

Genetically modified food and agricultural biotechnology have generated considerable interest -- as well as controversy -- in the United States and elsewhere around the world. While some feel the technology to be extremely useful and tout its benefits, others raise questions about how the technology will impact the environment and are also concerned about the safety of the products for human health. This fact sheet is one in a series that the Pew Initiative on Food and Biotechnology has developed in an effort to answer some of the common questions that are frequently asked about genetically modified food and agricultural biotechnology.

U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food

I. OVERVIEW

Corn, cotton and soybeans are the most important field crops in the U.S., both in terms of volume and cash receipts; they are essential in the production of human food and animal feed, and are also the source of many ingredients used extensively in processed foods. These three crops are also major U.S. commodity exports. In the United States, large percentages of these crops are also genetically modified (GM): 69 percent of cotton, 68 percent of soybeans, and 26 percent of corn grown in the U.S. in 2001 was genetically engineered. The U.S. accounts for the lion's share of GM crops grown worldwide, with three quarters of all GM crops in the world now being planted in the U.S. (See the Pew Initiative's fact sheet "[Genetically Modified Crops in the United States](http://pewagbiotech.org/resources/factsheets/display.php3?FactsheetID=1) <http://pewagbiotech.org/resources/factsheets/display.php3?FactsheetID=1>).

In Europe, a recent string of highly publicized food safety crises have heightened public concerns about food and made consumers there particularly wary of GM foods. Reflecting those concerns, the European Union (EU) has required mandatory labeling of GM foods since 1997, and no new GM crops have been approved since 1998. In July 2001, the European Commission (EC) proposed a new set of stronger proposals to "restore confidence" in GM foods. The proposals calls for strict labeling and tracing of all food and animal feed produced from GM crops. On June 4, 2002, the Environment Committee of the European Parliament took the first step to push this new regulatory proposal through by voting narrowly on a stricter proposal than the original European Commission's version.

The Committee approved a measure to lower the threshold at which mandatory labeling would be required, lowering it from one percent (as proposed by the EC originally) to 0.5% per ingredient. From here, the measure will be taken up by the European Parliament plenary in July, then will go back to the Commission and EU governments, and then back to the Parliament for final approval.

The EC proposals threaten to further sour trade relations between the U.S. and the EU, which are already embittered due to conflicts over banana and beef exports, and more recently, steel tariffs. U.S. agricultural producers feel the proposed EU rules are unworkable, expensive and unnecessary since they believe that GM foods are as safe as and should be treated no differently than conventionally-produced foods. The EC, on the

other hand, states that the rules are needed in light of strong European consumer concerns about GM foods.

This fact sheet summarizes the regulations under consideration by the EC and their effects on U.S.-EU agricultural trade, and looks at the background issues dividing the U.S. and EU on this topic.

II. BACKGROUND

U.S.-EU trade is big business

Looking at goods and services combined, the EU and U.S. are each other's main trading partners and account for the largest bilateral trade relationship in the world. The two markets have very similar export figures in agricultural products. For example, in fiscal year 2001, the value of U.S. exports of agricultural products to the EU was \$6.3 billion. The main products exported were soybeans, tobacco, and animal feed, including corn gluten. Similarly, the value of EU exports of agricultural products to the U.S. was \$7.9 billion. The main products were wine and beer.



Past European Actions on GM Foods

In 1996, then U.S. Agriculture Secretary Dan Glickman got an early glimpse of the unfolding controversy over GM foods when protesters at the World Food Summit in Rome pelted him with grain, calling for a ban on GM crops. Following food safety concerns over mad cow disease and other food scares (see the section: Consumer Opposition to GM Foods in Europe, below), the EU adopted in 1997 regulations for the mandatory labeling of foods containing GM ingredients. By 1998, the approval of new GM crops in the EU came to a halt when six countries, led by France, vowed to block permits for GM crops unless existing labeling and safety regulations were tightened further. (Since 1998, 13 GM crop applications have been pending approval in the EU.)

