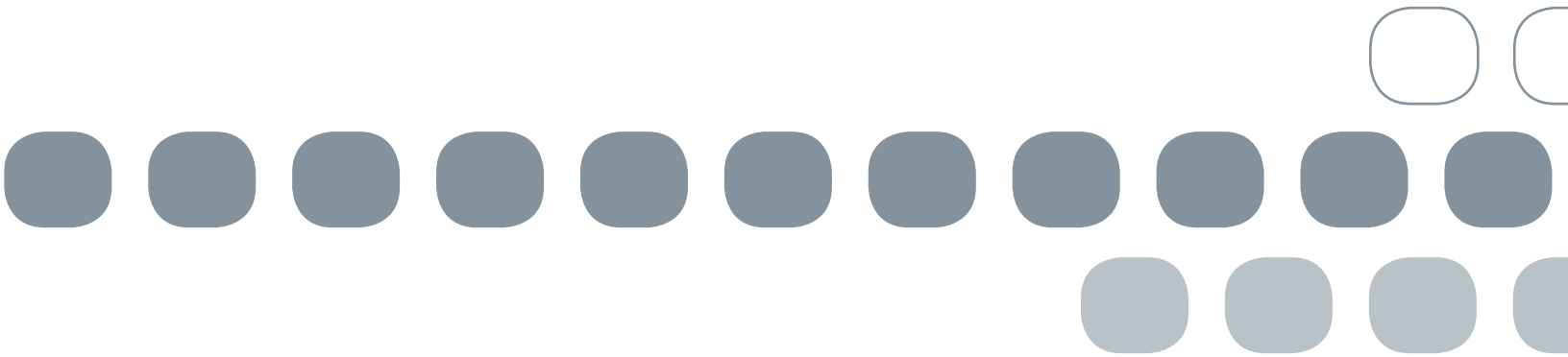
U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food

Pew Initiative on Food and Biotechnology · DECEMBER 2005



This issue brief, originally published in June 2002, was first updated in August 2003 to reflect recent activities relating to the trade dispute between the U.S. and the European Union (EU) on genetically modified food. This edition represents the third update.

The Pew Initiative on Food and Biotechnology is 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.

Table of Contents

U.S. vs. EU:

I. INTRODUCTION & SUMMARY

Over the last ten years, U.S. farmers have planted millions of acres of genetically-modified varieties of corn, cotton, and soybeans. In 2004, about 45% of the corn, 85% of soybeans, and 76% of cotton planted in the U.S. were genetically modified varieties.[1] Since much of the corn and soybeans harvested each year are processed into products like corn oil and lecithin, it is not surprising that an estimated 75% of processed food sold in the United States contains ingredients derived from genetically modified (GM) crops.

In the United States, the introduction of GM foods—foods derived from GM crops or containing ingredients derived from GM crops—has not elicited strong public concern or widespread opposition. Indeed, most Americans are unaware of the extent to which genetically modified foods have been introduced into the marketplace.[2]

Europe, however, is a different matter. With public confidence in food safety shaken by a series of food scares unrelated to GM foods, including a serious outbreak of mad cow disease or bovine spongiform encephalopathy (BSE), European consumers are wary about GM foods. European Union (EU) member states grow few GM crops, and very few (if any) foods carrying the required GM label appear to be available for sale in the EU marketplace. Faced with popular opposition to GM foods and a concern about an inadequate regulatory system, the European Commission failed to approve any new GM foods or crops between 1998 and 2004, despite general scientific consensus that they posed no food safety or environmental risks. In 2004, new EU laws went into effect providing for the approval of GM crops, as well as GM food and feed, and establishing new requirements for labeling and traceability. Since then, the Commission has moved through a lengthy process to approve several GM crops and food and feeds derived from GM crops. In June 2005, however, a

1 See PIFB, Genetically Modified Crops in the United States (http://pewagbiotech.org/resources/factsheets/display.php3?FactsheetID=2)

2 See PIFB, Public Sentiment about Genetically Modified Food Update November 2004 http://pewagbiotech.org/research/2004update/

qualified majority of the Council of Ministers refused to lift certain EU member state bans on GM products that had been approved by the Commission, creating new doubts about the viability of an EU-wide policy on GM crops, food and feed.

Export markets remain a critical source of revenue for U.S. farmers. EU opposition to GM food has harmed U.S. exports, particularly corn shipments which typically include GM varieties not approved by the EU. Charging that the EU failure to approve GM crops during the *de facto* moratorium of 1988 to 2004 was without a scientific basis and therefore inconsistent with the Agreement on the Application of Sanitary and Phytosanitary Measures, the U.S. initiated an unfair trade practices complaint in the World Trade Organization (WTO) in May 2003. A preliminary decision from the trade dispute panel is expected in January 2006.

In addition, the U.S. reportedly has been considering a second WTO complaint that would challenge the new EU requirements for traceability and labeling. These measures have also been attacked by U.S. officials and agricultural industry representatives as unnecessary and unworkable, while EU officials have defended them as non-discriminatory and necessary to rebuild consumer confidence in the EU food safety regulatory system and in GM foods generally.

This issue brief provides an overview of the history of the dispute between the U.S. and the EU over GM foods and crops, the impacts of the dispute on U.S. trade, and a summary of current EU regulations and its approval process. The Appendices provide additional background on other on-going international negotiations that may also affect trade in GM crops, as well as information about the evolving structure of EU governance.

II. BACKGROUND: U.S.–EU TRADE

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 recent accession in 2004 of 10 new member states[3] into the EU increases the importance of the EU both as an export market, a global economic competitor, and as a source of imported goods and services. (For general information on the EU and its institutions see *Appendix E: Backgrounder on the EU.*)

The EU is the fourth largest market for U.S. agricultural exports. According to U.S. Department of Agriculture (USDA), agricultural exports from the U.S. to the EU are projected at $7 billion for 2005, nearly 12% of all U.S. agricultural exports. The main export products are soybeans, tobacco, and animal feed, including corn gluten. (For more detail see *Appendix B: Details on U.S. Agricultural Trade with the EU 1998–2004.*)

The U.S. also is a major importer of EU agricultural and horticultural products, including cheese, oils, wine and beer. USDA projects 2005 agricultural imports from the EU to the U.S. at $13 billion.

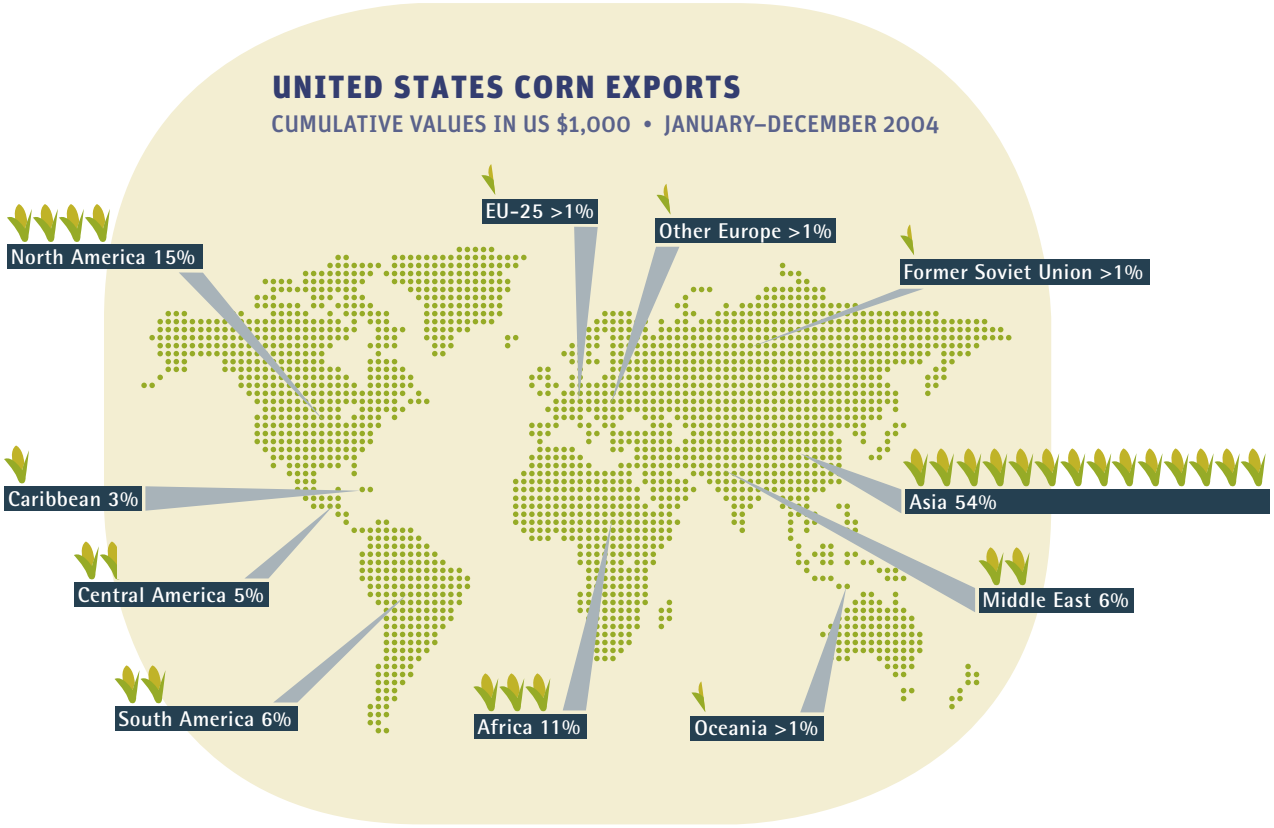
Exports are a critical source of revenue for U.S. producers of commodity crops. In 2002, according to USDA estimates, exports of crops accounted for over one-quarter of the total value of U.S. crop production. In terms of volume and farm income, the most important field crops grown in the U.S. are corn, cotton, and soybeans. 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, such as high fructose corn syrup.

