered Goods." The New York Times. February 25, 1999.

nations. The Protocol 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 from importing countries before proceeding with the first shipment of a particular LMO meant for release into the environment (such as seeds, microbes, or fish). The requirement does not apply to exports of agricultural commodities intended for consumption or processing. With regard 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."

One of the most important aspects of the treaty is its inclusion of the "precautionary principle." According to the Protocol, countries now have the right to refuse the importation of any GMOs meant for release into the environment—even if there is insufficient scientific evidence to prove that the product will in fact cause environmental harm.

Outlook

In 1999, rather than 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. Given its main objective of using the Seattle Ministerial as a springboard to successfully launch a new round of multilateral trade negotiations, USTR was concerned primarily with maintaining the EU's support for key issues related to WTO operations and procedures.

However, the issue of biotechnology continues to create conflict between the U.S. and EU, and the need for mutually acceptable rules and guidelines has become increasingly urgent. Regardless of when a new round of multilateral trade negotiations is or is not launched, the two countries will need to continue to negotiate biotechnology issues at both the 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. In the words of the U.S. Agriculture Secretary, any escalation of the transatlantic disputes over bioengineered crops "could make beef hormones look like the minor leagues."[33]

[33] Quoted in St. Louis Post-Dispatch, May 25, 1999.

COMMERCIAL ANALYSIS

The European View

From a European viewpoint, the commercial benefit of GMOs is intrinsically linked to the issue of food safety. As pointed out by Commissioner Byrne in a recent speech, high levels of consumer confidence are necessary in order to boost trade and competitiveness.[34] 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 economic viability of the whole agri-food sector.

The EU's agriculture sector produces 600 billion euros worth of goods annually—approximately 15% of total EU manufacturing output. It also provides about 10 million jobs. Even a slight dip in confidence could have a significant economic effect, and the Europeans have plenty of recent examples of how this can happen. Last year, animal feed tainted with polychlorinated biphenyls and furans was sold to 1,700 Belgian farmers and found its way into chickens, pigs, and cattle. The contamination 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.[35]

The American View

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 on the marketing of new GM foods. According to U.S. Trade Representative Charlene Barshefsky, the delays are already costing U.S. corn farmers some $200 million annually in lost sales.[36] The U.S. exports more than $50 billion worth of agricultural products per year, and more and more of the major commodity crops are genetically engineered.[37]

U.S. farmers have vehemently opposed all mandatory labelling schemes mainly because such schemes require producers to segregate GM and conventional crops and such segregation would be very costly. 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

[34] 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.
[35] Shereen El Feki, "Growing Pains: Agriculture and Technology." The Economist. March 25, 2000.
[36] "Europe Clamps Down on GMOs." Chemistry & Industry Magazine. http://ci.mond.org/current/991304.htm, July 5, 1999 (retrieved February 23, 2000).
[37] Andrew Pollack, "Setting Rules on Biotechnology Trade." The New York Times. February 15, 1999.

by as much as 150%.[38] Accordingly, it is not surprising that the U.S. government has threatened a trade war in response to the EU's demand for segregation and labelling.[39]

U.S. farmers have adopted genetically modified crops because they promise higher yields, lower costs, and greater ease of management. Soybean growers have switched to the genetically modified Roundup Ready soybean seed largely because it facilitates weed control. 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.[40] Indeed, 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.[41] Another study found that gains from planting Bt cotton amounted to $200 million in 1997.[42]

[38] Debora MacKenzie, "How to Price What We Put on Our Plate." New Scientist. February 27, 1999.
[39] Ibid.
[40] Janet Carpenter and Leonard Gianessi, "Why U.S. Farmers are Adopting Genetically Modified Crops." Economic Perspectives. Vol. 4, No. 4, October 1999, p. 22.
[41] "Modern Food Biotechnology: Facts and Figures." The Alliance for Better Foods Fact Sheet.. September 23, 1999.
[42] Greg Taxler and Jose Falck-Zepeda, cited in Shereen El Feki.

POLITICAL ANALYSIS (EU)

On August 12, 1999, a McDonald's restaurant in the French town of Millau became an object of worldwide attention when it was ransacked and demolished by an angry crowd of farmers and ecologists protesting against American "multinationals of foul food."[43] *Their leader, José Bové, a Parisian intellectual turned activist-farmer, has become the lead figure for European opposition to genetically modified organisms (GMOs) 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 McDonald's, which he sees as a symbol of an American-led globalization effort that is threatening the culinary sovereignty of EU member countries and the right of European consumers to eat as they see fit.*[44]

In Europe, public protests against genetically engineered foods have been mounting for more than three years. The outcry from France and Britain has been particularly loud. Prince Charles, one of the most prominent figures in the EU campaign against GMOs, has publicly stated that he will not allow any genetically altered food ever to 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."[45]

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 fear toward a new technology that is widely perceived to be completely dominated by American

[43] Roger Cohen, "Fearful Over the Future, Europe Seizes on Food." The New York Times. August 29, 1999.
[44] Kenneth Klee, "Frankenstein Foods?" Newsweek. September 13, 1999, p. 33.
[45] Specter.

multinational corporations. Alain Duhamel, a French political analyst, believes that a widespread rejection of cultural and culinary dispossession is at the root of the protests. According to this theory, Europeans are "allergic" to the amount of power the United States has accumulated since the end of the Cold War, and its most virulent expression is culinary sovereignty.[46] As José Bové has stated, 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."[47]

Other experts have emphasized the ethical aspect of the issue. Indeed, genetic engineering strikes at our fundamental ability to control the environment in which we live. 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?"[48]

Critics, however, 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-yield seeds belong to large American corporations such as Monsanto, DuPont and Dow.[49] Biotechnology allows agricultural production to become more vertically integrated, consolidated, and centralized—all in the hands of multinational corporations—and European agricultural interests are scared by the fact that it is American companies that dominate this industry. This viewpoint is somewhat weakened, however, by the EU's March 2000 decision 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.[50] All three varieties had been produced by European biotechnology companies: AgrEvo, Danisco, Hoechst AG, and Shering AG.

The truth behind Europe's opposition to GMOs is undoubtedly a mix of all these factors. Regardless, it is also true that the many benefits of biotechnology 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.[51] Similarly, at least one study found that just 7% of the $200 million gained by planting Bt cotton went to consumers—42% and 35% went to farmers and Monsanto (the gene patent holder) respectively.[52] The public's attitude towards GMOs in Europe

[46] Cohen.
[47] Ibid.
[48] Lisa Y. Lefferts, "Safety and Choice: Key Consumer Issues for Genetically Modified Foods." Economic Perspectives. Vol. 4, No. 4, October 1999.
[49] Craig R. Whitney, "Europe Loses its Appetite for High-Tech Food." The New York Times. June 27, 1999.
[50] Andrew Osborne, "EU Keeps Moratorium on New GM Crops." Reuters. March 9, 2000.
[51] Lefferts.
[52] Greg Taxler and Jose Falck-Zepeda, cited in Shereen El Feki.

is not likely to change until the biotechnology industry successfully manages to inform and convince consumers of the merits of this new technology.

Europe's Concerns About Biotechnology

In light of the recent public health scares in Europe, such as the outbreak of mad cow disease and the dioxin contamination in Belgium, 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 authorities who are ostensibly in charge of monitoring and ensuring the highest standards of food safety.[53]

Europeans are also greatly concerned about biotechnology issues such as animal welfare, sustainable agriculture, and consumers' right to information. And environmental protection is of particular concern. 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).[54] Not surprisingly, the European Green Parties have taken a very firm stance against GMOs. They have argued that not enough scientific testing has been done to determine the effect of GMOs on the environment; any premature release of GMOs into the environment, they have warned, could result in serious disruption, if not devastation, of the ecosystem.

Among the EU member states, Sweden, Denmark, Spain, and Greece have been the most vocal in calling for ethical considerations to be taken into account when approving new GMOs.[55] In Sweden, the Green Party and 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.[56] Traditionally, the Green Parties of the Nordic countries, as well as those of 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.

Consumer Calls for Mandatory Labelling

Europeans have consistently demanded that genetically modified food be labelled in order to enable consumers to make informed choices about the products they buy. 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 too have the demands for complete information on production methods and product labelling. In a 1998 survey, 86% of Europeans called for mandatory labelling of genetically modified food.[57] Commissioner Byrne

[53] Speech by Mr. David Byrne.
[54] http://www.greenparty.uk.org (February 13, 2000).
[55] Nordic Business Report, June 14, 1999.
[56] http://www.mjv.se/mat/upprop2.html (February 13, 2000).
[57] Speech by Mr. 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.[58]

One of the points made in support of mandatory labelling is that GM foods have the potential to cause allergic reactions. It is a scientific fact that genetic engineering can introduce unknown allergens into food because virtually every gene transfer results in some protein production, and proteins are what trigger allergic reactions.[59] If a person is at risk for an allergic reaction to a conventional food, he or she can avoid exposing himself/herself to that allergen by checking the food label, which typically identifies all the ingredients. However, if a person 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.[60]

Another argument in support of mandatory labelling of genetically modified products rests on the fact that many Europeans find GMOs objectionable for ethical or religious reasons. These individuals have demanded their right to know whether the products they consume contain spliced genes from animals or species that are proscribed by certain religions. Labelling would allow these consumers to make purchasing decisions that do not conflict with their beliefs.[61]

Attempts to Address Public Concerns About GMOs

In response to public concerns about food safety, the European Commission is working to improve legislation on GMO labelling and to create a legal framework for a "GMO-free" line of products (to which producers may adhere on a voluntary basis). The Commission has also recommended that the European Working Party on Ethics in Science and New Technology be consulted prior to allowing any new products that contain GMOs to be placed on the market,[62] and it recently issued a white paper that outlines 80 separate actions for making relevant EU legislation more coherent, responsive, and flexible. The white paper includes specific proposals for dealing with GMO-related issues such as the application of the precautionary principle in risk management decisions and the introduction of adequate procedures for food traceability. It also calls for the establishment of an independent European Food Authority with responsibility for risk assessment and risk communication.[63]

Within the private sector, several groups of European distributors have joined forces in a bid to rid their supermarket shelves of GM products, regardless of what 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 was subsequently adopted by the other six distribution members

[58] Ibid.
[59] Lefferts.
[60] Ibid.
[61] Ibid.
[62] European Report, June 19, 1999.
[63] Though there are many similarities between this proposed agency and the U.S. Food and Drug Administration, the European Food Authority would not have any regulatory powers and hence would not get into the area of risk management. Any decision-making with regard to risk management would continue to be the responsibility of the EU Commission, Parliament, and Council of Ministers.

of the Sainsbury consortium: Marks and Spencer (U.K.), Carrefour (France), Effelunga (Italy), Migros (Switzerland), Delhaize (Belgium), and Superquinn (Finland).[64] As early as February 1997, Novartis (a giant Swiss agribusiness, chemical and drug company) announced its intent to advocate that all genetically engineered crops and foods be clearly labelled.[65] The head of Novartis' agribusiness unit, Wolfgang Samo, explained the move stating: "There is no need [for labels] 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."[66]

[64] "Genetic Engineering: European Retailers Join Forces Against Transgenic Food." Europe Agri. March 19, 1999.
[65] Barnaby J. Feder, "Biotech Firm to Advocate Labels on Genetically Altered Products." The New York Times. February 24, 1997.
[66] Ibid.

POLITICAL ANALYSIS (U.S.)

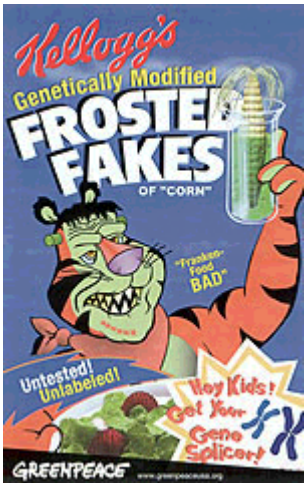
Whereas the debate over GMOs in Europe has been characterized by public protests and a high level of consumer activism, the American public has been relatively slow to react to this new technology. Unlike the British, for instance, whose concerns about food safety have been on the rise since the outbreak of mad cow disease in 1996, Americans have seemed largely indifferent to genetically modified foods.

An important reason for this apparent lack of concern is that only a very few Americans have been aware of the introduction of GMOs into the food chain. 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, the only foods subject to mandatory labelling are those with ingredients that are proven to either change the nutritional content of a food or cause allergic reactions.