For a more comprehensive timeline of events leading up to the current dispute, see the Appendix).

U.S. Agricultural Exports Have Been Hurt by European Opposition to Biotechnology

U.S. farmers and biotechnology companies have expressed increasing frustration with this de facto GM moratorium in the EU.

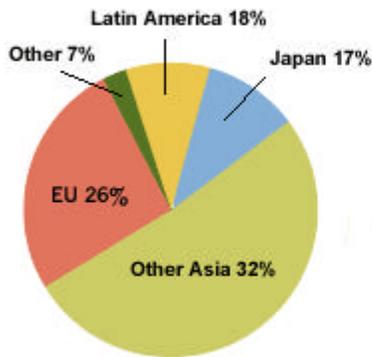
Before 1997, the U.S. sold about 1.75 million tons of corn annually to Spain and Portugal, – the two countries in the EU that account for most US corn exports. But in the 1998-99 crop year, Spain bought less than a tenth of that amount of U.S. corn and Portugal bought none at all. The sharp decline in corn exports to the EU was due in large part to the moratorium on EU approval of new corn varieties already grown by U.S. farmers.

While the decline in U.S. corn exports to the EU has been dramatic, Europe has accounted for only a small percentage of U.S. corn exports, only 4 percent in 1999. (See Figure 3). However, the EU is the most important U.S. export market for corn *byproducts*, such as the corn gluten used in animal feed, accounting for more than 85 percent of total exports. EU rules to date have not required the labeling of such byproducts.

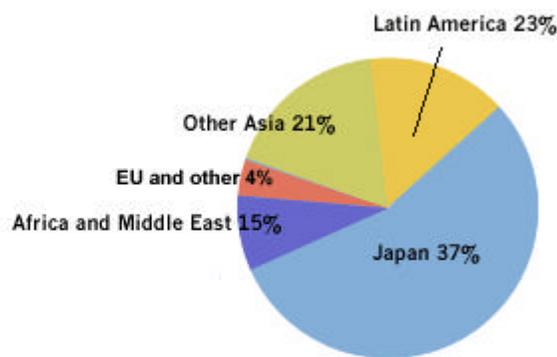
Unlike GM corn, there is only one type of GM soybeans in general production in the U.S. and that variety has also been approved in the EU. As a result, U.S. soybean exports to date have not suffered any losses as a result of the EU regulations on GM food. Because the EU market accounts for a significant proportion (26 percent in 1999) of U.S. soybean exports, American soybean producers have been reluctant to introduce new biotech varieties that have not been approved for the European market.

Major export markets of US Soybeans and Corn

Soybeans exports



Corn exports



The figures are for 1999, when total soybeans exports valued \$4.5 billion and total corn exports, \$4.9 billion. Exports were 29% and 18% of production, respectively.

Source: USDA, Economic Research Service.

Consumer Opposition to GM Foods in Europe

Several food crises have made consumers in Europe (and in the United Kingdom in particular), extremely wary of changes to the food supply and have led to a waning faith in regulatory agencies. Although these crises have not been caused by GM food, GM food has been caught up in the general suspicion about food safety.

This first of these major food crises, “mad cow disease,” or bovine spongiform encephalopathy (BSE), started in the U.K. in the 1990s, before spreading to the rest of Europe. BSE causes the brains of cows to deteriorate after they have eaten tainted feed (sheep brains were commonly fed to cows in the U.K as a cheap source of feed; some of this feed contained the infectious agent that causes the disease scrapie, which is thought to have caused BSE in the cattle). Originally, food safety authorities in the U.K. asserted that BSE existed only in cattle and could not be transmitted to human beings if they ate infected animals.