Prior to 1997, corn exports to Europe represented about 4% of total U.S. corn exports, generating about $300 million in sales. Starting in 1997, however, the U.S. largely stopped shipping bulk commodity corn to the EU because such shipments typically commingled corn from many farms, including genetically modified varieties not approved by the EU. The change was dramatic. For example, before 1997, the U.S. sold about 1.75 million tons of corn annually to Spain and Portugal, the two largest importers of U.S. corn in the EU. But in the 1998–99 crop year, Spain bought less than a tenth of the previous year's amount and Portugal bought none at

3 The ten new member states are: Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia.

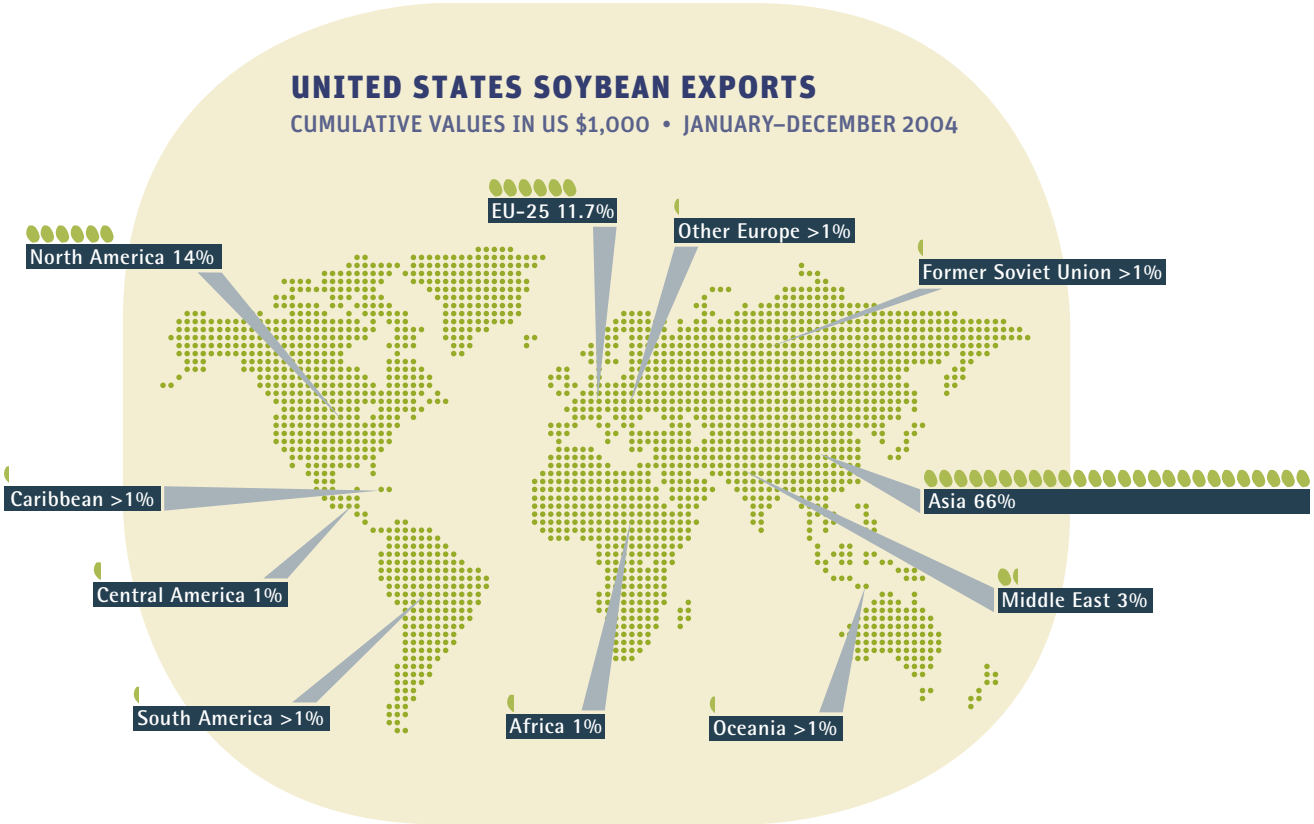
all. By 2004, the EU share of the total corn export market had fallen to less than 0.1 percent. (See *Appendix B: Details on U.S. Agriculture Trade with the EU 1998–2004 and figure below.*)

Some commodity crop exports have not been affected directly by the ban on some GM varieties. For example, Europe remains the most important U.S. export market for corn byproducts, such as the corn gluten used in animal feed, accounting for more than 54 percent of total exports in 2004. The trade of corn byproducts thus far has not been affected by EU regulations on GM products.[4]



4 In March, 2005, Syngenta announced that it had inadvertently distributed small amounts of an unauthorized GM corn (Bt10) over a 4-year period. U.S. regulatory authorities stated that the unauthorized GM corn posed no safety risk because it contained the same GM protein that was in BT11, a GM variety approved both in the U.S. and in Europe for food. However, the Bt10 variety also included an antibiotic resistance marker gene which, while unlikely to create a food safety problem, had not been approved in the EU. As a result, the Commission temporarily suspended shipments of corn imports, including corn gluten, until the development of a test protocol to determine the presence of Bt10. As of May 2005, testing was available and corn shipments resumed.

Similarly, GM soybean exports to the EU have not been affected by the *de facto* moratorium. The EU had approved one variety of GM soybean prior to 1998. Because the EU market accounts for a significant proportion (11.7% in 2004) 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. While U.S. soybean exports to the EU have fallen (from 9.8 million tons in 1995 to 3.6 million tons in 2004), the decline is more likely due to increased competition from lower-cost agricultural producers such as Brazil, whose exports have risen from 3.0 million tons in 1995 to 8.9 million tons in 2002.[5]



5 USDA Economic Research Service, "Briefing Room: Soybeans and Oil Crops: Trade" www.ers.usda.gov/briefing/soybeansoilcrops/trade.htm.

III. THE EUROPEAN EXPERIENCE WITH GM FOODS

A. European Attitudes toward GM Crops and Foods

In 1996, then U.S. Agriculture Secretary Dan Glickman got an early glimpse of the unfolding controversy over GM foods in Europe when protesters at the World Food Summit in Rome pelted him with grain, calling for a ban on GM crops. (For a timeline of critical events, see *Appendix D: Timeline of events relevant to U.S.–EU agricultural biotechnology trade issues*.)

European attitudes toward GM crops and food have been shaped by a variety of factors, including the experience of a major food safety crisis (mad cow disease), the lack of confidence in food regulators, different cultural attitudes toward food and farms, widespread media coverage of the issue, and activism by politically influential environmental, consumer and anti-globalization groups.

European public opinion surveys show strong opposition to GM crops and foods. An EU-wide study in 2002 found that while attitudes varied among nations, majorities in most EU countries rejected GM foods, which were seen as "risky" and "not useful" for society.[6] In the different EU countries, between 30% and 65% percent rejected all the reasons for buying GM foods. Countries with the highest percentage of those rejecting GM foods were Greece, Ireland and France, and those with the lowest percentage rejecting GM foods were the UK, Austria and Finland. While the 2002 Eurobarometer poll also suggests that opposition to GM crops and foods had waned in recent years, significant majorities in most countries continued to oppose them. More recently, a 2005 Eurobarometer poll showed that safety concerns about GM food persist in Europe, although opinion again differs by nation as well as other demographic factors.[7] Over two-thirds of those polled in Austria, Cyprus, and Greece agreed with the statement that foods made from GMOs were "dangerous", but even in more supportive countries such as the Netherlands and the United Kingdom, nearly one-third agreed with that statement.

6 Eurobarometer 58.0 Europeans and Biotechnology in 2002. http://europa.eu.int/comm/public_opinion/archives/ebs/ebs_177_en.pdf

7 Special Eurobarometer 224, "Europeans, Science & Technology", 2005. http://Europa.eu.int/comm/public_opinion/archives/ebs/ebs_224_report_en.pdf

B. Food Safety Crises

Negative public opinion about GM crops and foods is largely the product of several widely-publicized food safety scares in the mid-1990s that have made European consumers extremely wary of changes to the food supply and distrustful of government regulatory agencies. Although these crises were not caused by GM food, GM food has been caught up in the general concern about food safety.

The most significant of these food crises was "mad cow disease," or bovine spongiform encephalopathy (BSE), which was discovered in the U.K. in the 1990s before being found in other countries. BSE is an infectious degenerative brain disease in cows. It is believed that the infectious agent was introduced to cows in the U.K. through feed that contained parts of sheep brains that were infected with scrapie. (The infectious mechanism of BSE is still not entirely understood.)

Originally, food safety authorities in the U.K. asserted that BSE posed no food safety threat to humans, and that it could not be transmitted to human beings if they ate meat from infected animals. In 1996, however, scientists discovered a link between some cases of a fatal degenerative brain disease in humans (called Creutzfeldt–Jacob disease, or CJD) and consumption of meat from cows infected with BSE. Initially, government officials dismissed the research and minimized the link between BSE and its human form. But later, British officials were forced to recognize the link and take drastic steps to protect human and animal health, including the destruction of 4.5 million cattle to prevent the spread of the disease. Despite these measures, the government was harshly criticized for acting too late and not effectively communicating risks to the public.

The impact on the beef market—and on public opinion—was dramatic. The British beef market was crippled. Throughout Europe, fears about CJD and pictures of thousands of sick cattle being incinerated dominated news, particularly when BSE was discovered in other European countries.

Public concern was escalated by early estimates that suggested as many as 100,000 people would die from CJD in the UK. While those estimates are now believed to be far too high, there remains significant uncertainty about the eventual toll BSE will have on human health. As of 2005, 149 deaths in the UK have been caused by CJD.[8]

8 Data from CJD surveillance program at the University of Edinburgh, http://www.cjd.ed.ac.uk

Combined with several later highly publicized food and agricultural crises, including dioxin-tainted meat in Belgium and foot-and-mouth disease outbreaks all over Europe, the BSE debacle dramatically eroded trust in government food safety regulators. In the 2002 Eurobarometer poll, only 14 percent of Europeans polled said that they trusted national governmental bodies to "tell the truth" about biotechnology.

GM crops began to be introduced to the European market in 1996, the same year when the BSE crisis began unfolding. Governmental and scientific authorities, particularly in Britain, strongly endorsed the safety of agricultural biotechnology. To many, these assurances were all too reminiscent of those given for BSE-infected meat. The European press extensively covered environmental and consumer groups and scientific critics who warned about unknown food safety and environmental risks of GM crops and foods. The concerns quickly caught the attention of wary European consumers who trusted NGOs more than the government. In the 2002 Eurobarometer public opinion survey, the two institutions most likely to be trusted to "tell the truth" about biotechnology, after medical doctors (54%), were consumer organizations (49%) and environmental organizations (46%).

C. Cultural attitudes and other issues

Concerns about food safety are not the only factor influencing European public opinion about GM crops and foods. Historically, Europeans seem to have a deeper cultural connection to their food than do most Americans. Most European countries have cuisines based on traditional foods connected with regional and even local production practices. Supermarkets have not entirely replaced the local, specialized food producers—bakers, butchers, and neighborhood produce stands. In contrast, most urban American consumers have little connection with the food production process, and most products are marketed and shipped nationwide, often with an emphasis on novelty, consistency and convenience.