Nonetheless, public opinion in the U.S. is rapidly shifting in favor of stricter regulations and mandatory labelling for GM products. According to a recent poll by *Time* magazine, 81% of Americans want GM food to be labelled.

NGOs' Attempts to Contain GMOs

NGO efforts are largely responsible for the American public's newfound concern over GMOs. In late fall 1999, Greenpeace invaded cereal maker Kellogg's headquarters in Battle Creek, Michigan, to protest 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. Many U.S. environmentalist and consumer activist groups have since launched their own campaigns against GMOs, although Greenpeace remains one of the most vocal organizations in the U.S. Through its True Food Network, Greenpeace has been instrumental in pressuring companies such as Heinz and Gerber to drop genetically altered soybeans and corn from their baby formulas. In Europe, Kellogg's has already begun to phase out their GM products in response to Greenpeace's demands.[67]



[67] Frederic Golden, "Who's Afraid of Frankenfood?" Time Magazine. Vol. 154, No. 22, November 29, 1999.

American NGOs have also turned to the law in their efforts to protect the environment from the advances of biotechnology. In late February 1999, 65 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.[68] The suit demands that the EPA immediately withdraw its approval of all Bt plants and refrain from making any new approvals until a complete, scientific environmental impact assessment has been carried.

While the EPA has rejected all accusations that it may have approved any biotechnology products without due consideration of their potentially harmful environmental effects, some scientist groups, such as the Union of Concerned Scientists, have confirmed that the EPA's current approval process for biotech crops is inadequate.[69] In response, EPA's Scientific Advisory Panel announced in February 2000 that it would advise the EPA to test crops on a wider variety of insects than the four species currently tested. It also recommended that the EPA require more data from seed companies on the impact of GM crops in the field.[70]

American Legislators' Attempts to Contain GMOs

The concern over the safety of genetically engineered products has also begun to infiltrate U.S. politics. In October 1999, Representatives David Bonior, Dennis Kucinich, and Chris Shayes and 46 other House members sent a letter to FDA Commissioner Jane Henney calling for mandatory labelling of genetically engineered foods. A month later, Representative Kucinich introduced Bill H.R. 3377, the "Genetically Engineered Food Right to Know Act, " which states that all foods that contain or are produced with genetically engineered material must be labelled as follows:

GENETICALLY ENGINEERED

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. In late February this year, Barbara Boxer introduced a similar bill (S. 2080) in the Senate.

On March 9, 2000, Representative Kucinich upped the ante further when he introduced bill HR 3883, "The Genetically Engineered Food Safety Act." This bill would require all GM foods to be examined for allergenicity, unintended effects, toxicity, functional characteristics, and nutrient

[68] Bob Holmes, "The Great Divide." New Scientist. February 27, 1999.
[69] Philip Brasher, "Tighter Biotech Crop Regs Urged." Associated Press. February 17, 2000.
[70] Ibid.

levels—in addition to passing FDA's regulations for food additives. The bill would also require the FDA to 1) allow a public comment period of at least thirty days once a completed safety application is available to the public, and 2) disclose all studies performed by the applicant to the public. Bill HR 3883 has the support of nine co-sponsors.

Passing these bills, however, will not be easy. 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" of seeking to provide "short-term protection to their farmers….[and] limit the productivity of foreign farmers" by exploiting public fears of genetically engineered foods.[71] Senator Bond, with the support of 23 other Senators,[72] urged the Administration to be firm in its negotiations on biotechnology products, and to not yield from its insistence on science-based, rather than politically influenced, risk assessments. Senator Bond also criticized food companies that have chosen to forego using GM inputs in their products for "knowingly undermining our scientists and trade negotiators to placate the Luddites and protectionists."

U.S. Industry's Views

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 not adopt new labelling policies for foods that contain genetically engineered additives.[73] 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. By changing the current policy to require special labelling, the FDA also would run the risk of undermining its own credibility.

Nonetheless, on August 31 1999, Archer Daniels Midland Company (ADM) issued its recommendation that farmers selling to the company segregate non-genetically enhanced crops to preserve their identity.[74] Although ADM later modified its stance and issued a statement explaining that it would not turn away genetically modified grains, other American (and Canadian) companies have stuck with their decisions to eliminate GMOs from their products:

- Seagram no longer accepts GMO corn (beginning in the fall 2000).[75]
- McCain Foods Ltd. no longer accepts genetically modified potatoes.

[71] Congressional Record, pages S58-S63.
[72] Senators who supported Bond were Kerry, Durbin, Hagel, Craig, Frist, Conrad, Lugar, Gorton, Grassley, Ashcroft, Robb, Burns, Grams, Gordon, Smith, Baucus, Helms, Hutchinson, Roberts, Bayh, Brownback, Crapo, and Coverdell.
[73] "Agri-food Community Open Letter to President Clinton on Science-based Labelling of Foods." http://www.monsanto.com/monsanto/mediacenter/background/99nov12_agrifood.htm (downloaded February 5, 2000).
[74] "Japan, EU Demands for Non-GMO Crops Reverberates in U.S." Inside U.S. Trade. Vol. 17, No. 37, September 17, 1999.
[75] Stuart Laidlaw, "Seagram Quietly Rules out Using Modified Corn." The Toronto Star. February 10, 2000.

- 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 is banning genetically engineered foods from its store brands.

LEGAL ANALYSIS

EU Regulation of GM Products

The main EU legislation concerning the release of GMOs into the environment is Council Directive 90/220/EEC, which was adopted on April 23, 1990, and amended by Commission Directive 94/15/EC of April 15, 1994, and Commission Directive 97/35/EC of June 18, 1997. Under this legislation, EU countries 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."[76] Any person seeking to release GMOs into the environment (plant seeds, for example) must submit a notification of intent to the competent authority of the country in which the release will take place. The notification must be accompanied by 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.[77]

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.[78]

Critics of these regulations have complained that the EU's legal framework concerning labeling is not fully transparent. Specifically, producers of genetically engineered goods have called for harmonization of the EU's and the individual EU countries' regulations on GMOs.[79]

In response, the EU Commission presented a proposal in October 1999 (IP/99/783) for completing the current labelling rules and providing greater legal certainty for both producers and consumers. The proposal included two main provisions: 1) a *de minimis* labelling threshold of 1% to allow for the accidental inclusion of GM content in a product's ingredients, and 2) new

[76] Council Directive 90/220/EEC of 23 April, 1990. For complete content and description of this measure, see Appendix I.
[77] Ibid.
[78] For complete content of EU Regulation No. 258/97 (Novel Foods Regulation) and Regulation No. 1139/98, see Appendix II and Appendix III, respectively.
[79] "EU Regulation of Biotechnology." http://www.useu.be/agri/issues.html. (Downloaded June 30, 1999).

rules for making foods containing GMO-derived additives and flavorings subject to the same labelling rules as those of the Novel Foods Regulation.[80]

The *de minimus* threshold is intended 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. However, the proposed threshold only applies to goods already authorized for human consumption in the EU. The threshold allowance is also subject to the following conditions:

- The origin of the GM material must be accidental (i.e., producers must submit evidence that they have avoided GM source materials).
- The proportion of GM material accidentally present must not be higher than 1% of each individual ingredient. 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.

The Novel Foods Regulation requires labels to identify foods that:

- have additives or flavorings that are, contain, or consist of GMOs;
- raise a particular safety (e.g. allergies) or ethical concern; and
- are not equivalent to their conventionally produced counterparts (i.e. 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 a set of new regulations for GMOs and to put a hold on the authorization of new GMOs until a new directive comes into force 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 EU member countries will have to abide by the new regulations.

The agreement's provisions include more stringent risk assessments of all GMO releases, a post-market monitoring regime for all releases, a more comprehensive labelling scheme, and the phasing out of antibiotic marker genes.[81] The Council also decided to replace open-ended authorizations for 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 introduction (and importation) of new genetically altered goods until 2002.

[80] Press Release: "Commission Proposes de Minimis Threshold and Labelling Rules for GMOs." Brussels, October 22, 1999. http://europa.eu.int/comm/dg03/press/1999/IP99783.htm. (Downloaded November 22, 1999).
[81] "Trade War Looming over GMO Dispute." Farmers Guardian. July 2, 1999, p. 6.

The Potential for a WTO Challenge of the EU's New Regulations

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. So far, however, all efforts to build a solid legal basis for a formal challenge against the EU have come up short because the EU has not explicitly rejected more GMO approvals, but merely postponed further action until a new directive is in place. [82]

Absent the EU's clear rejection of GMOs, the U.S.'s 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). However, this provision is not legally defined in the Agreement, and the EU could dispute the applicability of the entire Agreement in relation to GMOs because biotechnology products do not fit under any of the Agreement's four categories of risk factors: additives, toxins, contaminants, and disease-causing organisms.[83] The challenge for the U.S. would then become one of changing or negotiating an understanding on the SPS Agreement so as to accommodate GMOs. So far, the U.S. Administration, lobbied heavily by domestic agricultural groups, has 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.[84]

There are two other WTO agreements that may provide support for 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 regulations—a rule that could possibly be used to challenge the EU's labelling requirements for GM and GM-containing products. Similarly, if genetically engineered agricultural products are patented, the TRIPS Agreement might diminish the ability of the EU governments to restrict the release and sale of those products.

The Precautionary Principle

Although the WTO SPS Agreement recognizes the relevance of the precautionary principle to trade measures, it gives no specific definition for this safety first approach to regulation:

> "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

[82] "U.S. Explores SPS Case on EU GMO Approvals, Comes Up Short So Far." Inside US Trade. Vol. 17, No. 29, July 23, 1999.
[83] "U.S. Ag Interests Split on How to Tackle Biotech in WTO Rounc." Inside US Trade. Vol. 17, No. 38, September 24, 1999.
[84] Ibid.

> necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."[85]

Nonetheless, the EU has used the precautionary principle to justify its import bans on potentially hazardous goods—despite the United States' insistence on the use of "sound scientific data" for determining risk. The EU rationale comes, in part, from the EC Treaty, which incorporates the following provisions already introduced by the Maastricht Treaty of 1992:

> "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. . . ."[86]

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 was directed to the Community, it also seeks to provide input to the ongoing international debate over the proper application of the principle.

The U.S., along with the rest of the Miami group, however, has pushed for WTO legal supremacy over the Biosafety Protocol, which explicitly adopted the precautionary principle.[87] The so-called Like-Minded Group, which consists of over one hundred developing nations, along with the EU, has taken the position that the Biosafety Protocol should be co-equal to the WTO.

"Substantial Equivalence"

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

[85] SPS Agreement, Article 5, paragraph 7.
[86] Maastricht Treaty, Article 174.
[87] Article 19, paragraph 6.

World Health Organization (WHO) three years later, and it has been employed ever since.[88] As a result of the OECD Conference, however, 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 to develop global legal standards on how to evaluate the safety of GM foods by 2003.

[88] Patricia Reaney, "Consumer Groups Want Labels on All GM Products." Reuters. February 29, 2000.

RECOMMENDATION

Because European consumers have consistently demanded that GM food be labelled, not for safety reasons, but so that informed consumption choices are possible, the EU should pursue a bilateral agreement with the U.S. that mandates labels for foods that contain GM inputs. Such an agreement is the only way to ensure that consumers have a choice as to whether or not to eat GM foods. Additionally, the EU should seek agreement concerning use of the precautionary principle, which allows countries to take a safety first approach to GMO regulation.

To reach such agreements, the European Commission should seek informal consultations with USTR. The consultations should address the labelling issue and the more general need for a comprehensive and integrated approach to biotechnology regulation. To help ensure the success of these consultations, the EU will first need to:

- Develop and gain internal agreement on a harmonized, transparent regime for regulating genetically engineered products.
- Begin building pressure on the U.S. government to accept a labelling requirement for GM products. (This will involve raising U.S. public awareness of the issue and building and international alliances of countries that favor GM regulations).

Given the growing public protest against GMOs on both sides of the Atlantic, there is no need for the EU to develop a formal negotiation strategy. Indeed, the EU's position is considerably stronger than that of the U.S.—at least from a public opinion perspective—and the U.S. has already proposed both standards for GM-free food labels and improved oversight of gene-altered crops.