On March 20, 1996, however, scientific evidence revealed a link between some cases of a similar disease in humans (called Creutzfeldt-Jacob disease, or CJD) and consumption of meat from cows with BSE. Government officials at first dismissed the research and minimized the link between BSE and its human form, but later, the British government took drastic steps to protect human and animal health, including the destruction of millions of cattle. Pictures of the animals infected with BSE, struggling to stand up and later, masses of their carcasses being plowed into incinerators, punctuated television news throughout Europe. Despite these measures, the government was harshly criticized for acting too late and not effectively communicating risks to the public.

Over the last seven years, since the link between BSE and Creutzfeldt-Jacob Disease was discovered, over 4.5 million cattle have been slaughtered in the UK to prevent the spread of the disease. In addition, numerous cows outside the U.K. have been found to have BSE and estimates vary as to how many human cases of the disease may still occur.

Since 1986, there have been a total of 125 cases of CJD worldwide -- including 88 in the U.K., three in France and one in Ireland. Many scientists have voiced concern that this number might represent only the tip of the iceberg. Since the incubation time of the disease is unknown, it is difficult to predict how many people might have been infected during the peak of the BSE epidemic, which is estimated to have taken place in cows from 1992 to 1993. Some British epidemiologists had estimated that the human form of mad cow may peak at 100 cases per year in Britain and kill a few thousand people in coming decades. A recent study published in the journal *Science* from experts at the London School of Hygiene and Tropical Medicine says that those numbers are based on overly optimistic assumptions and that more than 100,000 people may die from the disease in the next several decades (*Science*, October 26, 2001).

As foods made with GM ingredients were being introduced to the market in Europe, some authorities, such as those in Britain, strongly endorsed agricultural biotechnology. While other scientists warned about possible effects of introducing foreign genetic material into plants, U.K. government scientists gave consumers assurances about GM crop safety, which reminded some European about the government's promises about BSE. Perhaps because of this timing, many consumers in the U.K. and across Europe seemed to question or reject the new foods.

This failure in the regulatory system, which then spread throughout Europe, combined with later food and agricultural crises (such as dioxin-tainted meat in Belgium and foot-and-mouth disease outbreaks all over Europe) further demonstrated to consumers the government's inability to safeguard the food supply -- likely further contributing to consumer skepticism.

At the same time, the environmental movement experienced success in pushing the GMO issue to the forefront of political debate in Europe and the issue was quickly brought into governmental policy circles, aided in part by the representation of the Green Party in a number of European parliaments and cabinets.

The historical and cultural context in which Europeans view food and biotechnology helps to explain the growing distrust of food-safety regulators and laws. Historically, Europeans seem to have a deeper cultural connection to their food than do Americans, for example. "The French connection -- between food and pleasure -- has been shaken in the last handful of years by mad cow disease, by diseased Belgian chickens, and now by growing anxiety about genetically modified foods, a sticking point in trade negotiations between the United States and the European Union," wrote columnist Ellen Goodman (*Boston Globe*, April 18, 2002).

Biotechnology, especially taking genes from one species and putting them into another, is seen by some as “unnatural” or unethical. For example, Britain’s Prince Charles has stated that the development of genetically-altered foods “takes mankind into realms that belong to God, and to God alone.”

To many Europeans, GM foods are not perceived to have any direct consumer benefits since the GM crops produced to date are resistant to pesticides but have no added nutritional value or improved taste. “Until now, in a context of food surplus, GM food has no added value, so why take the risk, the EU consumer is asking,” said Tony Van der haegen, Minister-Counselor for Agriculture, Fisheries and Consumer Affairs of the EC.

III. THE EUROPEAN APPROACH TO THE GM FOOD ISSUE: THE EC PROPOSAL

The European Commission’s Labeling and Traceability Proposal

The **European Commission** [link to http://europa.eu.int/comm/role_en.htm] (which is made up of 20 individuals drawn up from the 15 member states and acts as the executive branch of the European Union. The Commission unveiled its proposals concerning GM foods on July 25, 2001. The two legislative bodies of the EU—the Council of the European Union and the European Parliament— will review and amend the proposals prior to voting on them, a process that takes approximately 18 months. Commission officials anticipate that the regulations could go into effect in 2002 or 2003.