In addition to these cultural differences, the European public appears to be more sympathetic than Americans to the perception that biotechnology is unnatural or even unethical. Britain's Prince Charles reflected some of this concern when he stated that the development of genetically modified foods "takes mankind into realms that belong to God, and to God alone."

Europeans are also skeptical about the value of GM crops and foods for European consumers and farmers. To many Europeans, GM crops produced to date may be

valuable to U.S. farmers and multinational seed companies, but have no direct consumer benefit, such as added nutritional value or improved taste.[9]

D. European Regulation of GM Crops and Foods Prior to 1998

Prior to 1998, the EU had adopted two sets of EU-wide laws relating to GMOs and GM food and feed. The first, Directive 90/220/EC, adopted in 1990, established a process for the assessment and approval of all GM organisms (including GM crops and seeds) before they were deliberately released into the environment, such as for field trials or commercial cultivation. Before the outbreak of the BSE crisis and the ensuing controversy over food safety, a number of GM crops were approved under Directive 90/220/EC, some for restricted uses. Prior to 1998, fourteen GM plants, including 11 crops, had been approved for some form of release. (See *Appendix F: Status of GMOs in the EU.*) An additional thirteen applications for approval had received favorable opinions from the Scientific Committee on Plants and were pending authorization in 1998.

A second set of laws, Regulation (EC) No 258/1997, or the "Regulation on Novel Foods and Novel Food Ingredients" was adopted in 1997 and addressed GM food safety issues. The Novel Foods regulation required the labeling of novel food products containing or consisting of genetically modified ingredients, or which had been produced from GMOs. Regulation 258/97/EC also created a more simplified approval procedure for food products that are "derived from GMOs" but do not contain GMOs, such as highly refined soy oil or corn syrup. A food "derived from GMOs" could be brought to the market as long as the developer had a scientific basis for determining that the product was "substantially equivalent" to existing foods, notified the Commission, and delivered an opinion to the same effect from competent authorities of a Member State. Under the Novel Food regulation, a number of products derived from GM crops, including oils and products that use oils, entered into the EU market. (See *Appendix F: Status of GMOs in the EU.*)

9 Comments of Tony Van der haegan, Minister-Counselor for Agriculture, Fisheries, and Consumer Affairs of the European Commission, PIFB, *Are the U.S. and EU Headed for a Food Fight over Genetically Modified Food?,* Policy Forum at the National Press Club, October 24, 2001 (http://pewagbiotech.org/events/1024/).

IV. THE DE FACTO MORATORIUM ON GMOS

A. EU–wide approval process falls apart

These EU-level efforts in the 1990s were an attempt to develop a uniform EU-wide policy for approvals and trade in GM crops and foods, which was growing increasingly controversial in a number of member states in the mid and late 1990s. Widespread media coverage of anti-GM activists helped move the issue of GM foods quickly to the forefront of political debate in Europe. Increased representation of the Green Party in member state parliaments and cabinets, as well as in the European Parliament, ensured that these concerns would be reflected in national and European politics. Almost overnight, GMOs became politically unpopular and politicians found it difficult to approve GM crops and foods despite scientific reviews that failed to raise safety concerns. (For details on the EU regulatory system and legislative process see *Appendix E: Backgrounder on the EU.*)

By 1997, the effort to craft a uniform EU-wide policy on GMOs was coming apart. Despite EU approvals for commercialization of several GM crops under Directive 90/220/EEC, a number of member states invoked a "safeguard clause" to ban the use of the approved GM crops in their respective countries. (The "safeguard clause" is discussed below.) In 1997, Austria and Luxembourg banned several EU-approved GM crops. Over the next several years, additional bans on EU-approved crops followed in Austria, Italy, Greece and Germany. While the Commission could have taken legal action to force compliance, it chose not to do so at that time.

In 1998, a number of EU member states, led by France, vowed to block approval of GM crops unless existing labeling and safety regulations were further tightened. As a result, no new GM foods or crops were approved beginning in 1998 through 2004, constituting a *de facto* moratorium on GMO approvals while the EU was working to develop new EU-wide legislation more acceptable to the member states.

B. The U.S. Responds with a WTO trade complaint

U.S. farm organizations, biotechnology companies, and other companies in the food production and processing chain, strongly objected to the EU *de facto* moratorium,

as well as its failure to take action against some member states that banned GM crops that had been approved by the Commission. Objections were also strongly voiced by U.S. government officials in both the Clinton and Bush administrations. U.S. officials argued that the *de facto* moratorium and the EU's failure to enforce its own trade rules violated free trade agreements, particularly the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), and the Agreement on Technical Barriers to Trade (TBT). Under those agreements, U.S. officials argued, the EU cannot raise barriers to trade in crops and food for safety concerns without a scientific basis, which the U.S. believed was entirely lacking.

EU officials responded that a delay was necessary while they were developing new legislation for GM food and feed approvals that would be more acceptable to member states and that the approval process would start up when new legislation was in place.

In May 2003, the U.S., along with Canada and Argentina, launched a formal complaint using the World Trade Organization's dispute settlement mechanism, arguing that the *de facto* moratorium was not in compliance with WTO agreements. Under WTO rules, if a member does not comply with WTO recommendations, then trade sanctions may follow. A preliminary decision by the Dispute Settlement Body has been expected several times. It is now expected in January 2006. (For details on the dispute process see *Appendix C: The WTO Trade Dispute Process*.)

Some have questioned the ultimate effect of the trade complaint, noting that the action is likely to generate additional hostility to GM foods in Europe and that the EU has begun approving new GM foods under new laws adopted in 2003, discussed below.[10] However, U.S. farm and industry officials have strongly expressed the view that the EU *de facto* moratorium is an illegal restraint on trade because it is a violation of the EU's own trade rules and procedures. In addition, they believe that GM crops and foods are as safe as conventional foods and that there is no scientific basis for health or safety restrictions. This sentiment was echoed by the Canadian trade representatives in their June 2004 argument in the first round of arbitration that [the EU] ``has maintained its moratorium even in the face of the uncontroverted opinions of its own scientists that there is sufficient evidence to reach conclusions about the safety of these products.''[11]

10 PIFB, *Should the U.S. Press A WTO Case Against Europe's Genetically Modified Food Policies?*, Policy Forum at the National Press Club, February 2003 policy dialogue, http://pewagbiotech.org/events/0213

11 "U.S., Canada, Ask WTO to Force Open EU's Biotech Seed Market", Bloomberg. June 4, 2004

U.S. officials also believe that a challenge is necessary to discourage other countries, especially those in the developing world, from using the EU regulatory approach as the basis for their own regulations on agricultural biotechnology products, which could result in even wider-scale disruptions of U.S. trade. President Bush is concerned that stringent EU restrictions have led to the refusal of several south African nations to accept U.S. food aid that included GM corn, further exacerbating famine, a charge that EU officials vehemently reject.

V. EU ADOPTS NEW LEGISLATION ON GMOS

A. New EU Legislation

In 2003, the EU approved new legislation governing approval of GM food and feed for commercialization and requiring labeling and traceability. It went into effect in April 2004. The EU legislation expanded the existing labeling requirements significantly and also required "traceability"—the ability to track a GM product from the farm through all of the distribution, processing, and manufacturing steps to the final consumer product. The legislation also established a more streamlined, centralized authorization procedure for GM crops and GM food ingredients and their release in the environment and in the marketplace.

LABELING. Under Regulation (EC) 1830/2003, all food and feed consisting of GMOs or produced from GMOs are required to be labeled. Products required to be labeled, must state that "This product contains genetically modified organisms" or that it has been "produced from genetically modified (name of organism)." For the first time, refined products, like soy oil or high fructose corn syrup, are required to be labeled, even in the absence of any detectable amounts of GM DNA or proteins because they are "produced from" GMOs. The accidental and unavoidable presence (up to 0.9%) of GM material in food is exempted from the labeling obligation. The regulations also require animal feed to be labeled along the same principles as for GM food, but do not 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 enzymes produced by GM microorganisms, also do not need to be labeled. According to Commission officials, this distinction was made to be consistent with existing EU law that does not require labeling of any enzyme used as a processing aid.

According to the European Commission, more extensive labeling information is meant to help restore consumer confidence in the food regulatory system, to provide consumers with greater choice about what they eat, and build consumer confidence in GM products.

TRACEABILITY. The EU legislation also requires businesses that grow, store, transport, or process GM products to track them throughout the commercial food chain, from "farm to fork." Under these rules, industry must ensure that systems are in place to

identify to whom and from whom GM products are made available and to retain records for five years. All foods require documentation demonstrating whether they contained ingredients derived from GM crops, even if the presence of GM-derived material can not be detected in the final product.

According to the European Commission, 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.

APPROVAL. Regulation (EC) 1829/2003 establishes a "one door–one key" procedure for GM food and feed by which a developer may file a single application for all intended uses of the GMO—cultivation, importation, and processing. An application first goes to a member state where the product is requested to be marketed. A scientific risk assessment is then carried out by a single agency—the European Food Safety Authority (EFSA). Following the risk assessment by the EFSA, the Commission drafts a proposal for granting or denying the authorization; if it disagrees with the EFSA opinion, it must justify its position.

The Commission's draft proposal is submitted for approval by a qualified majority of the member states within the Committee on the Food Chain and Animal Health. If the Committee approves it, the Commission then adopts the decision. If not, the draft decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council fails to act, or fails to muster a qualified majority to accept or reject the proposal, the Commission then adopts the decision. (For a discussion of the "qualified majority vote", see *Appendix E: Backgrounder on the EU.*)

According to the European Commission, the risk assessment and approval process is intended to streamline the approval process and to pave the way for the approval of new GM crops stalled under the former regulatory approach.

B. Experience under the new EU system

LABELING. The EU's new laws went into effect in April 2004. More than a year later, few, if any, consumer products in the EU market appear to be labeled as containing GMOs. Fearing negative consumer reaction from GM-labeled foods, food manufacturers have reportedly "reformulated" products with non-GM ingredients to avoid labeling. For example, a manufacturer could substitute sugar syrup made from

sugar cane or sugar beets, which are not genetically modified, for the corn syrup that comes from GM corn; alternatively, the manufacturer could source ingredients from non-GM sources. Further, some EU retailers appear to be wary about consumer reaction (and possible activist protests) from stocking GMO-labeled foods.

APPROVALS. In May 2004, the Commission approved its first GM food under the new regulations and the first since 1998. The Commission approved the import of Syngenta's GM canned sweet corn, under the labeling and traceability provisions of the new regulations. A few months later, in July 2004, the Commission also approved a Monsanto GM Roundup Ready maize variety (NK 603) for human and animal consumption, but not for planting. In August 2005, the Commission approved the import of Monsanto GM maize MON863 for animal feed, but not for cultivation or food use.