Instead, the Commission should request meetings with the U.S. concerning consumers' right to clear information on GM products. The EU stands to gain a lot from such consultation; it has little if anything to lose. In addition to opening the possibility of finding a mutually agreeable solution to the labelling issue, such engagement will demonstrate the EU's willingness to work out agricultural trade disputes on a bilateral basis, without the intervention of the WTO.

Preferred Outcome

The preferred outcome for the EU Commission in these informal negotiations with the U.S. is a bilateral agreement concerning mutually acceptable, mandatory labels for foods containing or derived from genetically engineered material.

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Additionally, the EU should seek to gain U.S. acceptance of the precautionary principle in matters related to new biotechnological advances. Ideally, this agreement would be achieved promptly and without the significant legal costs involved in formal WTO dispute settlement.

Best Alternative to a Negotiated Agreement

Given the current status of the global GMO debate, the EU's best alternative to a negotiated agreement with the U.S. is to let the WTO dispute settlement body rule in the matter. In view of the stipulations of the recently completed Biosafety Protocol and the level of international public support for mandatory labelling of GMOs, a WTO panel would likely rule in favor of the EU's right to maintain its temporary ban on GMOs until more is known about their potential dangers.

EU STRATEGY

The goal of the legislative strategy for the EU is to establish a coherent, flexible, and transparent legal framework on GMOs that addresses public concerns about GMOs and mitigates the growing tensions between the U.S. and the EU concerning trade in biotechnology products.

The strategy has two parts:

- Consensus building within the EU Commission. The focus should be on clarifying current procedures for approving and labelling GM products and making these procedures more transparent and coherent across all of the EU countries. This strategy will focus in particular on the European Commissioners for Agriculture (Mr. Franz Fischler), Enterprise and Information Society (Mr. Erkki Liikanen), Trade (Mr. Pascual Lamy), Health and Consumer Protection (Mr. David Byrne), and Environment (Ms. Margot Wallström).

- Building public support for the Commission's biotech policy. The focus should be on protecting the consumers' right to clear and complete information and ensuring the public's participation in the development of the EU's food safety policy. This strategy will involve initiating a balanced dialogue regarding the risks and benefits related to biotechnology products.

Consensus Building within the EU Commission

The consensus building strategy should focus on implementing the white paper on food safety that was released on January 12 of this year by Mr. David Byrne, Commissioner for Health and Consumer Protection, and Mr. Erkki Liikanen, Commissioner for Enterprise and Information Society.

Building on the EU's "farm to table" philosophy, the white paper is an ambitious plan for overhauling the EU's policy on food safety, including its current policy on GMOs. The guiding principle behind the paper is that the Commission's policy on food safety must be based on a comprehensive, integrated approach. Among the more than 80 separate actions put forth is the establishment of an independent European Food Safety Authority by the year 2002. Although this Authority is not envisioned to have any regulatory powers (i.e., it will not engage in risk *management* because this area of decision-making remains the responsibility of the Commission, the Parliament, and the Council of Ministers), it will be in charge of risk *assessment* and risk *communication*.

With regard to GMOs, the paper proposes 1) that EU policy on novel foods[89] should be tightened and streamlined, and 2) that the labelling provisions for genetically engineered products need to be completed and harmonized.

Action Plan:

- As a first step in the legislative strategy, the Commission should adopt an implementing regulation to clarify the procedures of the Novel Food Regulation (EC) No. 258/97 (see Appendix II) and present a proposal to improve this regulation in accordance with Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

- Second, a task force should be created to harmonize the GMO policies of the Directorates-General of Agriculture, Environment, Health and Consumer Protection, Enterprise and Information Society, and Trade. This task force should be led by the Commission's Head of Food Legislation, Mr. Patrick Deboyser, who also represents the EU Commission in the Codex Alimentarius *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. Other members of the proposed task force should include Mr. Roland Feral and Ms. Nathalie Sauze, who also represent the European Community in the Codex Alimentarius Committee on Food Labelling.

- Working closely with the task force mentioned above, the Commission should develop a set of transparent regulations governing the labelling of "conventional" food products (so-called GMO-free food), as well as clarify the existing rules for labelling GM food. The Commission should seek to incorporate, as far as possible, the results of the 28th session of the Codex Committee on Food Labelling (which will be held in Ottawa, Canada, on May 9-12 this year).

Building Public Support for the Commission's Biotech Policy

The only way to adequately address the controversy surrounding biotechnology is to promote a balanced dialogue between all stakeholders: scientists, agribusiness, farmers, and consumers. Accordingly, this strategy focuses on initiating a dialogue that will raise public awareness of biotechnology issues and equip consumers with the tools they need to make informed choices.

Action Plan:

- The Commission should pursue the formation of an international panel on the ethical, environmental, social, and political implications of biotechnology. Originally suggested by Britain's chief scientific adviser, Sir Robert May, during the OECD Conference on GM food held in Edinburgh in late February, the purpose of such a panel would be to keep the public

[89] Novel foods are foods and food ingredients that have not yet been used for human consumption and in particular those containing or derived from genetically modified organisms.

informed about issues concerning genetically modified food and biotechnology. Using the Intergovernmental Panel on Climate Change (IPCC) as a model, the panel on GM food should include scientists who are both supporters and critics of biotechnology.

- NGOs should be invited to participate in the development of the EU's GMO policies. This can be accomplished by sponsoring a series of public fora where representatives from the biotechnology industry, consumer groups, and environmental organizations discuss the risks and benefits of this new technology. Ideally, these informal hearings/meetings should be arranged in all EU countries.

Given the high level of media exposure already given to GMOs and biotechnology advances, there is no separate media component of the EU strategy for this project. Instead, it is assumed that the media will continuously cover all further developments related to the sale and marketing of genetically engineered products.

This paper was researched and written to fulfill the M.A. project requirement for completing the Monterey Institute of International Studies' Master of Arts in Commercial Diplomacy. It was not commissioned by any government or other organization. The views and analysis presented are those of the student alone. For more information about the Commercial Diplomacy program and the M.A. project requirement, please visit www.commercialdiplomacy.org.

U.S. STRATEGY

The general goal of the U.S. strategy is to put pressure on the U.S. government to accept an agreement that mandates labels for GM products. The strategy has three parts:

- Building coalitions in the U.S. among farmers, consumer groups, the business community, and environmental organizations. The focus should be on building a lobby campaign that can push for passage of the mandatory labelling bills that were recently introduced by Rep. Dennis Kucinich (D-OH), and Senator Barbara Boxer (D-CA).[90] This effort should be led by the NGOs that operate in both Europe and the U.S. such as Greenpeace, Friends of the Earth, and Consumers International.

- Raising public awareness via the media. The focus should be on gaining press coverage of the controversies surrounding GM products. The NGOs mentioned above should send op-ed articles to the major U.S. media outlets. The op-eds should explain the need for 1) mandatory labelling of GM foods and 2) stricter rules for risk analysis of GMOs. Additionally, the European Commission should invite U.S. media representatives to attend its public fora on biotechnology issues.

- Forging an international alliance. The focus should be on putting added pressure on the U.S. by building an international coalition among countries that have opposed the unregulated sale of genetically altered products.

Building Coalitions in the U.S. among Farmers, Consumer Groups, the Business Community, and Environmental Organizations

Action Plan:

- Several companies have already publicly announced "GM-free" policies in response to the growing pressure from EU consumers. These companies should be lobbied by U.S. consumer groups to endorse the push for mandatory labelling:

  Nestlé
  McCain Foods
  Anheuser-Busch

[90] For H.R. 3377 bill summary and list of co-sponsors, see Appendix V.

Danone
Seagram's
Unilever
Coca-Cola
Wild Oats Market
Kirin Brewery
Heinz
Kellogg's
Mars
Whole Foods
PepsiCo (Pepsi-Cola, Frito-Lay)
Diageo (Pillsbury, Burger King)

- The following NGOs operating in the U.S. should be contacted by their European counterparts, and encouraged to lobby all elected representatives to support Bill H.R. 3377:

  Greenpeace
  Friends of the Earth
  Consumers Union
  Union of Concerned Scientists
  Organic Consumers Association
  Environmental Defense Fund
  Alliance for Bio-Integrity
  Consumers International
  Consumers Choice Council
  Alliance to Label Genetically Engineered Food
  Citizens for Health
  Council for Responsible Genetics
  Soil Association
  Council for Responsible Nutrition
  International Alliance of Dietary/Food Supplements Associations
  Seeds of Resistance
  International Food Information Council

- The European Commission should seek an invitation to testify before Congress on the importance of consumer choice and the need for mandatory labelling of food products that contain genetically engineered material.

Raising Public Awareness via the Media

This effort should highlight 1) the need to maintain a cautious stance on biotechnology products and 2) consumers' right to clear and unambiguous labels on GM food.

Action Plan:

- Write op-ed articles for publication in *The New York Times*, *Washington Post*, *USA Today*, *Atlanta Journal and Constitution*, *San Francisco Chronicle*, and *Los Angeles Times*.

- Invite journalists such as Andrew Pollack (*The New York Times*) and Anita Manning (*USA Today*), who have already written on the U.S.-EU dispute over GMOs, to write about the need for mandatory labelling of genetically engineered foods and the justified use of the precautionary principle.

Forging an International Alliance

The European Commission's most important ally on this issue is the Japanese government. Japan has recently announced its intent to require mandatory safety tests for GM foods in addition to its labelling requirement. Moreover, Japan has significant leverage over the U.S.; it currently imports over 700,000 tons of U.S. soybeans per year, and it represents a crucial market for U.S. agricultural exports generally.

The European Commission should seek to align itself with Japan and other countries that support mandatory labelling (New Zealand, Australia) in order to strengthen its bargaining position vis-à-vis the U.S. In addition, the European Commission should solidify the support of the so-called Like-Minded Group in its opposition to the U.S.'s current GMO policies.

Action Plan:

- Engage in informal bilateral consultations with potential alliance partners with the aim of developing a common strategy for pressuring the U.S. government.

BIBLIOGRAPHY

"A Conventional Argument." The Economist. January 29, 2000. (U.S. Edition).

"Administration Wrestles with WTO Approach on Biotechnology." Inside U.S. Trade. Vol. 17, No. 42, October 22, 1999.

"Agri-Food Community Open Letter to President Clinton on Science-Based Labelling of Foods." http://www.monsanto.com/monsanto/mediacenter/background/99nov12_agrifood.htm November 12, 1999. (February 5, 2000).

Alden, Edward. "Accord on GMO Protocol 'Vital' Biodiversity Chairman of Montreal Talks Delivers Warning." Financial Times. London Edition, January 25, 2000, p. 14.

Alden, Edward, and Bilefsky, Dan. "Gene-Modified Foods Take Root at Centre of Next Trade Dispute: A New Confrontation Between the US and EU Over Global Rules is On the Way." Financial Times. London Edition, January 24, 2000, p. 10.

"American Industry Fears Marketing Ban in the EU." Europe Agri. April 30, 1999.

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

Bates, Stephen. "Tougher EU Controls Mean Moratorium on GM Crops." The Guardian. June 26, 1999.

"Biodiversity - Threatened by GMOs?" Consumer Voice. No. 4, 1999. http://www.europa.eu.int/comm/dg24/library/pub/cv/cv994/cv994-02_en.htm (February 23, 2000).

Bond, Christopher, Senator (R-Missouri). "The Benefits and Politics of Biotechnology." Congressional Record, pgs. S58-S63. January 26, 2000. http://www.monsanto.com/monsanto/mediacenter/background/00jan26_bond.htm (February 5, 2000).

Brasher, Philip. "Tightened Biotech Crop Regs Urged." Yahoo!News AP. February 17, 2000. http://dailynews.yahoo.com/h/ap/20000217/pl/biotech_crops.1.htm (February 25, 2000).

Burros, Marian. "Genes are Changed, but Not the Label." The New York Times. September 8, 1999.

Burros, Marian. "Lines Redrawn in International Food Fight." The New York Times. July 14, 1999.

Carruthers, Fiona. "Cooking with Genes." Time. International edition. Vol. 154, No. 7, August 16, 1999.

"Caution Needed." The Economist. February 5, 2000. (U.S. Edition).

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"Clinton, Prodi Agree to Efforts on Developing Countries, GMOs." Inside U.S. Trade. Vol. 17, No. 43, October 29, 1999.

Cohen, Roger. "Fearful Over the Future, Europe Seizes on Food." The New York Times. August 29, 1999

"Commission Proposes de Minimis Threshold and Labelling Rules for GMOs" Brussels, October 22, 1999. http://europa.eu.int/comm/dg03/press/1999/IP99783.htm (November 22, 1999).