No new GM crops have been approved for use in the EU since October 1998. To address consumer concerns over the safety of GM food and help resume the approval process for new products, the European Commission had proposed two pieces of legislation; if passed into law, they would:

- Require documentation to trace the presence of GM foods through each step of the production and distribution chains (the "traceability requirement") – i.e. the ability to trace a product through the various distribution channels food travels from farm to processor to manufacturer to store
- Introduce mandatory labeling of GM animal feed;
- Extend the current labeling rules on GM food by requiring labeling of all food derived from GM crops or seeds, whether or not there is any DNA or protein of GM origin in the final product; and
- Establish a more streamlined, centralized authorization procedure for GM crops and GM food ingredients and their release in the environment and in the marketplace.

The laws on GM food labeling currently in place in the EU are based on the ability to measure differences in the composition of foods free of GM ingredients from those that contain GM ingredients (in other words, it is based on the ability to detect DNA or protein of GM origin). This means that a product like vegetable oil made from a GM crop, which is refined and processed to the point that it is indistinguishable from oil from non-GM crops, does not need to be labeled. In addition, if small amounts (less than 1

percent) of GM ingredients are unintentionally present in the final food, the product also does not have to be labeled. This one percent is known as the “threshold” amount.

Under these EC-proposed rules, all foods would require documentation demonstrating whether they contained ingredients derived from GM or non-GM crops, even if the presence of GM-derived material could not be detected in the final form. The accidental presence (up to 1 percent) of GM material in food would continue to be exempted from the labeling obligation. The new regulations also impose for the first time labeling requirements for GM animal feed along the same principles as for GM food.

The original EC proposal does not, however, require labeling of products such as meat, milk or eggs obtained from animals fed GM feed or treated with GM medicinal products. Products such as cheese or beer, which are often produced with the aid of GM enzymes, also do not need to be labeled. The rationale for this distinction, according to Tony Van der haegen, Minister-Counselor for Agriculture, Fisheries and Consumer Affairs, Delegation of the European Commission to the United States, is that these products are produced with GM processing aids (enzymes and bacteria that are genetically modified to aid in fermentation) that are not present in the final product.

However, on June 4, 2002, proposals favored by the Green party, which are stricter than the ones originally proposed by the Commission, were voted on in the Parliament’s Environment Committee, passing by a narrow margin. This version of the regulation requires mandatory labeling for eggs, meat and milk if the animal from which those food products were derived had been fed any GM products – a more stringent version than the original proposal. In addition, the current version of the proposal, which is likely to be amended as it winds its way through the EC, sets the threshold at which mandatory labeling would kick in at 0.5 percent, instead of the original one percent proposed by the Commission.

The revised, stricter proposal coming out of the Environment Committee, which passed quite narrowly, should only be considered the first step. Next, the European Parliament will take up the Committee’s measure later this summer. After that, the draft must be reviewed by all 15 European Union governments as well as the European Commission again, which has already objected to many of the amendments passed on June 4, 2002. From there, it goes to a second reading in the parliament for final passage.

Please change the title to read: Labeling of Food and GM Feed As Proposed by the European Commission in July 2001