In each of these cases, the Commission acted to approve the applications after the Council failed to approve or reject the Commission's proposed action by a qualified majority vote.

APPLICATIONS. When Directive 2001/18/EC took effect, some of the pending applications from under the previous directive, Directive 90/220/EEC were withdrawn, while others were resubmitted, and other new applications were submitted for authorization. As of March 2005, twenty-four applications had been submitted for approval under Directive 2001/18/EC. These applications included eight varieties of maize, five varieties of oilseed rape, five varieties of cotton, three varieties of beets, one variety of potato, one variety of rice, and one variety of soybean.

MEMBER STATE RESISTANCE. Despite the new EU legislation, GMOs remain unpopular in many parts of Europe and national politicians have acted to assert independence and autonomy over GM crops and foods. Five countries (Austria, France, Germany, Greece, Luxembourg) are currently blocking the use of five GMO varieties that had been previously approved by the Commission (three modified maize varieties and two types of oilseed rape) by invoking the "safeguard clause."[12] The "safeguard

12 Austria, France, Germany, Greece, Luxembourg, and the UK initially invoked the "safeguard" clause that had previously appeared in the now-repealed Directive 90/220/EEC. In 2003, the Commission requested those states to reconsider their invocation in light of the new regulatory framework and if necessary to resubmit them under the safeguard clause now found in article 23 of Directive 2001/18/EEC. In 2004, Greece and Austria submitted further information in support of their bans but no response was received from the other member states. In July 2004, EFSA concluded that the additional information did not invalidate the original risk assessment. In January, 2005, Hungary also invoked the safeguard clause to ban the planting of MON810, a Bt corn variety; the Commission is currently examining the case.

clause" provides that a Member State may provisionally restrict or prohibit the use or sale of an approved GMO if there is "new or additional information…or scientific knowledge" that gives it "detailed grounds" that the GMO "constitutes a risk to human health or the environment." The Commission and the EFSA reviewed the information provided by the member states to justify their bans, and in April 2005, the Commission called on those five nations to lift their national bans.

In June 2005, however, the Commission recommendation to force the lifting of the national bans was rejected by a qualified majority of the Council, leaving the national bans in place. The rejection "raises a host of questions", according to a Commission statement. "The Commission will have to carefully consider the legal and scientific bases that underpin any further proposals, as well as the implications for EU internal market and trading partners." The Council's decision leaves in doubt the ability of the Commission to create a uniform approval process through the EU, despite the new legislation.

In addition, politicians in Ireland, Wales, Austria, parts of France, and the Scottish Highlands have all petitioned their respective governments to create GM free zones, and to institute local bans on the cultivation of GM crops. In October, 2005, the EU's second-highest court ruled that Austria's ban of a GM crop was unlawful.

In the wake of these member state actions driven by popular opposition and politically powerful activist groups, the Commission clearly is continuing to struggle to implement a consistent and enforceable EU-wide policy on GM crops and food. The Commission faces the task of trying to manage the conflict between autonomous member states where GMOs are highly unpopular with the authority of the EU system. Uncertainty has also been compounded by recent changes in the Commission membership.[13]

In addition to assessments and approvals for GMOs, another GM crop-related issue generating debate within the EU is the potential liability of GM crop growers or seed companies for the accidental "contamination" of non-GM crops. In the past, the EU has indicated that rules for "coexistence" should be left to the member states, but more recently there has been interest in adopting EU-wide policies.

13 New Commissioners were appointed to the European Commission in 2004 and will serve 5-year terms.

C. U.S. Reaction to new EU regulations on GMOs

U.S. government officials, farm groups, biotechnology companies, and food processors and manufacturers have expressed deep concern over the impacts of the new EU labeling and traceability requirements. They regard the EU rules as costly, unworkable, unenforceable, unnecessary and discriminatory against U.S. agricultural products. The Administration is reportedly considering filing a second WTO complaint against the new labeling and traceability requirements. U.S. farm groups and others are pushing for the U.S. to initiate such a challenge. The American Farm Bureau Federation has said that the labeling and traceability rules are "just as inconsistent with the WTO agreement on technical barriers to trade and sanitary and phytosanitary measures as the moratorium itself is."

U.S. farmers, food manufacturers and food and grain exporters have been working to comply with the EU regulations since they became effective in April 2004. In some instances, as noted above, foods with GMO ingredients have been reformulated to avoid the labeling requirement. Developing traceability and product identification systems to ensure compliance with EU labeling, threshold, and traceability requirements has been challenging. The U.S. commodity grain system routinely mixes GM varieties in with conventional varieties of corn and soybeans. To avoid the EU threshold for labeling, U.S. farmers and food producers need to segregate GM crops and foods derived from such crops at every step of the production process—a costly requirement. Meeting the EU threshold of no more than 0.9 percent GM content is also difficult to achieve and equally difficult to test with consistency, creating uncertainty about liability despite efforts to comply.

Although total costs of compliance are not available, such efforts have undoubtedly been costly for U.S. industry. Nevertheless, bulk commodity grain traders and others involved in the grain processing and distribution channel appear to be meeting the EU requirements.

These requirements apply to food and feed that are intended to be marketed as non-GM. However, unlike food, there is still active demand for GM feed in the EU. While GM feed itself must be labeled, meat, milk and eggs derived from animals fed with GM feed are not required to be labeled. As a result, some U.S. exports, such as soy and corn gluten intended for feed uses, do not need to be segregated since there continues to be an active EU market for GM-labeled feed. (Feed intended to be marketed as GM-free would, of course, need to be segregated.)

The Bush Administration believes that the EU labeling regime is both unnecessary and discriminatory. The U.S. argues that there is no scientific basis to treat GM food and feed any differently from food or feed produced through conventional breeding and that labeling and segregation requirements are based on politics, not science. Furthermore, labels that identify foods as derived from biotechnology are likely to be seen by consumers as "warning labels," which would be misleading and decrease the demand for these products. U.S. officials point out that the EU rules do not require labeling of products like beer and cheese (major European agricultural exports) that are made using enzymes produced with biotechnology, while soy oil derived from GM soybeans would have to be labeled even if no GM protein could be detected.

SOURCES

Office of the United States Trade Representative

United States Department of Agriculture

Foreign Agriculture Service

European Commission

Congressional Research Service report, RS21556, "Agricultural Biotechnology: The U.S.-EU Dispute" updated March 16, 2004.

APPENDIX A

The International Regulation of Biotechnology and Its Trade

The main international body that regulates trade is the World Trade Organization (WTO). The U.S. Trade Representative (USTR) represents U.S. interests at WTO meetings. Ambassador Allen Johnson of the USTR's office oversees negotiations for the U.S. at the WTO on agricultural trade. World trade rules are currently governed by the last round of negotiations between WTO members, which took place in Uruguay in 1994. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures and Agreement on Technical Barriers to Trade and the Trade Dispute Process are the mechanisms used for the resolution of issues on agricultural biotechnology products. Negotiations currently taking place under the Doha Development Agenda will most likely also address biotechnology and agriculture.

A number of entities within the United States government 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), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), 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), USDA's Foreign Agricultural Service (USDA/FAS) and the U.S. Department of State are involved because of their responsibilities for trade, export facilitation, or diplomatic negotiations.

The Codex Alimentarius Commission, an entity established by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) 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. In July 2003, the Commission adopted new proposed standards regarding risk analysis and guidelines for conducting safety risk assessments for foods derived from biotechnology. Both traceability and food labeling were named as risk management tools.

The United Nations Convention on Biological Diversity[14] developed an environmental agreement, the Cartagena Biosafety Protocol,[15] covering the trans-shipment and

14 The text of the United Nations Convention on Biodiversity may be found at http://www.biodiv.org .

15 The text of the Cartagena Biosafety Protocol may be found at http://www.biodiv.org/biosafety.

use of living modified organisms (LMOs). The Biosafety Protocol became effective in September 2003. 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.

The Organization for Economic Cooperation and Development, to which the United States and the European Union are parties, may also address agricultural biotechnology trade issues in the context of international harmonization of biotechnology regulations. OECD attempts to foster free trade and market economies through the development of consensus documents, information, and outreach.

APPENDIX B

Details on U.S. Agricultural Trade with the EU 1998–2004

CHART 1: U.S. AGRICULTURAL EXPORTS TO THE EU–25 BY THE VALUE IN US DOLLARS

	1998	1999	2000	2001	2002	2003	2004	Total % change from 2003–2004	Total % change from 1998–2004
Total US Agricultural Exports to the EU	8,205,259	6,832,014	6,483,054	6,630,571	6,338,013	6,659,443	6,810,903	2%	-17%
Soybeans	1,534,416	1,032,870	1,154,675	1,159,355	1,168,350	1,113,840	863,121	-22%	- 43%
Cotton	115,697	51,388	75,563	56,452	71,526	87,650	94,458	8%	- 18%
Maize	36,768	15,053	28,822	12,897	15,141	10,034	8,945	-11%	- 75%

CHART 2: U.S AGRICULTURAL EXPORTS TO THE EU-25 BY VOLUME IN METRIC TONS

	1998 (in 1,000 metric tons)	1999 (in 1,000 metric tons)	2000 (in 1,000 metric tons)	2001 (in 1,000 metric tons)	2002 (in 1,000 metric tons)	2003 (in 1,000 metric tons)	2004 (in 1,000 metric tons)	Total % change from 2003–2004	Total % change from 1998–2004
Total US Agricultural Exports to the EU	19,565,335.5	18,076,661.9	17,972,788.6	17,694,366.7	16,330,373.2	14,093,206.1	12,540,160.4	-11%	- 36%
Soybeans	6,447,288.0	5,393,468.0	6,167,160.0	6,443,726.0	5,981,741.0	4,346,492	3,676,785.0	-15%	-43%
Cotton	69,622.0	31,270	42,089	33,138.4	59,425.9	62,428.5	68,227.9	9%	- 2%
Maize	331,337.0	164,714	317,300.0	140,189.0	153,939.0	93,541.0	80,384.0	-14%	-75%

CHART 3: U.S. AGRICULTURAL EXPORTS TO THE EU–25 BY PERCENTAGE OF TOTAL U.S. AGRICULTURAL EXPORTS WORLDWIDE

	Percentage of Total US Agri. Exports 1998	1999	2000	2001	2002	2003	2004
Total US Agricultural Exports to the EU	14%	11%	11%	11%	10%	11%	11%
Soybeans	32%	23%	23%	22%	22%	14%	14%
Cotton	4%	4%	3%	2%	3%	2%	2%
Maize	4%	1%	0.1%	0.1%	>0.1%	>0.1%	0.1%

APPENDIX C

The WTO Trade Dispute Process

THE WTO DISPUTE SETTLEMENT PROCESS

In the first stage of the WTO dispute process, the aggrieved nations file a formal complaint to the WTO and then enter into consultations with the accused nation (or party to the WTO), that is believed to have violated WTO rules.[16] The consultation phase may take up to 60 days to complete, and is intended to provide an opportunity for the parties to come to agreement without further action.