"Commissioner Wallström Comments on Biosafety Agreement in Montreal." Brussels, January 28, 2000. http://www.europa.eu.int/comm/trade/whats_new/bio.htm (February 23, 2000).

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

"Consumers Have a Right to Clear Labels." The Irish Times. May 21, 1999, p. 72.

"Efforts to Strike Biosafety Protocol to Resume Early Next Year." Inside U.S. Trade. Vol. 17, No. 38, September 24, 1999.

Eskenazi, Mike. "Frankenfood: Why does Europe Find it Scarier?" Time Daily. October 15, 1999. http://www.pathfinder.com/time/daily/0,2960,32706,00.html (November 1, 1999).

"Ethical Concerns at Heart of Discussions on GMO Directive." European Report. June 19, 1999.

"EU Moves to Take France to European Court of Justice Over GMOs." Inside U.S. Trade. Vol. 17, No. 29, July 23, 1999.

"EuropaBio Welcomes OECD Consultation on Genetically Modified Foods." PRNewswire. February 25, 2000. http://news.excite.com/news/pr/000225/sct-europabio-oecd (March 3, 2000).

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

"Farm Bureau WTO Objectives." Inside U.S. Trade. Vol. 17, No. 39, October 1, 1999.

Feder, Barnaby J. "Biotech Firm to Advocate Labels on Genetically Altered Products." The New York Times. February 24, 1997.

"Finnish Environment Minister Urges Caution on GMO Legislation." Nordic Business Report. June 14, 1999.

"Genetic Engineering – European Parliament Puts Safety First as More Problems Arise." European Report. February 17, 1999.

"Genetic Engineering – European Retailers Join Forces Against Transgenic Food." Europe Agri. March 19, 1999.

"Genetic Engineering – GMO-Free Food is Flavour of the Month." Europe Agri. September 10, 1999.

"Genetic Engineering – Greenpeace Attacks United States' EPA for Approval of GM-bacteria." Europe Agri. February 11, 2000.

"Genetic Engineering – Pending GMO Notifications to be Suspended?" Europe Agri. July 16, 1999.

Gibson, Helen. "Who's Afraid of GM Food?" Time. Vol. 153, No. 8, March 1, 1999.

Golden, Frederic. "Who's Afraid of Frankenfood?" Time. Vol. 154, No. 22, November 29, 1999.

"Good News on Biotechnology From ADM, Says National Corn Growers." February 4, 2000. http://www.monsanto.com/monsanto/mediacenter/background/00feb3_ncga.htm (February 5, 2000).

"Greenpeace Intercept Ship Carrying GM Crop." Yahoo!News UK & Ireland. February 25, 2000. http://uk.news.yahoo.com/000225/75/a0pkc.htm (February 25, 2000).

Hachey, Leanne. "The Food Fight." http://www.cbc.ca/news/indepth/foodfight/index.htm CBC News Online. (February 25, 2000).

Hoge, Warren. "Britons Skirmish Over Genetically Modified Crops." The New York Times. August 23, 1999.

Holmes, Bob. "The Great Divide." New Scientist. February 27, 1999.

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

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

Jonquieres, Guy, de. "U.S. Says it Will Meet EU Rules on Gene-Modified Food Labels." Financial Times. London Edition. January 22, 2000, p. 10.

Kilman, Scott. "Biotech Scare Sweeps Europe, and Companies Wonder if U.S. is Next." Wall Street Journal. October 7, 1999, p. 1.

Klee, Kenneth. "Frankenstein Foods?" Newsweek. September 13, 1999, p. 33.

Kluger, Jeffrey. "Bad Seeds." Time. International edition. Vol. 154, No. 12, September 20, 1999.

Laidlaw, Stuart. "Seagram Quietly Rules Out Using Modified Corn." The Toronto Star. February 10, 2000.

Larson, Alan. "Biotechnology: Finding a Practical Approach to a Promising Technology." Economic Perspectives. Vol. 4, No. 4, October 1999.

Luhnow, David. "Activists Say Rich Nations Promoting GM Foods." Reuters. February 28, 2000. http://news.excite.com/news/r/000228/12/science-crops-dissent (March 3, 2000).

MacKenzie, Deborah. "How to Price What We Put on Our Plate." New Scientist. February 27, 1999.

Manning, Anita. "Altered Food Might Mutate Trade." USA Today. July 14, 1999.

"Modified Foods to Face New Regulation." Financial Times. London Edition. July 14, 1999, p. 5.

Oko, Dan. "Whole Foods Loses its Taste for Genetically Modified Foods." News & Opinion: Natural Selection Austin Chronicle. January 31, 2000. http://www.weeklywire.com/ww/01-31-00/austin_pols_feature.htm (February 25, 2000).

Osborn, Andrew. "EU Keeps Moratorium on New GM Crops." Reuters. March 9, 2000. http://news.excite.com/news/r/000309/12/food-eu-gmos (March 17, 2000).

"Outcome of June Council of Ministers Meeting." UK Environment News Ltd. Vol. 3, Issue 5, September 1999.

Palmer, Doug. "U.S. Sees Faults in EU Precautionary Principal (sic) Paper." March 22, 2000. http://news.excite.com/news/r/000322/18/trade-europe-food (March 26, 2000).

Petersen, Melody. "New Trade Threat for U.S. Farmers." The New York Times. August 29, 1999. http://www.nytimes.com/library/national/science/082999sci-gm-consumers.html (January 27, 2000).

Pollack, Andrew. "F.D.A. Hearing Draws 2 Sides of Altered Food Issue." The New York Times. December 14, 1999. http://www.nytimes.com/library/national/science/health/121499hth-gm-food.html (January 27, 2000).

Pollack, Andrew. "Nations Agree on Safety Rules For Biotech Foods." The New York Times. January 30, 2000.

Pollack, Andrew. "Setting Rules on Biotechnology Trade." The New York Times. February 15, 1999.

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

Pollock, Laurence. "Crops Create Food for Thought." The Independent. April 1, 1999, p. 11.

Press Pack, WTO 3rd Ministerial Conference, Seattle.

"Pressure Grows on U.S. Over GM Foods." PA News. January 23, 2000.

Raeburn, Paul. "Biotech Foods: Why a Hard Line Could Stunt U.S. Trade." Business Week. January 31, 2000, pg. 47.

Reaney, Patricia. "Adviser Calls for International GM Foods Panel." Reuters. February 29, 2000. http://news.excite.com/news/r/000229/12/science-gm-panel (March 2, 2000).

Reaney, Patricia. "Consumer Groups Want Labels On All GM Products." Reuters. February 29, 2000. http://news.excite.com/news/r/000229/11/science-science-gm (March 3, 2000).

Reaney, Patricia. "No Evidence of Harmful Effects of GM Food." Reuters. March 1, 2000. http://news.excite.com/news/r/000301/14/science-health.gm (March 3, 2000).

Reaney, Patricia. "Scientists, Consumer Groups to Gnaw Over GM Food." Reuters. February 25, 2000 http://news.excite.com/news/r/000225/03/science-gm2 (March 3, 2000).

Rosén, Sara. "Genmanipulerad fisk kan snart vara här." Gotlands Allehanda. July 19, 1999.

Saltus, Richard. "Biotech Analyst Calls for an Informed Public." The Boston Globe. March 29, 2000.

Speaking Note for Commissioner Byrne, Arthur Cox Conference on Food Law, November 5, 1999. http://europa.eu.int/comm/dg24/library/speeches/speech23_en.html (November 22, 1999).

Specter, Michael. "Bucking U.S. Trend, Europe Blocks Gene-Altered Food." The New York Times. International, July 20, 1998.

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. http://europa.eu.int/comm/dg24/library/speeches/speech36_en.html (January 26, 2000).

Steyer, Robert. "Food Labelling is Seen as a Way to Win Support for Genetically Altered Foods: Recommendation on Labels is Expected by July." St. Louis Post-Dipatch. May 25, 1999, p. A1.

Takada, Aya. "Japan to Hold Meeting on GMO Safety Standards." Reuters. March 2, 2000. http://news.excite.com/news/r/000302/00/food-japan-gmo (March 3, 2000).

"Trade War Looming Over GMO Dispute." Farmers Guardian. July 2, 1999, p. 6.

"Two Cheers for Montreal." New Scientist. Editorial. February 6, 2000.

"U.K.'s Blair Eases GM Food Praise on Eve of Meeting." Reuters. February 27, 2000. http://news.excite.com/news/r/000227/05/science-science-gm (March 3, 2000).

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

"U.S. Explores SPS Case on EU GMO Approvals, Comes up Short so far." Inside U.S. Trade. Vol. 17, No. 29, July 23, 1999.

"U.S. Trade Representative Welcomes Successful Completion of the Biosafety Protocol Negotiations." USTR Press Release February 1, 2000. http://www.ustr.gov

Walsh, James. "Alien Seed?" Time. Vol. 152, No. 8, August 24, 1998.

Whitney, Craig R. "Europe Loses its Appetite for High-Tech Food." The New York Times. June 27, 1999.

APPENDIX I

390L0220

Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms

Official Journal L 117 , 08/05/1990 p. 0015 - 0027
Finnish special edition....: Chapter 15 Volume 9 p. 212
Swedish special edition...: Chapter 15 Volume 9 p. 212

Amendments:
*Incorporated by **294A0103(70)** (OJ L 001 03.01.94 p.494)*
*Amended by **394L0015** (OJ L 103 22.04.94 p.20)*
*Amended by **397L0035** (OJ L 169 27.06.97 p.72)*

Text:
COUNCIL DIRECTIVE of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (90/220/EEC)
THE COUNCIL OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,
Having regard to the proposal from the Commission (1),
In cooperation with the European Parliament (2),
Having regard to the opinion of the Economic and Social Committee (3),
Whereas, under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken;
Whereas living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States; whereas the effects of such releases on the environment may be irreversible;
Whereas the protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release of genetically modified organisms (GMOs) into the environment;
Whereas disparity between the rules which are in effect or in preparation in the Member States concerning the deliberate release into the environment of GMOs may create unequal conditions of competition or barriers to trade in products containing such organisms, thus affecting the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this respect;
Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market should, inasmuch as they concern health, safety, environmental and consumer protection, be based on a high level of protection throughout the Community;
Whereas it is necessary to ensure the safe development of industrial products utilizing GMOs;

OJ No C 246, 27. 9. 1989, p. 5.

OJ No C 96, 17. 4. 1990.

Whereas this Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record;
Whereas it is necessary to establish harmonized procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment;
Whereas a case-by-case environmental risk assessment should always be carried out prior to a release;

Whereas the deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing, GMOs;
Whereas the introduction of GMOs into the environment should be carried out according to the 'step by step' principle; whereas this means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken;
Whereas no product containing, or consisting of, GMOs and intended for deliberate release shall be considered for placing on the market without it first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by its use;
Whereas it is necessary to establish a Community authorization procedure for the placing on the market of products containing, or consisting of, GMOs where the intended use of the product involves the deliberate release of the organism(s) into the environment;
Whereas any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of a product containing, or consisting of, GMOs, where the intended use of that product involves its deliberate release into the environment, shall submit a notification to the national competent authority;
Whereas that notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging;
Whereas, after notification, no deliberate release of GMOs should be carried out unless the consent of the competent authority has been obtained;
Whereas the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment;
Whereas it may be considered appropriate in certain cases to consult the public on the deliberate release of GMOs into the environment;
Whereas it is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on deliberate releases of GMOs notified under this Directive;
Whereas it is important to follow closely the development and use of GMOs; whereas a list should be published of all the products authorized under this Directive;
Whereas, when a product containing a GMO or a combination of GMOs is placed on the market, and where such a product has been properly authorized under this Directive, a Member State may not on grounds relating to matters covered by this Directive, prohibit, restrict or impede the deliberate release of the organism in that product on its territory where the conditions set out in the consent are respected; whereas a safeguard procedure should be provided in case of risk to human health or the environment;
Whereas the provisions of this Directive relating to placing on the market of products should not apply to products containing, or consisting of, GMOs covered by other Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive;
Whereas a Committee should be set up to assist the Commission on matters relating to the implementation of this Directive and to its adaptation to technical progress,
HAS ADOPTED THIS DIRECTIVE:

PART A
General provisions

Article 1
1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment:
- when carrying out the deliberate release of genetically modified organisms into the environment,
- when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment.
2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

Article 2
For the purposes of this Directive:

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(1) ‘organism’ is any biological entity capable of replication or of transferring genetic material;
(2) ‘genetically modified organism (GMO)’ means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
Within the terms of this definition:
i(i) genetic modification occurs at least through the use of the techniques listed in Annex I A Part 1;
(ii) the techniques listed in Annex I A Part 2 are not considered to result in genetic modification;
(3) ‘deliberate release’ means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;
(4) ‘product’ means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;
(5) ‘placing on the market’ means supplying or making available to third parties;
(6) ‘notification’ means the presentation of documents containing the requisite information to the competent authority of a Member State. The person making the presentation shall be referred to as ‘the notifier’;
(7) ‘use’ means the deliberate release of a product which has been placed on the market. The persons carrying out this use will be referred to as ‘users’;
(8) ‘environmental risk assessment’ means the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs.