Labeling of GM food and GM feed

| GM product type | Example | Labeling required at present | Labeling required if new regulations are adopted |
|------------------------------------------------|-----------------------------------------------------------------------|------------------------------|--------------------------------------------------|
| GM plant | Chicory | Yes | Yes |
| GM seed | Corn seeds | Yes | Yes |
| GM food | Corn, Soybean sprouts, tomato | Yes | Yes |
| Food produced from plant or seed | Corn flour* | Yes | Yes |
| | Refined corn oil, Soybean oil, Rape seed oil** | No | Yes |
| | Glucose syrup produced from corn starch** | No | Yes |
| Food from animals fed on GM feed | Eggs, Meat, Milk | No | No |
| Food produced with the help of a GM enzyme | Bakery products produced with the help of amylase | No | No |
| Food additive produced from GM plant or seed | Highly filtered lecithin extracted from GM soybeans used in chocolate | No | Yes |
| Animal GM feed | Corn | Yes | Yes |
| Animal feed produced from a GM plant or seed | Corn gluten feed, Soybean meal | No | Yes |
| Feed additive produced from a GM plant or seed | Vitamin B2 (riboflavin) | No | Yes |

*DNA or protein of GM origin detectable in final product.

**DNA or protein of GM origin not detectable in final product.

Source: European Commission

Lifting the De-Facto Moratorium on New GM Crops

The Commission's proposal combines the labeling and traceability requirements, which the U.S. objects to, with a lifting of the de-facto moratorium on new GM crop approvals, which the U.S. supports. A European Union official said recently that the EU would restart its approval process for genetically modified crops on Oct. 17, 2002, according to Reuters. This date would likely be just prior to the implementation of the labeling and traceability requirement.

Thus, part of the proposal concerns the regulatory procedures for approving new GM crops and seeds. Currently the responsibility for assessing and authorizing GM crops and foods containing GM ingredients is divided among EU member states and the European Commission. Under the proposed regulations, a "one door-one key" procedure would be

established. All scientific risk assessment would be carried out by a single agency—the European Food Safety Authority—which would also be responsible for communicating risks to the public. The regulation for the establishment of the Authority was formally adopted by the EU Parliament on January 28, 2002 and the Authority is expected to be operating by the end of the year.

The EC's Rationale: Labeling and Traceability Will Increase Consumer Confidence

According to the European Commission, more extensive labeling information is meant to help restore consumer confidence in the food regulatory system and to provide consumers with greater choice about what they eat. The objectives for requiring traceability of GM products are to facilitate the withdrawal of a product in the event of an unforeseen risk to human health or the environment, to aid in the monitoring for potential health or environmental effects, and to control and verify labeling claims. The Commission hopes that these measures will help lift the de facto moratorium on approvals of new GM foods.

In a statement following the release of the guidelines, EU Environment Commissioner Margot Wallström said, “Certainly, there is a cost for the producers and for trade, but what is at stake is our ability to build public confidence.” She also said that the need for the rules could be attributed to the “concerned and very confused public opinion.” Tony Van der haegen, Minister-Counselor for Agriculture, Fisheries and Consumer Affairs of the EC, said at a Pew Initiative on Food and Biotechnology debate on this topic: “Unless we restore EU consumer confidence in this new technology, genetic modification of food is dead in Europe. The Commission’s July labeling and traceability proposal is intended to be a first step to increase that confidence. . . . Although genetically modified foods may even be safer than conventional products, our consumers are nevertheless demanding that we in government protect their ‘right to know’ the content and origin of the food they consume.” (Pew Initiative on Food and Biotechnology policy dialogue “Are the U.S. and Europe Headed for a Food Fight Over GM Foods?”, October 2001. See <http://pewagbiotech.org/events/1024/> for more information.)

U.S. Reaction to the EU Proposal: Costly and Unworkable

U.S. biotechnology industry representatives and government officials dismiss the EC’s claims about the need for the new regulations. Instead, they regard the EC proposal as costly, unworkable, unnecessary and discriminatory against U.S. agricultural products.

David Hegwood, Trade Advisor to U.S. Department of Agriculture Secretary Ann Veneman, said recently, “We continue to express serious concerns about the EC’s July 25th proposal for traceability and mandatory process-based labeling. We believe the EU proposal would disrupt international trade without serving any legitimate food safety or environmental safety objectives.” In July 2001, Alan Larson, the US Undersecretary of State for Economic, Business and Agricultural Affairs stated that the regulations would “effectively block \$4 billion of U.S. exports to Europe and would undermine, not reinforce efforts to restore public confidence.”