After 60 days are up, or before if no conclusion has or can be been reached by the parties during negotiation, the WTO forms a three person panel called a Dispute Settlement Body (DSB) within 45 days of the request for the empanelment by the parties to the suit. This panel will hear arguments from the parties to the suit over a period of 6–9 months, with 9 months being the maximum time allowed. The DSB panelists will adjudicate the dispute, giving both a confidential Interim and Final Report to the parties, and then distribute the Final Report and their conclusion to the WTO Members. At the end of 60 days from the public issuance of the Final Report to the WTO Members, the DSB will adopt the report as final.

If either of the parties disagrees with the decision of the DSB, they may file an appeal. The WTO Appellate Body is composed of permanent members and issues a second opinion on the DSB report within 90 days. There is no appeal from this decision. If there is an appeal, the DSB will adopt the decision of the Appellate Body.

The next stage of the dispute resolution process is the implementation of the ruling. The losing party to the suit should remove the illegal measure immediately, but if it is impractical to do so, the party is given a "reasonable period of time" either mutually agreed upon by the parties, or determined through binding arbitration. The illegal measure must, in all cases, be removed within 15 months of the decision.

If the losing party does not act in compliance with the decision of the dispute resolution process, other countries may withdraw trade concessions and impose retaliatory tariffs under the authorization of a DSB. The possibility of retaliation may also be arbitrated through the DSB. If there is disagreement on the implementation of the

16 Submissions to the WTO are available on the WTO website, http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm.

conclusion, the parties resort to the original DSB panel, which will examine the consistency of the implementation of the measures. If the panel finds the losing party has indeed conformed the process is completed. If they find that the losing party has not implemented the measure in full, retaliatory tariffs and withdrawal trade concession may take place as described above.

THE TRADE DISPUTE OVER GMOS

The U.S. trade representatives to the WTO filed a formal complaint against the EU with the WTO in May 2003. The suit filed by the U.S. is co-supported by Argentina and Canada,[17] and has third party support from nine other nations.

The consultation in this suit took place in Geneva beginning on June 19th, 2003 and quickly broke down. The delegation from the United States found no chance for settlement by negotiation. As soon as the consultation ended, the U.S. delegation requested that a Dispute Settlement Body (DSB) be empanelled.

A Dispute Settlement Body was established and the U.S. and other parties have filed briefs on the various issues. By joint request of the parties, the various deadlines have been extended in order to give the parties additional times to identify and select experts, to prepare additional submissions to the Body, and to consider scientific opinion. The chairman of the dispute settlement Body has indicated that the interim confidential report is expected in the first week of January 2006.

SOURCES FOR APPENDIX C

Office of the United States Trade Representative

World Trade Organization

European Union

17 The suit was originally also supported by Egypt, who withdrew from the complaint on May 30, 2003.

APPENDIX D

Timeline of events relevant to U.S.–EU agricultural biotechnology trade issues

1990–APRIL

The EU adopts Directive 90/220/EC, which establishes a process for the approval of agricultural biotechnology products.

1994–1998

The EU authorizes the commercial use of nine GM products and plants.

1995–MAY

The U.S. approves the first commercially significant biotech soybean, Monsanto's "Round-up Ready."

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–FEBRUARY

Austria bans Novartis Bt176, a GM maize that has already been approved for use in the EU. The Commission does not challenge the action. Luxembourg also bans an EU-approved maize variety.

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. Relevant authorities in that member state then decide either to allow the product on the market or to 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

France bans two EU-approved rapeseed varieties; Greece bans one EU-approved rapeseed variety.

1998–OCTOBER

Approval of new agricultural biotechnology products in the EU comes to a halt. The EU Commission tells the U.S. that they will begin to approve products again if the companies submitting applications agree to follow newly proposed revisions before they become law. Despite applicant compliance, the EU approval processes does not resume.

1999

Austria bans two more EU-approved maize varieties.

1999–JUNE

EU members call for a moratorium on new approvals of GM products. The EU Environmental Council says traceability and labeling must be linked with a new approval process. Ministers from Denmark, France, Greece, Italy, and Luxembourg declare a refusal to approve new products until new rules are in place.

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

Italy bans four EU-approved maize varieties; Germany bans one EU-approved maize variety.

2000–JANUARY 11

The European Commission publishes a regulation providing a one 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

More than 130 countries adopt the Cartagena Protocol on Biosafety, aimed at providing a framework for assessing the environmental impact of bioengineered products that cross international borders. Fifty countries must ratify it before it goes into effect. The scope of the protocol does not cover food safety.

2000–MARCH

The Codex Ad Hoc Task Force on Foods Derived from Biotechnology has its first meeting in Japan.

2000–APRIL

The European Food Standards Agency (EFSA) is created in the EU to "protect public heath 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–JUNE

French Environmental Minister Dominique Voynet, speaking for the five states who voted for a moratorium on GMOs, insists on the inclusion of a liability scheme for biotechnology products.

2000–JULY

EU Environmental Ministers meet informally and decide to support the moratorium at least until the Commission prepares labeling and traceability proposals for biotech products. The Commission tells the U.S. that it will complete the proposals by the end of the year so that the approval process could start up again.

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) issues 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 legislation amending Directive 2001/18/EC on labeling and traceability and assures the U.S. that the moratorium will be lifted within weeks.

2001–OCTOBER

At an informal meeting of the Environmental Ministers Council, France, Austria, Finland, Luxembourg, Denmark, Italy, the Netherlands, and Sweden all reject the Commission's plan to restart the GMO approval process, and declare the new regulations must be in force before the process should be allowed to operate.

2002

The European Food Safety Authority becomes operational.

2002–MARCH 21

The Economic and Social Committee issues its opinion on the Commission's 2001 proposal on labeling and traceability.

2002–MAY 16

The Committee of the Regions issues its opinion on the Commission's 2001 proposal on labeling and traceability.

2002–JUNE 3

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 percent per ingredient.

2002–AUGUST 27

The European Union ratifies the Cartagena Protocol on Biosafety.

2002–SUMMER

Mid-term report of the Codex Ad Hoc Task Force on Foods Derived From Biotechnology is made to the Codex Executive Committee.

2002–SEPTEMBER 15

The European Commission resubmits a revised proposal to amend Directive 2001/18/EC based on the amendments requested by the Parliament's first reading in June 2002.

2002–OCTOBER 17

Directive 2001/18/EC is implemented and Directive 90/220/EEC is repealed. This implementation requires that the 15 member states have all implemented national legislation that adopt Directive 2001/18/EC, and have notified the Commission of their action. Twelve of the 15 member states fail to meet this deadline, continuing to ban new GM products.

2002–DECEMBER

The Council of Ministers on the Environment agrees to a common position on traceability and labeling. The Danish delegation declares the moratorium should remain in place until the EU has developed and implemented liability legislation for biotech products.

2003–MARCH 11–14

The Codex Ad Hoc Task Force on Foods Derived From Biotechnology meets in Yokohama, Japan.

2003–MARCH 17

The EU Council of Ministers concludes a Common Position on the Commission's September 2002 amendments to its 2001 proposal. The Common Position is forwarded to the European Parliament.

2003–APRIL 10

The European Commission formally requests action to be taken in France, Luxembourg, Belgium, Netherlands, Germany, Italy, Ireland, Greece, Spain, Portugal, and Austria to adopt and notify the Commission of national legislation that implemented Directive 2001/18/EC.

2003–MAY 15

The U.S. files a complaint to the WTO to dispute the EU moratorium on GM imports.

2003–MAY 20

The United States' President Bush accuses the EU of impeding the fight against famine in Africa, calling the ban on GM foods morally wrong and based on "unscientific fears." EU Commissioner on Trade Pascal Lamy answers back that the accusations are "unacceptable" and "should not be used in this kind of debate."

2003–JUNE 13

Palau becomes the 50th country to ratify the Cartagena Protocol on Biosafety, permitting it to enter into force in September 2003.

2003–JUNE 19

The United States and EU begin consultation in regards to the WTO suit brought by the U.S. The consultations break down shortly after they begin, and the U.S. delegation announces their intent to ask for the empanelment of a WTO Dispute Settlement Body.

2003–JUNE 30–JULY 7

The 26th Session of the Codex Alimentarius Commission, meets in Rome, Italy. The Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms from the Ad Hoc Committee on Foods Derived From Biotechnology is considered.

2003–JULY 2

The European Parliament passes the Commission's September version of the proposed amendments to Directive 2001/18/EC. The United States does not accept the action as "lifting the moratorium" and vows to continue its push for more favorable laws for its GM products.

2003–JULY 15

The European Commission refers Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands and Spain to the European Court of Justice for failing to adopt national legislation implementing Directive 2001/18/EC.

2003–JULY 22

The Council of Ministers approves the Commission's amendments to Directive 2001/18/EC on labeling and traceability.

2003–JULY 23

The European Commission publishes guidelines for the agricultural management of "co-existence" or growing GM crops along side non-GM crop varieties.

2004–APRIL 18

The labeling and traceability measures of 2001/18/EC and related legislation take effect in the EU market.

2004–MAY 19

The European Commission authorizes the marketing of canned sweet corn with the GM BT-11 trait for 10 years; this is the first GM authorization in the EU since 1998.

2004–MAY

Ten nations from eastern Europe are admitted into the European Union, bringing total membership to 25 countries.

2004–JULY

The European Commission authorizes the marketing (but not cultivation) of NK603, a Roundup Ready maize.

2005–JANUARY

Hungary invokes the "safeguard clause" to ban MON810 despite EC approval.

2005–FEBRUARY

Commission announces that it will sponsor a broad debate on biotechnology with the purpose to clarify the position of the EU-25 on matters related to the deadlock on GMO, the WTO case filed against the EU for its moratorium on new GMO imports, and the issues relating to "coexistence".

2005–APRIL

Commission temporarily suspends import of corn and corn products, including corn gluten, after Syngenta announces that small quantities of an unapproved GM variety of maize (Bt10) had inadvertently been released into commercial distribution channels over a four-year period.

2005–APRIL

EC tells Austria, France, Germany, Greece, and Luxembourg that their invocation of the "safeguard" clause to ban approved GMOs is not legitimate and that the bans must be lifted, or they will face legal action by the Commission.