Article 3
This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

Article 4
1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.
2. Member States shall designate the competent authority or authorities responsible for carrying out the requirements of this Directive and its Annexes.
3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

PART B
Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Article 5
Member States shall adopt the provisions necessary to ensure that:
(1) any person, before undertaking a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority referred to in Article 4 (2) of the Member State within whose territory the release is to take place;
(2) the notification shall include:
(a) a technical dossier supplying the information specified in Annex II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:
ii(i) general information including information on personnel and training,
i(ii) information relating to the GMO(s),
(iii) information relating to the conditions of release and the receiving environment,
(iv)
information on the interactions between the GMO(s) and the environment,
i(v)
information on monitoring, control, waste treatment and emergency response plans;
(b) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

(3) the competent authority may accept that releases
of a combination of GMOs on the same site or of the
same GMO on different sites for the same purpose and
within a limited period may be notified in a single notification;
(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either inside or outside the Community.
The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing;
(5) in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;
(6) in the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the risks for human health or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authority or after that authority has given its written consent, the notifier shall immediately:
(a) revise the measures specified in the notification,
(b) inform the competent authority in advance of any modification or as soon as the new information is available,
(c) take the measures necessary to protect human health and the environment.

Article 6
1. On receipt and after acknowledgment of the notification the competent authority shall:
- examine it for compliance with this Directive,
- evaluate the risks posed by the release,
- record its conclusions in writing,
and, if necessary,
- carry out tests or inspections as may be necessary for control purposes.
2. The competent authority, having considered, where appropriate, any comments by other Member States made in accordance with Article 9, shall respond in writing to the notifier within 90 days of receipt of the notification by either:
(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed, or
(b) indicating that the release does not fulfil the conditions of this Directive and the notification is therefore rejected.
3. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority:
- is awaiting further information which it may have requested from the notifier,
or
- is carrying out a public inquiry or consultation in accordance with Article 7
shall not be taken into account.
4. The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.
5. If the competent authority considers that sufficient experience has been obtained of releases of certain GMOs, it may submit to the Commission a request for the application of simplified procedures for releases of such types of GMOs. The Commission shall, in accordance with the procedures laid down in Article 21, establish appropriate criteria and take a decision accordingly on each application. The criteria shall be based on safety to human health and the environment and on the evidence available on such safety.
6. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

Article 7
Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on any aspect of the proposed deliberate release.

Article 8
After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at a later stage.

Article 9
1. The Commission shall set up a system of exchange of the information contained in the notifications. The competent authorities shall send to the Commission, within 30 days of its receipt, a summary of each notification received. The format of this summary will be established by the Commission in accordance with the procedure laid down in Article 21.
2. The Commission shall immediately forward these summaries to the other Member States, which may, within 30 days, ask for further information or present observations through the Commission or directly.
3. The competent authorities shall inform the other Member States and the Commission of the final decisions taken in compliance with Article 6 (2).
PART C
Placing on the market of products containing GMOs

Article 10
1. Consent may only be given for the placing on the market of products containing, or consisting of, GMOs, provided that:
- written consent has been given to a notification under Part B or if a risk analysis has been carried out based on the elements outlined in that Part;
- the products comply with the relevant Community product legislation;
- the products comply with the requirements of this Part of this Directive, concerning the environmental risk assessment.
2. Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive.
3. Not later than 12 months after notification of this Directive, the Commission, in accordance with the procedure laid down in Article 21, shall establish a list of Community legislation covering the products referred to in paragraph 2. This list will be re-examined periodically and, as necessary, revised in accordance with the said procedure.

Article 11
1. Before a GMO or a combination of GMOs are placed on the market as or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such a product is to be placed on the market for the first time. This notification shall contain:
- the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product and an assessent of any risks for human health and the environment related to the GMOs or a
combination of GMOs contained in the product, including information obtained from the research and development stage on the impact of the release on human health and the environment;
- the conditions for the placing on the market of the product, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III.
If on the basis of the results of any release notified under Part B of this Directive, or on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose a risk to human health and the environment, he may propose not to comply with one or more of the requirements of Annex III B.
2. The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community.
3. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing.
4. Each new product which, containing or consisting of the same GMO or combination of GMOs, is intended for a different use, shall be notified separately.

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5. The notifier may proceed with the release only when he has received the written consent of the competent authority in accordance with Article 13, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.
6. If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:
- revise the information and conditions specified in paragraph 1,
- inform the competent authority, and
- take the measures necessary to protect human health and the environment.

Article 12
1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.
2. At the latest 90 days after receipt of the notification, the competent authority shall either:
(a) forward the dossier to the Commission with a favourable opinion, or
(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.
3. In the case referred to in paragraph 2 (a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product.
The format of this summary shall be established by the Commission in accordance with the procedure laid down in Article 21.
In particular where the competent authority has acceded to the request of the notifier, under the terms of the last subparagraph of Article 11 (1), not to comply with some of the requirements of Annex III B, it shall at the same time inform the Commission thereof.
4. If the competent authority receives additional information pursuant to Article 11 (6), it shall immediately inform the Commission and the other Member States.
5. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account.

Article 13
1. On receipt of the dossier referred to in Article 12 (3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.
2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.
3. In cases where the competent authority of another Member State raises an objection - for which the reasons must be stated - and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.
4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.
5. Once a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.
6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent.

Article 14
Member States shall take all necessary measures to ensure that products containing, or consisting of, GMOs will be placed on the market only if their labelling and packaging is that specified in the written consent referred to in

Articles 12 and 13.

Article 15
Member States may not, on grounds relating to the notification and written consent of a deliberate release under this Directive, prohibit, restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive.

Article 16
1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.
2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.

Article 17
The Commission shall publish in the Official Journal of the European Communities a list of all the products receiving final written consent under this Directive. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

Article 18
1. Member States shall send to the Commission, at the end of each year, a brief factual report on the control of the use of all products placed on the market under this Directive.
2. The Commission shall send to the European Parliament and the Council, every three years, a report on the control by the Member States of the products placed on the market under this Directive.
3. When submitting this report for the first time, the Commission shall at the same time submit a specific report on the operation of this Part of this Directive including an assessment of all its implications.

PART D
Final provisions

Article 19
1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.
2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive position, that should therefore be treated as confidential. Verifiable justification must be given in such cases.
3. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.
4. In no case may the following information when submitted according to Articles 5 or 11 be kept confidential:
- description of the GMO or GMOs, name and address of the notifier, purpose of the release and location of release;
- methods and plans for monitoring of the GMO or GMOs and for emergency response;
- the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.
5. If, for whatever reasons, the notifier withdraws the notification, the competent authorities and the Commission must respect the confidentiality of the information supplied.

Article 20
According to the procedure laid down in Article 21, the Commission shall adapt Annexes II and III to technical progress in particular by amending the notification requirements to take into account the potential hazard of the GMOs.

Article 21
The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.
If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 22
1. Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release of GMOs into the environment.
2. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive, the first time being on 1 September 1992.
3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1993.

Article 23
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 23 October 1991.
2. Member States shall immediately inform the Commission of all laws, regulations and administrative provisions adopted in implementation of this Directive.

Article 24
This Directive is addressed to the Member States.

COMMISSION IMPLEMENTING MEASURES

Decision 91/274/EEC - Official Journal L 135, 30.05.1991
Commission Decision of 21 May 1991 on a list of Community legislation referred to in Article 10 of Directive 90/220/EEC.
Decision 92/146/EEC - Official Journal L 60, 05.03.1992
Commission Decision of 11 February 1992 concerning the summary notification information format referred to in Article 12 of Directive 90/220/EEC.
Commission Decision of 18 December 1992 concerning the placing on the market of products containing GMOs pursuant to Article 13 of Directive 90/220/EEC.
Decision 93/572/EEC - Official Journal L 276, 09.11.1993
Commission Decision of 19 October 1993 concerning the placing on the market of products containing GMOs pursuant to Article 13 of Directive 90/220/EEC.
Decision 93/584/EEC - Offical Journal L 279, 12.11.1993
Commission Decision of 22 October 1993 establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC.
This text applies only to genetically modified plants, which is the group of GMOs with which most of the experience has been acquired to date.
Directive 94/15/EC - Official Journal L 103, 22.04.1994
Commission Directive of 15 April 1994 adapting to technical progress for the first time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

Decision 94/211/EC - Official Journal L 105, 26.04.1994
Commission Decision of 15 April 1994 amending Council Decision 91/596/EEC concerning the summary notification information format referred to in Article 9 of Council Directive 90/220/EEC.
This decision replaces the annex to Decision 91/596/EEC.
Decision 94/730/EC - Official Journal L 292, 12.11.1994
Commission Decision of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6 (5) of Council Directive 90/220/EEC.
Decision 96/158/EC - Official Journal L 37, 15.02.1996
Commission Decision of 6 February 1996 concerning the placing on the market of a product consisting of a genetically modified organism, hybrid herbicide-tolerant swede-rape seeds (Brassica napus L. oleifera Metzq. MS1Bn × RF1Bn), pursuant to Council Directive 90/220/EEC.
Decision 96/281/EC - Official Journal L 107, 30.04.1996.
Commission Decision of 3 April 1996 concerning the placing on the market of genetically modified soya beans (Glycine max L.) with increased tolerance to the herbicide glyphosate, pursuant to Council Directive 90/220/EEC.
This Decision authorizes the United Kingdom to place on the market a product consisting of soya beans derived from the soya bean "Glycine max L cv A 5403".
Decision 96/424/EC - Official Journal L 175, 13.07.1996
Commission Decision of 20 May 1996 concerning the placing on the market of genetically modified male sterile chicory (Cichorium intybus L.) with partial tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC.
Decision 97/392/EC -Official Journal L 164, 21.06.1997
Commission Decision of 6 June 1997 concerning the placing on the market of genetically modified swede- rape (Brassica napus L. oleifera Metzg. MS1, RF1), pursuant to Council Directive 90/220/EEC.
Decision 97/393/EC - Official Journal L 164, 21.06.1997
Commission Decision of 6 June 1997 concerning the placing on the market of genetically modified swede- rape (Brassica napus L. oleifera Metzg. MS1, RF2), pursuant to Council Directive 90/220/EEC.
Decision 97/549/EC - Official Journal L 225, 15.08.1997
Commission Decision of 14 July 1997 concerning the placing on the market of T102-test (Streptococcus thermophilus T102) pursuant to Council Directive 90/220/EEC.
Decision 98/291/EC - Official Journal L 131, 05.05.1998
Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified spring swede rape (Brassica napus L. ssp. oleifera), pursuant to Council Directive 90/220/EEC.
Decision 98/292/EC - Official Journal L 131, 05.05.1998
Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line Bt-11), pursuant to Council Directive 90/220/EEC.
Decision 98/293/EC - Official Journal L 131, 05.05.1998
Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. T25), pursuant to Council Directive 90/220/EEC.
Decision 98/294/EC - Official Journal L 131, 05.05.1998
Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC.

APPENDIX II

397R0258

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients

Official Journal L 043 , 14/02/1997 p. 0001 - 0007

Article 1
1. This Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients.
2. This Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and which fall under the following categories:
(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;
(b) foods and food ingredients produced from, but not containing, genetically modified organisms;
(c) foods and food ingredients with a new or intentionally modified primary molecular structure;
(d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.
3. Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls within the scope of paragraph 2 of this Article.