In addition, U.S. and industry officials have expressed the concern that if the new legislation is not challenged, other countries, especially those in the developing world, may use the EU regulatory framework as the basis for their own regulations on agricultural biotechnology products, resulting in even wider-scale disruptions of U.S. trade.

If the EU adopts the its proposed regulatory measures, the resulting disruptions on U.S. trade could lead to the loss of billions of dollars (*AgBiotech Reporter*, May 2001). The estimated loss in U.S. exports was determined by 24 U.S. trade organizations, including the American Soybean Association, and the Grocers and Manufacturers Association, who wrote a letter to the USDA secretary urging the USDA to contact the European Commission and EU member state governments to express objection to the proposed EU guidelines.

To comply with the proposed labeling and traceability regulations, U.S. farmers and food producers would have to segregate GM crops and foods derived from such crops at every step of the crop harvesting and food processing processes — a requirement that experts say would undermine the efficiency and competitiveness of existing production systems.

In addition to being costly, the proposed regulations are seen as very difficult to implement, according to U.S. farmers. Many foods could not avoid the labeling requirements that would be triggered by the one percent threshold proposed by the European Commission or the 0.5 percent as the proposal now stands) for the presence of GM ingredients, according to U.S. officials, meaning that U.S. exporters could face the possibility that their products would not be bought by EU food manufacturers. Difficulty in accurately labeling all GM food products also creates enormous liability and risk for U.S. exporters. Even if different varieties of crops are kept separate, some unintentional mixing of GM grains with non-GM grains is likely to occur. For example, pollen drift is a natural occurrence that can lead to the unintended presence of GM material in non-GM crops. Beyond keeping GM and non-GM plots separate, farmers would have to prevent commingling during harvest, transport and storage by cleaning all equipment and on-farm storage facilities. Using current testing methods, which are sensitive enough to detect very small amounts of GM material, it would be difficult to clean equipment thoroughly enough to meet the very strict one percent EU standards required to avoid the GM label.

One of the ways in which the proposed regulations are viewed as discriminatory by the U.S. is that they would not require labeling of products like beer and cheese (major European agricultural exports) that are made using enzymes produced with biotechnology. On the other hand, a product like soybean oil would have to be labeled if it comes from soybeans that were a GM variety — even though one cannot detect or test for the presence of a GM ingredient any more than one can detect the GM enzymes used to produce many beers and cheeses.

U.S. producers argue that there is no scientific basis to presuppose that GM food products are more risky or substantially different from other products and that decisions to label foods should be based on science, not politics. Furthermore, labels that identify foods as

derived from biotechnology are likely to be seen by consumers as "warning labels," which would decrease the demand for these products.

The regulations are expected to be further debated in the European Parliament this summer. If agreed upon, they go into effect by 2003 (although it is possible that they will be adopted in a revised form). Once adopted, the labeling provisions for both food and feed will be reviewed after two years of operation.

If the GM regulations are enforced by the EC, the U.S. has indicated that it might bring the EC to the World Trade Organization's dispute settlement mechanism, arguing that the regulations are not in line with WTO agreements. If a member does not comply with WTO recommendations then trade sanctions may follow.

(For more information about the issues at the center of the debate over E.U. regulations, see the summary of the Pew Initiative event "Are the U.S. and Europe Heading for a Food Fight Over Genetically Modified Crops?" [**link to <http://pewagbiotech.org/events/1024/>**]).

This fact sheet was produced by the Pew Initiative on Food and Biotechnology, a nonprofit, nonpartisan research project whose goal is to inform the public and policymakers on issues about genetically modified food and agricultural biotechnology, including its importance, as well as concerns about it and its regulation. It is funded by a grant from the Pew Charitable Trusts to the University of Richmond. The information presented in this fact sheet was obtained from the United States Department of Agriculture Foreign Agricultural Service (<http://www.fas.usda.gov>), the United States Department of Agriculture Economic Research Service (<http://www.ers.usda.gov>), and the United States Department of State (<http://usinfo.state.gov/>).