2005–JUNE

The Council rejects by a qualified majority the Commission's proposal to lift the bans or restrictions on authorized GMOs adopted by Austria, France, Germany, Greece and Luxembourg. This represents the first time the Council mustered a qualified majority either for or against a Commission proposal on GMOs.

2005–AUGUST

The Commission authorizes the import of GM maize MON 863 for use in animal feed (but not for cultivation of human food) following the failure of the Council to reach a position on the Commission's proposal in June.

2005–OCTOBER

The European Court of First Instance, the EU's second-highest court, rejected an appeal by Austria from the Commission's finding that its ban of an EU-approved food was illegal.

SOURCES FOR APPENDIX D

Office of the United States Trade Representative

The European Commission

Codex Alimentaarius Commission

APPENDIX E

Backgrounder on the EU

1. WHAT IS THE EUROPEAN UNION?

The European Union is a supranational institutional framework for the construction of a united Europe. It currently consists of 25 member states: Belgium, France, the Federal Republic of Germany, Greece, Italy, Luxembourg, the Netherlands, the United Kingdom, Ireland, Denmark, Spain, Portugal, Austria, Finland, Sweden, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia.

The EU has grown from much smaller efforts in the post-World War II period of European reconstruction to control economic markets in a small number of countries, to a political, social, and monetary union through a series of treaties to form the EU as it exists—and continues to evolve—today. The EU's beginnings lie in the formation of the European Coal and Steel Community (ECSC) by France, Germany, Italy, Belgium, the Netherlands, and Luxembourg in the 1951 Treaty of Paris. Six years later, the six ECSC members signed the Treaty of Rome, establishing the European Economic Community (EEC), and the European Atomic Energy Community (EURATOM). In 1973, the United Kingdom, Ireland, and Denmark joined the EEC.

A European Monetary System was established in 1979 to contain inflation and stabilize exchange rates in Europe. Greece became the tenth member of the EEC in 1981 and Spain and Portugal acceded in 1986. Also in 1986, the member states signed the Single European Act (SEA), which laid the foundations for a single market by favoring national regulatory rules. The Treaty on European Union (TEU), also called the Maastricht Treaty, was signed in 1991, and set an ambitious plan for the 12 member states to enter monetary union and eventually come to a single currency, and to establish a common foreign and security policy. The accession of three more countries, Austria, Finland, and Sweden, occurred in 1995. The Treaty of Amsterdam in 1997 complemented the TEU on the policies of employment and foreign policy. In 1999, Economic and Monetary Union as sought under the TEU became a reality, and in 2002, 12 of the member states adopted a common currency, the Euro.

The framework of the EU was last modified under the Treaty of Nice, which took effect on February 1, 2003. The Treaty of Nice, among other changes, ratifies the European Commission recommendation that candidate countries Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia to join the EU. These states joined the EU in May 2004.

2. DETAILS ON THE EU REGULATORY SYSTEM

The political and regulatory system of the EU functions through a number of smaller institutions in which both the national interests of the member states and the political interests of the greater Europe are represented. These institutions are the European Commission, the Council of Ministers, and the European Parliament.

THE COMMISSION. The European Commission based in Brussels, Belgium, currently consists of 25 members, all of whom give up national citizenship to become representatives and proponents of the needs of the greater goal of a unified Europe acting independently of national governments. The Commissioners are appointed by common agreement among the member states and are approved as a body by the European Parliament to serve five-year terms. The current Commission was appointed in 2004 and will serve until 2009.

Each Commissioner holds a portfolio or area of expertise in which they propose policies and legislation. The Commission is responsible for administration of EU policies and international trade, and ensures that the provisions of the Treaties and the decisions of the institutions are properly implemented. The Commission is also the initiator of proposals for legislation.

THE COUNCIL. The Council of Ministers is composed of ministers representing the national governments of the 25 member states. It, along with the European Parliament, is the main decision-making institution and final legislative authority of the EU. The Council performs this role by enacting legislation binding throughout EU territory and directing intergovernmental cooperation. Depending on the agenda of a Council meeting, the ministers attending may be different. (For example a meeting of the ministers to consider legislation on wages would consist of the ministers on labor, a meeting to consider legislation on agricultural biotechnology and GM products would include the ministers on the environment.) The Presidency of the Council rotates among the

member states every six months. At the end of each Presidency there is a meeting of the European Council, which is composed of the Heads of State or Government of each of the member states.

The Council of Ministers enacts or rejects legislation by voting in one of two ways, unanimity, or qualified majority voting (QMV)(see description below). QMV is the most common method of decision-making in the Council of Ministers and is used in all but the most sensitive issues.

THE PARLIAMENT. The process of co-decision allows the European Parliament (EP) also to vote on issues that are decided on by the Council of Ministers by QMV. Parliament Members are directly elected by the populace of the EU for five-year terms. Members of Parliament represent political parties instead of national views. The EP is the public forum of the EU where issues of public importance are debated and questioning of the Commission and the Council takes place. The EP also holds the power to accept or reject most common legislation in the EU by the co-decision process introduced by the Treaty of Amsterdam in 1997.

3. THE LEGISLATIVE PROCESS

The legislative process is decided by the complex procedure of co-decision. First, the Commission proposes a legislative text to the EP for a first reading. The EP adopts a position on the proposed legislative text on the basis of a report by its relevant standing committee. Then, the EP usually suggests changes to the Commission proposal in the form of amendments. The EP then passes on its revised version of the proposed legislative text to the Council of Ministers. The Council either approves Parliament's amendments or modifies them by adopting a common position. If the Council approves the Parliament's amendments without any other modifications, the legislation is considered adopted and becomes law. If the Council does not adopt the EP's amendments and takes a common position, the Council passes the proposed legislative text back to the EP for a second reading. In the EP, the relevant standing committee gives a recommendation to the Parliament to approve, reject, or amend the Council's position.

At this point, the EP votes and can only approve, reject, or amend the legislation by an absolute majority (currently, 367 votes). The Commission then considers the EP's version from its second reading, and forwards an amended proposal to the Council. The Council may vote to adopt Parliament's amendments that have been accepted by the Commission by QMV or modify Parliament's amendments by unanimous vote.

If the Council can neither adopt the EP's second amendments by QMV, nor reject by unanimous vote, a conciliation committee is formed and meets for a maximum of six weeks. The conciliation committee consists of representatives from both the EP and the Council. Usually the EP and Council representatives reach an agreement. This agreement takes the form of a joint text. The EP then considers the joint text at a third reading and may accept or reject the proposed legislation. If the conciliation committee cannot reach agreement, the proposed legislation is considered dead.

4. THE CONSEQUENCE OF LEGISLATION

The political institutions work interdependently to create the laws of the EU. EU law takes precedence over the national laws of the EU member states under the principle of subsidiarity. In general, EU law is composed of three different kinds of legislation: primary legislation, secondary legislation, and case law. Primary legislation includes treaties and other agreements that have been agreed upon by direct negotiation between Member State governments. These treaties and their amendments are subject to ratification by the national parliaments of the member states and are binding as law in all member states. Secondary legislation is based on the treaties, meaning that the treaties make up the legal basis for the legislative action of the institutions in the EU regulatory system.

Secondary legislation is comprised of four different types of rules: regulations, directives, decisions, and recommendations/opinions. Regulations are directly applicable and binding in all EU member states without the need for any national implementing legislation. Directives bind member states as to the objectives to be achieved within a certain time-limit, but leave the form and means to be used to achieve those results up to the national governments. Decisions are binding in all their aspects for those to whom they are addressed including any or all member states, companies or individuals. Recommendations/opinions are not binding and simply express the opinion of the issuing body. Together with case law from the European Court of Justice (ECJ), these different types of legislation make up the "acquis communautaire" or body of laws to which EU member states and citizens must adhere.

If a Member State does not adhere to a binding law, such as a treaty, regulation or directive, the Commission may seek to force that Member State to comply through legal action in the European Court of Justice. The ECJ may issue sanctions or penalties against a non-complying party to a binding law.

5. QUALIFIED MAJORITY VOTING

Qualified Majority Voting (QMV) is the most common method for the Council of Ministers to make decisions on proposed legislation. Each Member State is assigned a certain number of votes. The number of votes each Member State receives are weighted depending on the size and population of that Member State. Under the Treaty of Nice, there are currently a total of 345 votes held by member states. A qualified majority of the current member states is a total of 255 votes as well as a majority of member states. In addition, the votes cast must represent 62 percent of the total population of Europe.

SOURCES FOR APPENDIX E

The European Commission

APPENDIX F

Status of GM Crops and Food in the EU

1. APPROVAL OF GM CROPS AND GM FOODS IN THE EU

Under various authorities, a number of GM crops and foods derived from GM crops have been approved for food use and marketing in the EU. (Table 1) Some, including a GM soy and GM maize variety, were approved for import and processing prior to 1998 under Directive 90/220/EEC. More recently, Bt11 sweet corn and NK603 maize were approved under the amended provisions of the Novel Food Regulation; NK603 maize and MON863 maize were also approved under Directive 2001/18. Finally, a number of processed foods derived from GM crops, such as canola, corn, and cottonseed, are authorized under the "substantially equivalent" notification provisions of Article 5 of the Novel Foods Regulation.