Article 2
1. This Regulation shall not apply to:
(a) food additives falling within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (12);
(b) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (13);
(c) extraction solvents used in the production of foodstuffs, falling within the scope of Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (14).
2. The exclusions from the scope of this Regulation referred to in paragraph 1, indents (a) to (c) shall only apply for so long as the safety levels laid down in Directives 89/107/EEC, 88/388/EEC and 88/344/EEC correspond to the safety level of this Regulation.
3. With due regard for Article 11 the Commission shall ensure that the safety levels laid down in the above Directives, as well as in the implementing measures for these Directives and this Regulation, correspond to the safety level of this Regulation.

Article 3

1. Foods and food ingredients falling within the scope of this Regulation must not:
- present a danger for the consumer,
- mislead the consumer,
- differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.
2. For the purpose of placing the foods and food ingredients falling within the scope of this Regulation on the market within the Community, the procedures laid down in Articles 4, 6, 7 and 8 shall apply on the basis of the criteria defined in paragraph 1 of this Article and the other relevant factors referred to in those Articles.
However, in the case of foods or food ingredients referred to in this Regulation derived from plant varieties subject to Directives 70/457/EEC and 70/458/EEC, the authorization decision referred to in Article 7 of this Regulation shall be taken in accordance with the procedures provided for in those Directives, provided they take account of the assessment principles laid down in this Regulation and the criteria set out in paragraph 1 of this Article, with the exception of the provisions relating to the labelling of such foods or food ingredients, which shall be established, pursuant to Article 8, in accordance with the procedure laid down in Article 13.
3. Paragraph 2 shall not apply to the foods and food ingredients referred to in Article 1 (2) (b) where the genetically modified organism used in the production of the food or food ingredient has been placed on the market in accordance with this Regulation.
4. By way of derogation from paragraph 2, the procedure laid down in Article 5 shall apply to foods or food ingredients referred to in Article 1 (2) (b), (d) and (e) which, on the basis of the scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4 (3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.
Where necessary, it may be determined in accordance with the procedure laid down in Article 13 whether a type of food or food ingredient falls under this paragraph.

Article 4
1. The person responsible for placing on the Community market (hereinafter ‘the applicant`) shall submit a request to the Member State in which the product is to be placed on the market for the first time. At the same time, he shall forward a copy of the request to the Commission.
2. An initial assessment as provided for in Article 6 shall be carried out.
Following the procedure referred to in Article 6 (4), the Member State referred to in paragraph 1 shall inform the applicant without delay:
- that he may place the food or food ingredient on the market, where the additional assessment referred to in Article 6 (3) is not required, and that no reasoned objection has been presented in accordance with Article 6 (4), or
- that, in accordance with Article 7, an authorization decision is required.
3. Each Member State shall notify to the Commission the name and address of the food assessment bodies responsible in its territory for preparing the initial assessment reports referred to in Article 6 (2).
4. Before the date of entry into force of this Regulation, the Commission shall publish recommendations concerning the scientific aspects of:
- the information necessary to support an application and the presentation of such information,
- the preparation of the initial assessment reports provided for in Article 6.
5. Any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 13.

Article 5
In the case of the foods or food ingredients referred to in Article 3 (4), the applicant shall notify the Commission of the placing on the market when he does so. Such notification shall be accompanied by the relevant details provided for in Article 3 (4). The Commission shall forward to Member States a copy of that notification within 60 days and, at the request of a Member State, a copy of the said relevant details. The Commission shall publish each year a summary of those notifications in the ‘C` series of the Official Journal of the European Communities.
With respect to labelling, the provisions of Article 8 shall apply.

Article 6
1. The request referred to in Article 4 (1) shall contain the necessary information, including a copy of the studies

which have been carried out and any other material which is available to demonstrate that the food or food ingredient complies with the criteria laid down in Article 3 (1), as well as an appropriate proposal for the presentation and labelling, in accordance with the requirements of Article 8, of the food or food ingredient. In addition, the request shall be accompanied by a summary of the dossier.
2. Upon receipt of the request, the Member State referred to in Article 4 (1) shall ensure that an initial assessment is carried out. To that end, it shall notify the Commission of the name of the competent food assessment body responsible for preparing the initial assessment report, or ask the Commission to arrange with another Member State for one of the competent food assessment bodies referred to in Article 4 (3) to prepare such a report.
The Commission shall forward to the Member States without delay a copy of the summary provided by the applicant and the name of the competent body responsible for carrying out the initial assessment.
3. The initial assessment report shall be drawn up within a period of three months from receipt of a request meeting the conditions laid down in paragraph 1, in accordance with the recommendations referred to in Article 4 (4), and shall decide whether or not the food or food ingredient requires additional assessment in accordance with Article 7.
4. The Member State concerned shall without delay forward the report of the competent food assessment body to the Commission, which shall forward it to the other Member States. Within a period of 60 days from the date of circulation of the report by the Commission, a Member State or the Commission may make comments or present a reasoned objection to the marketing of the food or food ingredient concerned. The comments or objections may also concern the presentation or labelling of the food or food ingredient.
Comments or objections shall be forwarded to the Commission, which shall circulate them to Member States within the period of 60 days referred to in the first subparagraph.
The applicant shall, where a Member State so requests, provide a copy of any pertinent information appearing in the request.

Article 7
1. Where an additional assessment is required in accordance with Article 6 (3) or an objection is raised in accordance with Article 6 (4), an authorization decision shall be taken in accordance with the procedure laid down in Article 13.
2. The decision shall define the scope of the authorization and shall establish, where appropriate:
- the conditions of use of the food or food ingredient,
- the designation of the food or food ingredient, and its specification,
- specific labelling requirements as referred to in Article 8.
3. The Commission shall without delay inform the applicant of the decision taken. Decisions shall be published in the Official Journal of the European Communities.

Article 8
1. Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of:
(a) any characteristic or food property such as:
- composition,
- nutritional value or nutritional effects,
- intended use of the food,
which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient.
A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this Article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics.
In this case, the labelling must indicate the characteristics or properties modified, together with the method by which that characteristic or property was obtained;
(b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;
(c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns;
(d) the presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list

of which is laid down in Annex I A, Part 1 of Directive 90/220/EEC.
2. In the absence of an existing equivalent food or food ingredient, appropriate provisions shall be adopted where necessary in order to ensure that consumers are adequately informed of the nature of the food or food ingredient.
3. Any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 13.

Article 9
1. Where a food or food ingredient falling within the scope of this Regulation contains or consists of a genetically modified organism within the meaning of Article 2 (1) and (2) of Directive 90/220/EEC, the information required in the request for placing on the market referred to in Article 6 (1) shall be accompanied by:
- a copy of the written consent, if any, from the competent authority, to the deliberate release of the genetically modified organisms for research and development purposes provided for in Article 6 (4) of Directive 90/220/EEC, together with the results of the release(s) with respect to any risk to human health and the environment;
- the complete technical dossier supplying the relevant information requested in Article 11 of Directive 90/220/EEC and the environmental risk assessment based on this information, the results of any studies carried out for the purposes of research and development or, where appropriate, the decision authorizing the placing on the market provided for in part C of Directive 90/220/EEC.
Articles 11 to 18 of Directive 90/220/EEC shall not apply to foods or food ingredients which contain or consist of genetically modified organisms.
2. In the case of foods or food ingredients falling within the scope of this Regulation containing or consisting of genetically modified organisms, the decision referred to in Article 7 shall respect the environmental safety requirements laid down by Directive 90/220/EEC to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of genetically modified organisms. During evaluation of requests for the placing on the market of products containing or consisting of genetically modified organisms, the necessary consultations shall be held by the Commission or the Member States with the bodies set up by the Community or the Member States in accordance with Directive 90/220/EEC.

Article 10
Detailed rules for the protection of the information provided by the applicant shall be adopted in accordance with the procedure laid down in Article 13.

Article 11
The Scientific Committee for Food shall be consulted on any matter falling within the scope of this Regulation likely to have an effect on public health.

Article 12
1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.
2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.

Article 13
1. Where the procedure defined in this Article is to be implemented, the Commission shall be assisted by the Standing Committee for Foodstuffs, hereinafter referred to as the ‘Committee`.
2. Matters shall be referred to the Committee by the Chairman either on his own initiative or at the request of the representative of a Member State.
3. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty

in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.
4. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.
(b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 14
1. No later than five years from the date of entry into force of this Regulation and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation accompanied, where appropriate, by any suitable proposal.
2. Notwithstanding the review provided for in paragraph 1, the Commission shall monitor the application of this Regulation and its impact on health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

Article 15
This Regulation shall enter into force 90 days following its publication in the Official Journal of the European Communities.

COMMISSION STATEMENT - AD ARTICLE 2
The Commission confirms that should it appear, in the light of experience, that there are gaps in the system of protection of public health provided for by the existing legal framework, in particular in respect of processing aids, it will formulate appropriate proposals in order to fill those gaps.

APPENDIX III

398R1139

Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC

Official Journal L 159 , 03/06/1998 p. 0004 - 0007

Amendments:
*Amended by **300R0049** (OJ L 006 11.01.00 p.13)*

Text:
COUNCIL REGULATION (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC
THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty establishing the European Community,
Having regard to Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (1), and in particular Article 4(2) thereof,
Having regard to the proposal from the Commission,
(1) Whereas, in accordance with the provisions of Part C of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (2), consents have been given for the placing on the market of certain genetically modified products by Commission Decision 96/281/EC of 3 April 1996 concerning the placing on the market of genetically modified soya beans (Glycine max L.) with increased tolerance to the herbicide glyphosate, pursuant to Council Directive 90/220/EEC (3), and by Commission Decision 97/98/EC of 23 January 1997 concerning the placing on the market of genetically modified maize (Zea mays L.) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC (4);
(2) Whereas in accordance with Directive 90/220/EEC there were no safety grounds for mentioning on the label of genetically modified soya beans (Glycine max L.) or of genetically modified maize (Zea mays L.) that they were obtained by genetic modification techniques;
(3) Whereas Directive 90/220/EEC does not cover non-viable products derived from genetically modified organisms (hereinafter referred to as 'GMOs`);
(4) Whereas certain Member States have taken measures in respect of the labelling of foods and food ingredients produced from the products concerned; whereas differences between those measures are liable to impede the free movement of those foods and food ingredients and thereby adversely affect the functioning of the internal market; whereas it is therefore necessary to adopt uniform Community labelling rules for the products concerned;
(5) Whereas Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (5), lays down, in Article 8, additional specific labelling requirements in order to ensure proper information for the final consumer; whereas those additional specific labelling requirements do not apply to foods or food ingredients which were used for human consumption to a significant degree within the Community before the entry into force of Regulation (EC) 258/97 and are for that reason considered not to be novel;
(6) Whereas, in order to prevent distortions of competition, labelling rules for the information of the final consumer based on the same principles should apply to foods and food ingredients consisting of or derived from GMOs which