Sidebar: The Trade Dispute Process

If the EU labeling and traceability requirements are enacted, in whatever form they finally take, they could create many issues for U.S. producers as outlined in this fact sheet. U.S. officials are therefore urging EU member governments to question whatever form the proposed regulations come to them in. In addition, the U.S. has argued that the new regulations violate the international agreements of the World Trade Organization and have threatened to lodge a formal complaint. There are public relations ramifications to a WTO complaint for the U.S., as several high-ranking Europeans have pointed out: if the U.S. lodges the complaint and wins, the European governments can tell their constituents that American multinationals are forcing GM foods down their throats. On the other hand, if the U.S. loses, the Europeans will be vindicated.

A number of entities within the U.S. represent U.S. interests in organizations responsible for regulating international trade. Some of the agencies, primarily those within the U.S. Department of Agriculture (USDA) [**link to <http://www.usda.gov>**], the Food and Drug Administration (FDA) [**link to <http://www.fda.gov>**], and the Environmental Protection

Agency (EPA) [[link to http://www.epa.gov](http://www.epa.gov)], play a role in agricultural trade negotiations because of their regulatory expertise in plant and animal health, food safety, or environmental protection. Other agencies, such as the Office of the U.S. Trade Representatives (USTR) [[link to http://www.ustr.gov](http://www.ustr.gov)], USDA's Foreign Agricultural Service (USDA/FAS) [[link to http://www.fas.usda.gov](http://www.fas.usda.gov)], and the U.S. Department of State [[link to http://usinfo.state.gov](http://usinfo.state.gov)] are involved because of their responsibilities for trade, export facilitation, or diplomatic negotiations.

The main international body that regulates trade is the World Trade Organization (WTO) [[link to http://www.wto.org](http://www.wto.org)]. A number of agreements of the WTO provide guidelines for developing regulations and labeling. The USTR represents U.S. interests at WTO meetings.

The Codex Alimentarius Commission [[link to http://www.codexalimentarius.net](http://www.codexalimentarius.net)], an entity established by the World Health Organization (WHO) [[link to http://www.who.org](http://www.who.org)] and the Food and Agriculture Organization (FAO) [[link to http://www.fao.org](http://www.fao.org)] of the United Nations, is in the process of developing international guidelines for countries that choose to establish mandatory labeling of food and food ingredients obtained through biotechnology. On March 4-8, 2002 the Codex Intergovernmental Task Force on Foods Derived From Biotechnology adopted two standards for foods derived from biotechnology—namely principles for risk analysis and guidelines for conducting safety assessments. (Both "traceability" and food labeling were named as risk management tools.) The standards will now be submitted to the next meeting of the Commission in July 2003 in Rome, Italy, where countries will make further comments. The Commission will then adopt the standards or send them back to the Task Force for further debate. Both the USDA and FDA lead U.S. delegations to Codex committees.

The United Nations Convention on Biological Diversity [[link to http://www.biodiv.org](http://www.biodiv.org)] developed an environmental agreement covering the trans-shipment and use of living modified organisms (LMOs). The Biosafety Protocol [[link to http://www.biodiv.org/biosafety](http://www.biodiv.org/biosafety)] takes effect upon ratification by 50 countries; so far 11 have ratified. The U.S. Department of State represents U.S. interests at Biosafety Protocol negotiations. However, since the U.S. is not party to the United Nations Convention on Biological Diversity, U.S. participation is limited.

Appendix: Timeline of events relevant to EU-U.S. agricultural biotechnology trade issues

1996

Crop varieties developed by biotechnology are first introduced for commercial production in the U.S.

1996 -- March 20

Scientific evidence reveals a link between some cases of a variant form of a brain wasting disease in humans and consumption of meat from cows with bovine spongiform

encephalitis (BSE or “mad cow disease”). The British government downplays the link and argues that meat is safe to eat.

1997 -- May 15

The EU adopts the “Novel Foods Regulation,” which requires that the person responsible for placing a novel food, including any food containing or produced from GM crops, on the market shall submit a request to the member state in which the product will first be marketed. Applications are examined by relevant authorities in that member states who then decide either to allow the product on the market or refer the application to the European Commission. In either case, the other member states have an opportunity to make their views known. The regulation also provides for special labeling of foods containing GM ingredients, provided that the GM content can be detected. The Novel Food Regulation included several exemptions for products that did not need to be labeled. It also did not define a standard for the percentage of a product that could contain GM ingredients before it had to carry the GM label.

1997 -- September 19

EU regulation provides for labeling of foods processed from certain *Bacillus thuringiensis* (Bt) corn, or corn that has been genetically engineered to produce its own insecticide, and herbicide-tolerant soybeans. These products were already on the market when the May 1997 novel foods labeling directive went into effect.

1998 -- October

Approval of new agricultural biotechnology products in the EU comes to a halt.

1999 -- December

The Ministerial Conference of the World Trade Organization (WTO) in Seattle is disrupted by demonstrations by people concerned about continued globalization of trade, as well as issues of agriculture and trade in GM foods. The U.S. and Canada propose a working group on biotechnology.

2000 -- January 11

The European Commission publishes a regulation providing a 1 percent labeling threshold for food for accidental commingling of corn and soy made by modern biotechnology. It is expected that the threshold will be adopted as the basis for labeling other foods containing ingredients made from biotechnology.

2000 -- January 29

The Cartagena Protocol on Biosafety, aimed at providing a framework for assessing the environmental impact of bioengineered products that cross international borders, is adopted by more than 130 countries. It must be ratified by 50 countries before it goes into effect. The scope of the protocol does not cover food safety.

2000 -- March

First meeting of the Codex Ad Hoc Task Force on Biotechnology in Japan.

2000 -- April

The Food Standards Agency (FSA) is created in the EU to "protect public health from risks which may arise in connection with the consumption of food, and otherwise to protect the interests of consumers in relation to food." This includes responsibility for issues relating to GM foods.

2000 -- September

StarLink corn—a GM corn variety approved only for animal consumption—is found in taco shells sold in the U.S.

2001 – January 17

The U.S. Food and Drug Administration (FDA) issued a proposed rule and a "Guidance for Industry" document for labeling GM products. The proposed rule would require food developers to notify FDA at least four months before putting a new GM food on the market, and the scientific description of the product is posted on the Internet during this time. The guidance on labeling was meant for manufacturers who wish to voluntarily label their foods as being made with or without the use of GM ingredients.

2001 -- June

At the G-8 Economic Summit in Italy, the U.S.-EU Summit includes a special session of World Trade Organization (WTO) agriculture negotiations.

2001 -- July 25

The European Commission proposes labeling and traceability legislation.

2002 – June 4

The Environment Committee of the European Parliament narrowly voted to require all food products derived from biotech ingredients be labeled -- even if no remnants of the genetic modification (DNA) are detectable in the final product on the shelves. In addition, the Committee approved a measure to lower the threshold at which mandatory labeling would be required, lowering it from one percent in the original EC proposal to 0.5% per ingredient.

2002- July (expected)

The Environment Committee's version of the measure will be taken up by the European Parliament plenary. From there, it will go back to the Commission and EU governments, and then back to the Parliament for final approval.

2002 -- Summer

Mid-term report of the Codex Ad Hoc Task Force on Biotechnology is due.

2002

The European Food Safety Authority will become operational and will be responsible for risk assessment and risk communication with the public.