were placed on the market before the entry into force of Regulation (EC) No 258/97 pursuant to a consent given under Directive 90/220/EEC, and to foods and food ingredients which are placed on the market thereafter;
(7) Whereas, therefore, Commission Regulation (EC) No 1813/97 of 19 September 1997 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC (6) laid down general labelling rules for the abovementioned products;
(8) Whereas it is now urgent to lay down detailed uniform Community rules for the labelling of the foodstuffs covered by Regulation (EC) No 1813/97;
(9) Whereas, in particular, drawing on the approach taken in Article 8 of Regulation (EC) No 258/97, it is necessary to ensure that the final consumer is informed of any characteristic or food property, such as composition, nutritional value or nutritional effects or the intended use of the food, which renders a food or food ingredient no longer equivalent to an existing food or food ingredient; whereas, for that purpose, foods and food ingredients produced from genetically modified soya beans or from genetically modified maize which are not equivalent to conventional counterparts should be subject to labelling requirements;
(10) Whereas, drawing on the approach taken in Article 8 of Regulation (EC) No 258/97, it is necessary that labelling requirements are based on scientific evaluation;
(11) Whereas it is necessary to establish clear labelling rules for the abovementioned products, allowing official control on a reliable, readily repeatable and practicable basis; whereas common scientifically validated testing methods should be developed;
(12) Whereas it is also necessary to ensure that the labelling requirements are no more burdensome than necessary but sufficiently detailed to supply consumers with the information they require;
(13) Whereas at this stage the presence in foods and food ingredients of protein or DNA resulting from genetic modification constitutes the criterion best complying with the abovementioned requirements; whereas such an approach could be reconsidered in the light of future developments in scientific knowledge;
(14) Whereas adventitious contamination of foodstuffs with DNA or protein resulting from genetic modification cannot be excluded; whereas labelling as a result of such contamination could be avoided by setting a threshold for the detection of DNA and protein;
(15) Whereas urgent consideration must be given, in the light of any relevant scientific advice, to the question of whether a de minimis threshold for the presence of DNA or protein resulting from genetic modification can be set and, if so, at what level;
(16) Whereas foods and food ingredients produced from genetically modified soya beans (Glycine max L.) or from genetically modified maize (Zea mays L.), in which DNA resulting from genetic modification is present, are not equivalent and should therefore be subject to labelling requirements;
(17) Whereas it is possible that protein or DNA resulting from genetic modification has been destroyed by successive stages of processing; whereas, in that case, foods and food ingredients should be considered equivalent for labelling purposes; whereas they should therefore not be subject to labelling requirements; whereas a list of such products should be drawn up;
(18) Whereas, nevertheless, some processing methods may eliminate DNA but not proteins; whereas the possibility cannot be excluded that such methods may be capable of being applied to food uses; whereas foods and food ingredients in which DNA resulting from genetic modification is not present but in which proteins resulting from genetic modification are present, cannot be considered to be equivalent; whereas therefore, they should be subject to labelling requirements;
(19) Whereas the necessary information should be provided in the list of ingredients except in the case of products for which no such list exists, in which case it should appear clearly on the labelling of the product;
(20) Whereas this Regulation is without prejudice to the operators' right to include voluntary claims in the labels of their products as to particulars other than those laid down in this Regulation (such as the absence of foods and food ingredients produced from genetically modified soya beans and maize, or the presence of such foods and food ingredients in cases where it is not scientifically verifiable but evidence of it is available through other means), provided that such claims are made in compliance with the provisions of Directive 79/112/EEC;
(21) Whereas, having regard to their scope and effects, the Community measures introduced by this Regulation are not only necessary but essential if the objectives set are to be attained; whereas those objectives cannot be attained by the Member States acting individually;
(22) Whereas this Regulation replaces Commission Regulation (EC) No 1813/97, which should therefore be repealed;

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(23) Whereas in pursuance of the procedure laid down in Article 17 of Directive 79/112/EEC, a draft of this text was submitted to the Standing Committee on Foodstuffs, which was unable to deliver an opinion, and whereas in accordance with the same procedure the Commission addressed a proposal to the Council, concerning the measures to be adopted,
HAS ADOPTED THIS REGULATION:

Article 1
1. This Regulation shall apply to foods and food ingredients which are to be delivered as such to the final consumer (hereinafter referred to as 'the specified foodstuffs`) produced, in whole or in part, from:
- genetically modified soya beans covered by Decision 96/281/EC,
- genetically modified maize covered by Decision 97/98/EC.
2. This Regulation shall not apply to food additives, flavourings for use in foodstuffs or extraction solvents used in the production of foodstuffs as referred to in Article 2(1) of Regulation (EC) No 258/97.

Article 2
1. The specified foodstuffs shall be subject to the additional specific labelling requirements laid down in paragraph 3.
2. However, the specified foodstuffs in which neither protein nor DNA resulting from genetic modification is present shall not be subject to the said additional specific labelling requirements.
A list of products not subject to the additional specific labelling requirements shall be drawn up under the procedure laid down in Article 17 of Directive 79/112/EEC, taking account of technical developments, the opinion of the Scientific Committee on Food and any other relevant scientific advice.
3. The additional specific labelling requirements shall be the following:
(a) where the food consists of more than one ingredient, the words 'produced from genetically modified soya` or 'produced from genetically modified maize`, as appropriate, shall appear in the list of ingredients provided for by Article 6 of Directive 79/112/EEC in parentheses immediately after the name of the ingredient concerned. Alternatively, these words may appear in a prominently displayed footnote to the list of ingredients, related by means of an asterisk (*) to the ingredient concerned. Where an ingredient is already listed as being produced from soya or maize the words 'produced from genetically modified` may be abbreviated to 'genetically modified`; if the abbreviated form of words is used as a footnote, the asterisk shall be directly attached to the word 'soya` or 'maize`. Where either form of words is used as a footnote, it shall have a typeface of at least the same size as the list of ingredients itself;
(b) in the case of products for which no list of ingredients exists, the words 'produced from genetically modified soya` or 'produced from genetically modified maize`, as appropriate, shall appear clearly on the labelling of the food;
(c) where in accordance with the provisions of the first indent of Article 6(5)(b) of Directive 79/112/EEC an ingredient is designated by the name of a category, that designation shall be completed by the words 'contains . . .
(*) produced from genetically modified soya/genetically modified maize
(*) Ingredient(s) to be specified.`, as appropriate;
(d) where an ingredient of a compound ingredient is derived from the specified foodstuffs, it shall be mentioned on the labelling of the final product, with the addition of the wording set out in point (b).
4. This Article shall be without prejudice to the other requirements of Community law concerning the labelling of foodstuffs.

Article 3
Commission Regulation (EC) No 1813/97 is hereby repealed.

Article 4
1. The labelling requirements of this Regulation shall not apply to products which have been lawfully manufactured and labelled in the Community, or which have been lawfully imported into the Community and put into free circulation, before the entry into force of this Regulation.
2. The application of Article 2 to products placed on the market with labelling complying with Commission Regulation (EC) No 1813/97 so as to indicate the presence of genetically modified material may be postponed until

six months after the entry into force of this Regulation.

Article 5
This Regulation shall enter into force 90 days after its publication in the Official Journal of the European Communities.

APPENDIX IV

REPORT OF THE FIRST SESSION OF THE CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Chiba, Japan 14-17 March 2000

INTRODUCTION

1. The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (CX/FTB) held its First Session in Chiba, Japan from 14 to 17 March 2000, by courtesy of the Government of Japan. The Session was presided over by Professor Hiroshi Yoshikura, Director General, Research Institute, International Medical Center of Japan. A complete list of participants is included as Appendix I to this report.

OPENING OF THE SESSION

2. The Session was opened by Mr Shingo Haketa, Vice-Minister for Health and Welfare, who welcomed the participants to Makuhari, Chiba, Japan. Mr Haketa stressed the expectation of the global community that this Task Force would reach an agreement toward the modality of safety assessment of food derived from biotechnology within its prescribed period of 4 years. Dr Hartwig de Haen, Assistant Director-General, Economic and Social Department of FAO and Dr Jørgen Schlundt, Cordinator Programme of Food Safety, WHO, gave welcome addresses on behalf of FAO and WHO, respectively. Both representatives expressed their sincere gratitude toward the Government of Japan for its hospitality and wished a successful meeting. They stressed the potential benefit of biotechnology if utilised in an appropriate manner and at the same time the concern of consumers about the safety of foods derived from biotechnology. It was also stressed that FAO and WHO, as parent organizations of the Codex Alimentarius Commission, would provide continuous support to the work of the Task Force.
3. Mr Thomas Billy, Chairman of the Codex Alimentarius Commission recalled that the Codex Alimentarius Commission had first raised the issue of safety evaluation of foods derived from biotechnology over decade ago and stressed the importance of a progressive and science-based exchange of views to reach a consensus in this controversial problem area.

ADOPTION OF THE AGENDA (Agenda Item 1)

4. The Task Force adopted the Provisional Agenda as the Agenda of the Session.

MATTERS REFERRED TO THE TASK FORCE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)

5. The Task Force noted the information presented in document CX/FBT 00/2 concerning the matters referred to the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology by the Codex Alimentarius Commission and other Codex Committees. The Task Force noted in particular the decision of the Commission amending the Rules of Procedures of the Codex Alimentarius Commission that every effort should be made to adopt Codex Standards by consensus (New Rule X.2).

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6. The Task Force noted the Terms of reference established by the Codex Alimentarius Commission for its work (Annex 2 to document CX/FBT 00/2).

REVIEW OF THE WORK BY INTERNATIONAL ORGANIZATIONS ON THE EVALUATION OF THE SAFETY AND NUTRITION ASPECTS OF FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 3)

7. The Committee noted the information presented in documents CX/FBT 00/3 and CX/FBT 00/3 Add. concerning the work by international organizations on the evaluation of the safety and nutrition aspects of foods derived from biotechnology.
8. Regarding the Expert Consultation on biotechnology to be held in June 2000, delegations stressed the importance of transparency and asked further clarification on the scope of the Consultation. Representatives of FAO and WHO informed the Task Force of current discussions on further improvements in transparency of the identification and selection procedures for the expert body and that experts would be selected on the basis of their personal capacity, that the selection process would be transparent and that member Governments would be involved in the process of identification and endorsement of experts. International NGOs would also be invited to nominate potential experts. It was announced that the scope of the Consultation would be to review the current methodology on safety assessment, including the concept of substantial equivalence, and also to study the nutritional aspects of foods derived from biotechnology. It was noted that the scope would be modified in the light of discussions at the present session of the Task Force.
9. Attention was drawn to the recommendation of the 1996 FAO/WHO Expert Consultation that developing countries should be provided with assistance and education regarding approaches to the safety assessment of foods and food components produced by genetic modification. The Representatives of FAO and WHO reaffirmed the support of these Organizations for technical assistance to developing countries and the Task Force so noted.

Convention on Biological Diversity: Cartagena Protocol on Biosafety
10. The Task Force was informed that the Protocol was adopted at the extended extraordinary session of the Conference of the Parties to the Convention in January 2000 in Montreal, Canada and would enter into force ninety days following the deposit of the fiftieth instrument of ratification. The text of the Protocol, which had not been available at the time of the preparation of the Secretariat's paper, was made available to delegations.
11. It was noted that the objective of the Protocol was "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."
12. Noting that interpretation of the provisions of the Protocol was beyond the mandate of the Commission, the Task Force noted that the Protocol formed part of the international regulatory framework within which the development, adoption, acceptance and use of Codex standards had to be undertaken. The objective and provisions of the Protocol would therefore need to be taken into account during the development of appropriate Codex texts by the Task Force.

CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER PRINCIPLES FOR FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 4)

13. Member countries and observer organizations were invited to express their views on identification of area of the work of the Task Force, work priorities, and key concepts and definitions to be developed by the Task Force. Member countries and observer organizations had been invited by means of CL 1999/27-FBT to submit their comments on these matters, and responses had been compiled in the working documents referenced for this agenda item.
14. Many delegations and observer organizations identified safety and nutrition assessment of foods derived from biotechnology as the main priority area of the work. While recognizing that the concept of the substantial equivalence was being used in safety assessment, several delegations and observer organizations stressed the need for further review of the concept and its applicability to safety assessment. Several delegations stated that risk

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management and especially pre-market approval were fundamental aspects of risk analysis in relation to foods derived from biotechnology. The Task Force noted the necessity to study marker genes and the potential for non-intentional and long-term health effects. Some delegations expressed the view that it would be useful to establish an international expert body that would be responsible for risk assessment.

15. Concerning legitimate factors other than science that were relevant to the health of consumers and the promotion of fair trade practice, several delegations and the observer from the European Commission proposed to develop a specific guideline to take into account those factors. Several other delegations were of the opinion that since the Codex Committee on General Principles (CCGP) was currently working on this issue, and that therefore the development of a guideline specific to the Task Force was not an immediate priority. The following factors were mentioned by some delegations as potential other legitimate factors: ethical/religious/cultural considerations, consumer concerns/interests, food security, enforcement capacity and environmental risk.

16. Many delegations and observers also pointed out the need for addressing precautionary principles/approaches to be recommended by the Task Force. Several other delegations stressed that the issue of precaution should first be discussed at the Codex Committee on General Principles (CCGP).

17. It was also proposed that the concept of "familiarity" used in environmental risk assessment should be considered. It was noted that this concept had not previously been used by Codex and that further clarification would be needed.

18. Many delegations and observers identified the development of a guideline for the monitoring and traceability of the foods derived from biotechnology as a priority, indicating that these issues were not related only to consumer information but to consumer health protection. Other delegations and observers stated that the concept of "traceability" was new to Codex and required further clarification and explanation including the implications for developing countries. It was also noted that the concept may not be exclusive to foods derived from biotechnology and may need to be considered at a more general level.

19. The need to consider the methods of analysis, including the detection methods of genetically modified foods was also pointed out by some delegations. Several delegations were of the view that these issues also required the involvement of the Codex Committee on Food Labelling (CCFL) or the Codex Committee on Method of Analysis and Sampling (CCMAS).

20. The need to develop a specific guideline on transparency and involvement of all stakeholders particularly consumers in the decision making process was emphasised by many of the delegations and observer organizations.

21. Regarding key concepts and definitions, many delegations emphasised the need to establish clear definitions on several key words. The definitions of "modern biotechnology" and "substantial equivalence" were identified by many delegations and it was suggested that the Task Force refer to definitions established or to be established by other fora, e.g. the definition on modern biotechnology to be developed by the Codex Committee on Food Labelling. The words "Recombinant DNA technique" and "Genetically Modified Organism (GMO)" were also identified by several delegations and observers as possibly requiring definitions.

22. Among various food categories that may fall under the scope of the Task Force, many delegations and observer organizations identified genetically modified foods derived from plants, microorganism and animals in order of the priority, while others were of the opinion that these three categories should all be addressed. Animal feed and food additives were also identified. It was noted by some delegations that animal feeding would be covered by the Codex *Ad Hoc* Intergovernmental Task Force on Animal Feeding to be held in Denmark in June 2000.

23. The Task Force finally elaborated, on the basis of an *aide-mémore* prepared by the Chairman, a list of subjects potentially to be dealt with in its work by summarizing the proposals made by delegations. The list is reproduced as Appendix II to this report and is considered to cover the maximum range of proposals made during discussions.

24. The Task Force recognized that the time frame prescribed in its terms of reference necessitated the prioritization of its work subjects and that a considerable part of the proposed subjects were duly or partly covered by other Codex Committees or other international organizations. The Task Force recalled also that, according to its terms of reference, the Task Force should coordinate and closely collaborate with appropriate Codex Committees and take full account of existing work carried out by other international organizations. It agreed to identify those subjects that were already under discussion by other Codex subsidiary bodies or other international organizations and which therefore would not need to be considered in detail in the priority areas of the work of the Task Force. It noted that the issue of labelling was covered by the Codex Committee on Food Labelling (CCFL) and agreed that the precautionary approach/ principle should be dealt with as a matter of priority by the Codex Committee on General Principles (CCGP). The Task Force further agreed that the environmental risk was addressed by other instruments or

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bodies such as the Cartagena Biosafety Protocol under the Convention on Biological Diversity, the International Plant Protection Convention (IPPC) and the Commission on Genetic Resources for Food and Agriculture (CGRFA).
25. For Methods (Analysis/Sampling) some delegations observed that this was primarily within the terms of reference of the Codex Committee on Methods of Analysis and Sampling (CCMAS) while others were of the opinion that the identification of methods appropriate for the detection of genetic modification should be done primarily by the Task Force. The Task Force agreed finally to include analytical methods within its work area, recognizing the use of such methods for control, monitoring and labelling purposes.
26. For other legitimate factors the Task Force recalled that this issue was dealt with by the Codex Committee on General Principles (CCGP) but other relevant Committees were also asked to identify legitimate factors other than science which were considered relevant for risk analysis. The Task Force noted that several factors had been proposed by delegations as such other legitimate factors but decided not to take a decision thereon at this stage, recognizing that the Task Force had not accumulated sufficient experiences on this subject.

Programme of Work
27. Taking into account the priorities discussed above, the Task Force decided that it would proceed with the elaboration of two major texts, namely:

- · A set of broad general principles for risk analysis of foods derived from biotechnology including matters such as:
  - · Science-based decision-making;
  - · Pre-market assessment;
  - · Transparency;
  - · Post-market monitoring [including traceability]; and
  - · Other legitimate factors as appropriate.
  - · Specific guidance on the risk assessment of foods derived from biotechnology including such matters as:
    - · Food safety and nutrition;
    - · "Substantial equivalence";
    - · Potential long-term health effects; and
    - · Non-intentional effects.

28. The Task Force agreed that in the preparation of these texts preference should be given to guidance that was applicable to all foods derived from biotechnology, however should it be necessary to prioritise the work, first priority should be given to foods of plant origin, followed by micro-organisms used directly in foods and then foods of animal origin. It was noted however, that early attention may have to be given to fish.
29. The Task Force also agreed that consideration should be given to the development of guidelines for transparency in decision-making and the participation of all stake-holders in the decision-making process. It was noted that the approach of establishing over-arching general principles would allow the development of further, detailed explanatory guidelines on specific issues if these were required and if time allowed.
30. It was agreed that careful attention should be paid to the development of adequate and appropriate definitions, drawing on definitions already developed and agreed to in other texts (such as the Cartagena Protocol) or by other bodies (such as the Codex Committee on Food Labelling).
31. Concerning the issues of *Traceability* and *Familiarity* raised by several delegations, the Task Force noted that a better understanding of these concepts and their implications was required before they could be included definitively in either of the main texts to be developed. It therefore agreed that discussion papers should be prepared on these issues as soon as possible. In the meantime, any reference to these issues in the main texts under development would remain in square brackets.
32. The Task Force agreed that a list of available **analytical methods** including those for the detection or identification of foods or food ingredients derived from biotechnology should be prepared, and that this list should indicate the performance criteria and status of the validation of each method. It was further agreed that the list of methods, once finalized, should be transmitted to the Codex Committee on Methods of Analysis and Sampling for endorsement.
33. The Task Force recognized that the work programme outlined above was very substantial taking into account the time-limited mandate assigned by the Codex Alimentarius Commission, and that it did not cover all of the items proposed for consideration. Nevertheless, there was a general consensus that the above issues had the highest priority and should be achievable within the time-frame allowed. It agreed that this programme of work should be

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reported to the Executive Committee for approval as new work at Step 1 of the Uniform Codex Procedure for the Elaboration of Standards and Related Texts.
34. Noting that finalization of its work programme would require the resolution of questions regarding labelling, the application and use of precautionary approaches, and consideration of legitimate factors other than science in decision-making, the Task Force called upon the Codex Committees on Food Labelling and on General Principles for an early resolution of these matters.

Establishment of *ad hoc* Working Groups
35. In order to develop the programme of work as quickly as possible, the Task Force decided to establish two ad hoc Working Groups open to the participation of all Members and Observers participating in the present session and other Members and international organizations that might later indicate their interest. The first of these Working Groups, to be chaired by the Delegation of Japan, was charged with the development of the proposed draft general principles and guidelines indicated in paras. 27 and 28 above. This Working Group would also develop draft definitions. It would also review the discussion papers on traceability and familiarity if they became available in time. The Delegation of Japan indicated that it was its intention for the Working Group to meet twice before the Second Session of the Task Force, probably in July and November 2000, after which proposed draft texts would be sent to Member governments and interested international organizations for comment at Step 3.
36. The second *ad hoc* Working Group, to be chaired by the Delegation of Germany, would compile a list of appropriate analytical methods for consideration by the Task Force, together with their performance characteristics and the status of their validation. To facilitate this work it was agreed that a Circular Letter would be sent to Members and interested international organizations requesting information and that the information received would be compiled by the Delegation of Germany for review by the Working Group at a one-half day meeting to be held immediately prior to the next Session of the Task Force.

Matters requiring expert advice
37. The Task Force welcomed the initiative of FAO and WHO to convene an Expert Consultation to support the scientific aspects of its work. In support of the programme of work outlined above, it requested advice on the five specific questions as contained in Appendix III to this report.
38. It requested FAO and WHO to make the results of the Consultation available as soon as possible to all interested parties and that responses to the questions contained in Appendix III be made available to the *ad hoc* Working Group chaired by Japan.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION (Agenda Item 5)

39. There was no other business.
40. The Task Force noted that the following matters would be included on the provisional agenda for its next Session:

- Matters referred or arising from other Codex Committees including the Executive Committee;
- Matters of interest from other international organizations;
- Discussion paper on *traceability*;
- Consideration of proposed draft general principles of a broad nature for the application of risk analysis to foods derived from biotechnology, guidelines (the precise title to be recommended by the *ad hoc* Working Group); including consideration of transparency and involvement of stakeholders in proposed draft general principles;
- Consideration of proposed draft guidelines for risk assessment with reference to food safety and nutrition for foods derived from biotechnology (the precise title to be recommended by the *ad hoc* Working Group);
- Information paper on *familiarity;* and
- Consideration of analytical methods.

41. It was noted that the Second Session of the Task Force would be held in Japan in March 2001, the precise dates and location to be identified by the Japanese and Codex Secretariats.

APPENDIX V

H.R.3377
Sponsor: Rep Kucinich, Dennis J. (introduced 11/16/1999)
Latest Major Action: 11/30/1999 Referred to House subcommittee
Title: To amend the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labelled accordingly.

COSPONSORS(51), ALPHABETICAL

Rep Andrews, Robert E. - 3/28/2000
Rep Bonior, David E. - 11/16/1999
Rep Carson, Julia - 3/28/2000
Rep Conyers, John, Jr. - 2/1/2000
Rep Delahunt, William D. - 2/1/2000
Rep Faleomavaega, Eni F. H. - 2/15/2000
Rep Hinchey, Maurice D. - 11/16/1999
Rep Kildee, Dale E. - 3/1/2000
Rep Kleczka, Gerald D. - 2/1/2000
Rep LaTourette, Steve C. - 2/1/2000
Rep Lewis, John - 2/1/2000
Rep Maloney, Carolyn B. - 11/18/1999
Rep Martinez, Matthew G. - 11/16/1999
Rep McGovern, James P. - 2/1/2000
Rep Metcalf, Jack - 11/16/1999
Rep Mink, Patsy T. - 11/16/1999
Rep Nadler, Jerrold - 2/1/2000
Rep Norton, Eleanor Holmes - 11/16/1999
Rep Owens, Major R. - 2/1/2000
Rep Rangel, Charles B. - 2/15/2000
Rep Sanders, Bernard - 11/16/1999
Rep Sherman, Brad - 2/15/2000
Rep Stark, Fortney Pete - 11/16/1999
Rep Udall, Tom - 3/1/2000
Rep Weiner, Anthony D. - 2/15/2000
Rep Wynn, Albert Russell - 2/1/2000
Rep Barrett, Thomas M. - 2/1/2000
Rep Brown, Sherrod - 11/16/1999
Rep Clay, William (Bill) - 2/1/2000
Rep DeFazio, Peter A. - 11/16/1999
Rep Doyle, Michael F. - 11/16/1999
Rep Gutierrez, Luis V. - 2/1/2000
Rep Jones, Stephanie Tubbs - 4/12/2000
Rep Kilpatrick, Carolyn C. - 2/1/2000
Rep Lantos, Tom - 3/16/2000
Rep Lee, Barbara - 11/16/1999
Rep Lipinski, William O. - 11/16/1999
Rep Markey, Edward J. - 2/1/2000
Rep McDermott, Jim - 11/16/1999
Rep McKinney, Cynthia A. - 2/1/2000
Rep Miller, George - 2/1/2000
Rep Moakley, John Joseph - 2/1/2000
Rep Neal, Richard E. - 3/1/2000
Rep Olver, John W. - 2/1/2000
Rep Pallone, Frank, Jr. - 2/1/2000
Rep Rivers, Lynn N. - 11/18/1999
Rep Schakowsky, Janice D. - 11/16/1999
Rep Smith, Christopher H. - 11/16/1999
Rep Udall, Mark - 2/1/2000
Rep Waters, Maxine - 11/16/1999
Rep Woolsey, Lynn C. - 11/16/1999

MOST RECENT SUMMARY:
11/16/1999--Introduced.
Genetically Engineered Food Right to Know Act - Amends the Federal Food, Drug, and Cosmetic Act (FDCA), Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA) to deem a food misbranded if it contains or was produced with a genetically engineered material unless its labelling contains statements meeting specified requirements. Excludes, in all three Acts, food: (1) served in restaurants; or (2) prepared primarily in a retail establishment, ready for human consumption, but not offered for sale for immediate consumption in the establishment. Excludes, for the FDCA, a medical food as defined in the Orphan Drug Act.

Subjects violators to civil monetary penalties. Exempts from the penalties: (1) any person (recipient) who establishes a guaranty or undertaking signed by the person (residing in the United States) from whom the recipient in good faith received the food to the effect that the food does not contain or was not produced with a genetically engineered material; and (2) for the FDCA, an agricultural producer of a food that does not contain and was not produced with a genetically engineered material if the food becomes contaminated with a genetically engineered material (including by mingling the two), so long as the contamination was neither intentional nor negligent.