TABLE 1: GM FOODS AUTHORIZED IN THE EU UNDER THE NOVEL FOOD REGULATION

Event	Crop	Applicant	Trait	Potential Food Uses	Date	Legal Basis
GTS 40/3/2	Soybean	Monsanto	Insect protection and herbicide tolerance	Soy foods. Soy foods include soy beverages, tofu, soy oil, soy flour, lecithin.	03.04.1996	Dir. 90/220/EEC Art. 13
Bt 176	Maize	Ciba-Geigy	Insect protection and herbicide tolerance	Maize foods. Maize foods include kernels, oil, maize flour, sugar, syrup.	23.01.1997	Dir. 90/220/EEC Art. 13
TOPAS 19/2	Oilseed rape	AgrEvo	Herbicide tolerance	Rapeseed oil. Products made with rapeseed oil may include fried foods, baked products and snack foods.	24.06.1997	Reg. (EC) 258/97 Art. 5
MS1/RF2	Oilseed rape	Plant Genetic Systmes	Herbicide tolerance		24.06.1997	Reg. (EC) 258/97 Art. 5
MS1/RF2	Oilseed rape	Plant Genetic Systmes	Herbicide tolerance		24.06.1997	Reg. (EC) 258/97 Art. 5
GT 73	Oilseed rape	Monsanto	Herbicide tolerance		21.11.1997	Reg. (EC) 258/97 Art. 5
MON 810	Maize	Monsanto	Insect protection	Maize derivatives. These may include maize oil, maize flour, sugar and syrup. Prodcuts made with maize derivatives may include snack foods, baked foods, fried foods, confectionary and soft drinks.	06.02.1998	Reg. (EC) 258/97 Art. 5
T 25	Maize	AgrEvo	Herbicide tolerance		06.02.1998	Reg. (EC) 258/97 Art. 5
Bt 11	Maize	Novartis	Insect protection		06.02.1998	Reg. (EC) 258/97 Art. 5
MON 809	Maize	Pioneer	Insect protection		23.10.1998	Reg. (EC) 258/97 Art. 5

Event	Crop	Applicant	Trait	Potential Food Uses	Date	Legal Basis
Falcon GS 40/90	Oilseed rape	Hoechst/ AgrEvo	Herbicide tolerance	Rapeseed oil. Products made with rapeseed oil may include fried foods, baked foods and snack foods	08.11.1999	Reg. (EC) 258/97 Art. 5
Liberator L62	Oilseed rape	Hoechst/ AgrEvo	Herbicide tolerance		08.11.1999	Reg. (EC) 258/97 Art. 5
MS8/RF3	Oilseed rape	Plant Genetic Systems	Herbicide tolerance		26.04.2000	Reg. (EC) 258/97 Art. 5
1445	Cotton	Monsanto	Herbicide tolerance	Cottonseed oil. Products made with cottonseed oil may include fried foods, baked foods and snack foods.	19.12.2002	Reg. (EC) 258/97 Art. 5
531	Cotton	Monsanto	Insect protection		19.12.2002	Reg. (EC) 258/97 Art. 5
pRF69/ pRF93	Bacillus subtilis	F. Hoffmann– La Roche	Riboflavin	Vitamin B2	23.03.2000	Reg. (EC) 258/97 Art. 5
Bt11	Maize	Syngenta	Insect resis-tance	Bt11 Sweet maize	19.05.2004	Reg. (EC) 258/97 Art. 7
NK603	Maize	Monsanto	Herbicide tolerance	Food and food ingredients derived from NK603 maize	26.10.2004	Reg. (EC) 258/97 Art. 7

GM Plants Approved Prior to 1998 under Directive 90/220/EEC

Fourteen GM plants were approved for release or marketing under previous Directive 90/220/EEC prior to 1998. The approved plants under Directive 90/220/EEC included a number of crops: four (4) varieties of maize, four (4) varieties of oilseed rape, three (3) varieties of carnation, one (1) variety of chicory, one (1) variety of soybean and one (1) variety of tobacco. The GM crops were approved for different uses: some for cultivation, some for import and processing, some as food and feed. (See Table 2)

These approvals were grandfathered in the repeal of Directive 90/220/EEC and the enactment of Directive 2001/18/EC, and therefore the approvals are still effective.

Additionally, thirteen applications for approval under 90/220/EEC, had received favorable opinion of the Scientific Committee on Plants and were pending authorization at the time that the new Directive 2001/18/EC took effect. These applications included five varieties of maize/sweet maize, three varieties of oilseed rape, and two varieties of cotton, one variety of chicory, and one variety of potato. Some of these applications have been resubmitted for consideration under Directive 2001/18/EC (see below).

TABLE 2: GMO CROPS APPROVED UNDER DIRECTIVE 90/220/EEC

Product	Notifier	Date of Commission Decision Member State Consent
Tobacco tolerant to bromoxynil	SEITA C/F/93/08-02	6/8/1994
Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1) Uses : breeding activities	Plant Genetic Systems C/UK/94/M1/1	2/6/1996
Soybeans tolerant to glyphosate Uses : import and processing	Monsanto C/UK/94/M3/1	4/3/1996
Male sterile chicory tolerant to glufosinate ammonium Uses : breeding activities	Bejo-Zaden BV C/NL/94/25	5/20/1996
Bt-maize tolerant to glufosinate ammonium (Bt-176)	Ciba-Geigy C/F/94/11-03	1/23/1997
Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF1) Uses : import and processing	Plant Genetic Systems C/F/95/05/01/A	6/6/1997 (not finally approved by France)
Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2)	Plant Genetic Systems C/F/95/05/01/B	6/6/1997 (not finally approved by France)
Swede rape tolerant to glufosinate ammonium (Topas 19/2) Uses : import and processing	AgrEvo C/UK/95/M5/1	4/22/1998
Maize tolerant to glufosinate ammonium (T25)	AgrEvo C/F/95/12/07	4/22/1998
Maize expressing the Bt *cryIA(b)* gene (MON 810)	Monsanto C/F/95/12-02	4/22/1998
Maize tolerant to glufosinate ammonium and expressing the Bt *cryIA(b)* gene (Bt-11) Uses : import and processing	Novartis (formerly Northrup King) C/UK/96/M4/1	4/22/1998

Source: European Commission (dated 2-16-05)

Notifications of "Substantially Equivalent" Foods Pursuant to Article 5 of Novel Food Regulation (EC) 258/97

A number of food products "derived from" GM crops, such as cooking oils, were introduced into the EU market as "substantially equivalent" to conventionally-produced products under the Novel Food Regulation (EC) 258/97. Table 3 lists the notifications of "substantially equivalent" foods, including those derived from GMOs, that have been made pursuant to article 5 of EC 258/97.

TABLE 3: NOTIFICATIONS PURSUANT TO ARTICLE 5 OF REGULATION (EC) NO 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS AT JULY 2004

Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
AgrEvo UK Limited Chesterford Park Saffron Walden UK–Essex CB10 1XL	Processed oil from genetically modified canola seed, transformation event TOPAS 19/2 and all conventional crossed	"Report on oil from a genetically modified (GM) glufosinate ammonium tolerant oilseed rape" (ACNFP)[1]	9 June 1997	24 June 1997
Plant Genetic Systems N.V. Jozef Plateaustraat 22 B–9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i)male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF2Bn (B94-2) oilseed rape line and all conventional crosses; iii) hybrid combination MS1XRF2	"Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape" (ACNFP)[1]	10 June 1997	24 June 1997 again 28 July 1998
Plant Genetic Systems N.V. Jozef Plateaustraat 22 B–9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i)male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF1Bn (B93-101) oilseed rape line and all conventional crosses; iii) hybrid combination MS1XRF1	"Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape" (ACNFP)[1]; and "Report on oil from genetically modified oilseed rape" (ACNFP)[1]	10 June 1997	24 June 1997 again 28 July 1998
Monsanto Services International S.A. Avenue de Tervuren 270–272 B–1150 Brussels	Refined oil from glyphosate tolerant oilseed rape line GT73	"Report on oil from genetically modified (GM) glyphosate tolerant oilseed rape" (ACNFP)[1]	10 November 1997	21 November 1997
Monsanto Services International S.A. Avenue de Tervuren 270–272 B–1150 Brussels	Food and food ingredients produced from maize flour, maize gluten, maize smolina, maize starch, maize glucose, and maize oil derived from the progeny of maize line MON 810	"Report on processed products from genetically modifed (GM) insect protected maize" (ACNFP)[1]	10 December 1997	6 February 1998

Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
AgrEvo France S.A. Les Algorithmes Bâtiment Thalés Saint Aubin F–91197 Gif-sur-Yvette Cedex	i) Starch and all its derivatives; ii) crude and refined oil; iii) all heat-processed or fermented products obtained from hominys, grits and flour (dry milled fragments) obtained rom the genetically modified maize, tolerant to glufosinate ammonium, transformation event T25 and all the varieties derived from	"Report on processed products from genetically modified (GM) glufosinate ammonium tolerant maize" (ACNFP)[1]	12 January 1998	6 February 1998
Novartis Seeds AG Schwarzwaldallee 215 CH–4058 Basel	Food and food ingredient products derived from the original transformant Bt11 crossed with the Northrup King Company inbred line #2044 (maize), as well as from any inbred and hybrid lines derived from it and containing the introduced genes	ACNFP[1] Report on grain from maize genetically modifed for insect resistance	30 January 1998	6 February 1998
Pioneer Overseas Corporation Avenue Tedesco , 7 B–1160 Brussels	Novel foods and novel food ingredients produced from genetically modifed maize line MON 809	ACNFP[1] Report on genetically modified (GM) insect protected maize Pioneer Hi-bred Internationl - line MON 809	14 October 1998	23 October 1998
Hoechst Schering, AgrEvo GmbH Industriepark Hoechst AgrEvo-Haus K 607 D–65926 Fankfurt am Main	Processed oil from genetically modified oilseed rape derived from Falcon GS 40/90	BgVV[2] Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte Falcon GS/40/90 gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999
Hoechst Schering, AgrEvo GmbH Industriepark Hoechst AgrEvo-Haus K 607 D–65926 Fankfurt am Main	Processed oil from genetically modified oilseed rape derived from Liberator L62	BgVV[2] Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte Liberator pHoe6/Ac gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999
Plant Genetic Systems N.V. Jozef Plateaustraat 22 B–9000 Gent	Processed oil from genetically modified oilseed rape derived from: the male sterile MS8 (DBN 230-0028) oilseed rape line and all conventional crosses; the fertility restorer RF (DBN212-0005) oilseed rape line and all conventional crosses; the hybrid combination MS8 x RF3	BgVV[2] Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte MS8/RF3 gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999
F. Hoffman - La Roche Ltd. Vitamins & Fine Chemicals Regulatory Affairs Bldg 241/283 CH–4070 Basel	Riboflavin from *Bacillus subtilis* as nutrient	ACNFP[1] Report on Riboflavin from fermentation using genetically modified (GM) *Bacillus subtilis*	20 March 2000	26 April 2000

Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
Mr. jean-Pierre Clavié "Vidalou" F–47300 Pujols	"Huile d'amandon de pruneau"	AFSSA[3] Avis relatif à la mise sur le marché d'une "Huile vierge d'amandons de pruneaux	24 July 2000	4 August 2000
Ms. Catherine Drevet CD & A sarl 14 avenue de l'opera F–75001 Paris	Huile d'argan (*Argania spinosa* L.)	AFSSA[3] Avis relatif à l'évaluation de l'équivalence en substance de l'huile d'argan (*Argania spinosa* L.) avec d'autres huiles alimentaires	23 July 2002	26 August 2002
Dr. Bruno Tinland Monsanto Services International Avenue de Tervuren 270–272 B–1150 Brussels	Cottonseed oil from genetically modified cotton line 1445 (herbicide resistant)	ACNFP[1] Request for an Article 5 opinion on the substantial equivalence of cotton seed oil and food ingredients derived from Roundup® Ready cotton	24 July 2002	19 December 2002
Dr. Bruno Tinland Monsanto Services International Avenue de Tervuren 270–272 B–1150 Brussels	Cottonseed oil from genetically modified cotton line 531 (insect protected)	ACNFP[1] Request for an Article 5 opinion on the substantial equivalence of cotton seed oil and food ingredients derived from insect protected cotton	24 July 2002	19 December 2002
M Jean-Paul Braud Innovalg S.A.R.L. Centre d'Algoculture Polder du Dain F–85230 Bouin	Microalga *Odontella aurita*	AFSSA[3] Avis de l'Agence française de sécurité sanitaire des aliments relatif à la demande d'évaluation de la démonstration de l'équivalence en substance d'une microalgue *Odontella aurita* avec des algues autorisées	9 December 2002	19 December 2002
Herr Matthias Werner NCT Nord Trading GmbH Albert-Schweitzer–Str. 20 D–85375 Neufahr b. Freising	Juice of the fruits of *Morinda citrifolia*	BVL[4] Stellungnahme zur Feststellung der wesentlichen Gleichwertigkeit von Saft aus der Frucht der Spezies *Morinda citrifolia* L. der Firma NCT Trading GmbH mit dem als neuartige Lebensmittelzutat zugelassenen „Noni Saft"	10 November 2003	5 December 2003

Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
Drs. René van Lohuizen Will Co. B.V. Postbus 46 NL 1170 AA Badhoevedorp Dellaertlaan 24 NL 1171 HG Badhoevedorp	Juice of the fruits of *Morinda citrifolia*	See above NCT Nord Trading Confirmed by Ministerie van Volksgezondheid, Welzijn en Sport (NL)	22 June 2004	6 July 2004
Poul A Svane Svane Trading apS Rypevang 4 DK–3450 Allerod	Juice of the fruits of *Morinda citrifolia*	See above NCT Nord Trading Confirmed by BVL[4] for MfFLoF[7]	6 July 2004	16 July 2004
Professor Dr. G.-W. von Rymon Lipinski Head Regulatory Services & Management Nutrinova Industriepark Höchst	DHA (docohexanoic-acid)-rich microalgal oil (DHActive™)	BfR[5] Stellungnahme zur Feststellung der wesentlichen Gleichwertigkeit des DHA45-Öls mit dem als neuartige Lebensmittelzutat zugelassenen Omega Gold™-Öl	10 November 2003	24 December 2003
Dr. Ernst Karrer Paracelsus Haus GmbH Freistädter Straße 236 A–4040 Linz	Noni juice (juice of the fruits of *Morinda citrifolia*)	AGES[6] (AT) Antrag auf Feststedllung der wesentlichen Gleichwertigkeit nach Art. 3 Abs. 3 VO (EG) Nr. 258/97 für „Bula Noni® Juice 100% Saft aus de Frucht der Spezies *Morinda citrifolia* L." der Fa. „Paracelsus Haus Handels- und Dienstleistungs GmbH" als neuartige Lebensmittelzutat	23 December 2003	14 January 2004
Herr Michael Gracher GSE–Vertrieb Biologische Nahrungsergänzungsund Heilmittel GmbH Saargemünder Str. 18 D–66119 Saarbrücken	Noni juice (juice of the fruits of *Morinda citrifolia*)	BVL[4] (D) Stellungnahme zur Feststellung der wesentlichen Gleichwertigkeit von Saft aus der Frucht der Spezies Morinda citrifolia L. der Firma GSE-Vertrieb mit dem als neuartige Lebensmittelzutat zugelassenen „Noni-Saft" (Saft aus der Frucht der Spezies *Morinda citrifolia* L.) der Fa. Morinda Inc.	24 December 2003	26 January 2004

Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
Herr Franz Brenner Botanical Products International F.M. Brenner GmbH Hauptstrasse 10 A–2392 Wienerwald/Grub	Noni juice (juice of the fruits of *Morinda citrifolia*)	AGES[6] (AT) Antrag auf Feststedllung der wesentlichen Gleichwertigkeit nach Art. 3 Abs. 3 der VO (EG) Nr. 258/97 für ein Noni–Saft–Konzentrat der Fa. „Botanical Products International (BPI) - F.M. Brenner GmbH" aus der Frucht der Spezies *Morinda citrifolia* L. als neuartige Lebesmittelzutat	9 January 2004	14 January 2004
Poul A Svane Svane Trading apS Rypevang 4 DK–3450 Allerod	Noni juice (juice of the fruits of *Morinda citrifolia*)	MfFLoF[7], Fødevaredirektoratet (DK) –Udtalelse vedrørende sammenlignelighed for nonisaft produkt fra Pouls Svane Trading med det godkendte produkt, jf. Kommissionens beslutning 2003/426/EF af 5. juni 2003 om tilladse til markedsforing af nonisaft (saft af frugten *Morinda citrifolia* L.) som en ny levnesmiddelingrediens	16 January 2004	6 February 2004
Tahiti Naturel EURL PO Box 14968 Arue–Tahiti French Polynesia c/o Mme Marysa Benjamin Tahiti Naturel 1 Square Xavier Monteny F–93220 Gagny.	Noni juice (juice of the fruits of *Morinda citrifolia*)	see 22	21 June 2004	29 June 2004
Herr Franz Mitterbauer FM Network Marketing GmbH Stadtplatz 13/1 A–5280 Braunau	Noni juice (juice of the fruits of *Morinda citrifolia*) with 10% grape juice concentrate	AGES[6] (AT) Antrag auf Feststedllung der wesentlichen Gleichwertigkeit nach Art. 3 Abs. 4 VO (EG) Nr. 258/97 für „Indian Noni Indian Mulberry, Morinda Saft mit 10% Traubensaftkonzentrat" der Fa. „FM NETWORK MARKETING GMBH" als neuartige Lebesmittelzutat	1 March 2004	16 March 2004

Applicant	Description of Food or Food Ingredient	Scientific Evidence	Notification	Transmission to Member States
Georg Jessner Planta Naturstoffe Vertriebsges.m.b.H. Erlgasse 48 A–1120 Wien	Noni juice (juice of the fruits of *Morinda citrifolia*)	AGES[6] (AT) Antrag auf Feststedllung der wesentlichen Gleichwertigkeit nach Art. 3 Abs. 4 VO (EG) Nr. 258/97 für „Nonivera Saft (Handelsbezeichnung), Bio Noni Saft" der Fa. „Planta Naturstoffe Vertriebsges.m.b.H." als neuartige Lebensmittelzutat	29 March 2004	21 April 2004
Els Deprez G.D.I. nv Wolvenhovenstraat 12 B–8870 Izegem	Noni juice (juice of the fruits of *Morinda citrifolia*)	Advies van de Hoge Gezondheidsraad (B) betreffende de aanvraag om erkenning van de wezenlijke gelijkwaardigheid van een nonisap ingediend door de firma GDI uit hoofde van artikel 3(4) van de verordening 258/97	24 May 2004	6 July 2004
Dr. John Wilkinson Herbal Sciences International Ltd. The Seed Bed Centre, Langston Road UK - Loughton Essex IG10 3TQ for US Nutra 2751 Nutra Lane USA 32726 Eustis FL	Capsules with Astaxanthin-rich Carotenoid Oleoresin extracted from *Haematococcus Pluvialis* (max 4 mg Astaxanthin/capsule)	ACNFP[1] (UK) Request for an Article 5 Opinion on the Substantial Equivalence of Astaxanthin-rich Carotenoid Oleoresin extracted from *Haematococcus Pluvialis*	28 June 2004	13 July 2004
Ms Leena Morander Teriaka Ltd. Siirakuja 3 FIN–01490 Vantaa	Milk type products and soya drinks with added phytosterols/phytostanols	NFB[8] (FIN) Opinion of the Novel Food Board on substantial equivalence in the case of a milk and soya drink	1 July 2004	16 July 2004

1 ACNFP Advisory Committee on Novel Foods and Processes (UK)
2 BgVV Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (D)
3 AFFSA Agence française de sécurite sanitaire des alimentes (F)
4 BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (D)
5 BfR Bundesinstitut für Risikobewertung (D)
6 AGES Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (A)
7 MfFLoF Ministeriet for Fødevarer, Landbrug og Fiskeri (DK)
8 NFB Novel Food Board (FIN)

Status of GM plants under Directive 2001/18/EC

In addition to the GM plants authorized under the prior Directive 90/220/EC, the Commission has approved two additional GM crops for import and use in feed and industrial processing, Monsanto's Roundup Ready Maize NK603 and Monsanto's MON863, under the new approval process set out in Directive 2001/18/EC.

TABLE 4: GMO PRODUCTS AUTHORISED UNDER DIRECTIVE 2001/18/EC AS OF 24 AUGUST 2005

Product	Notifier	Date of Commission Decision Member State Consent
Maize Roundup Ready NK603, tolerant to glyphosate herbicide Uses: import and use in feed and industrial processing, not for cultivation	Monsanto C/ES/00/01	Commission Decision 2004/643/EC of 19.07.04 notified under document number C(2004)2761
Maize–Zea mays L., line MON 863 - resistant to corn rootworm Uses: for import and use of grain and grain products, not for cultivation	Monsanto C/DE/02/9	Commission Decision 2005/608/EC of 08.08.05 notified under document number C(2005)2950

2-16-2005
Source: European Commission

Pending Applications for Approval under Directive 2001/18/EC

When Directive 2001/18/EC took effect, some of the pending applications from under the previous directive, Directive 90/220/EEC were withdrawn, while others such as the Bt11 corn were resubmitted, and other new applications were submitted for authorization. As of March 2005, twenty-four applications had been submitted for approval under Directive 2001/18/EC. These applications included eight (8) varieties of maize, five (5) varieties of oilseed rape, five (5) varieties of cotton, three (3) varieties of beets, one (1) variety of potato, one (1) variety of rice, and one (1) variety of soybean. Seven of these applications were pending under previous Directive 90/220/EC at the time of its replacement. Some applications request use for importing and processing, while others are requesting cultivation as a permitted use. (See Table 5.)

TABLE 5: GMO PRODUCTS – PENDING NOTIFICATIONS UNDER DIRECTIVE 2001/18/EC

2/16/2005

Product notification details	Company
1. Maize hybrid MON810 x NK603 (glyphosate-tolerant and containing Bt toxin) Received by UK under Dir 90/220/EC. (C/GB/02/M3/03) Received by the Commission under Dir 2001/18 : 15/01/03 Uses: import and use in feed and industrial processing, not for cultivation.	Monsanto
2. Oil seed rape – herbicide resistant GT 73 Received by the Netherlands (C/NL/98/11) under Dir 90/220/EC. Received by the Commission under Dir 2001/18 : 16/1/03 Uses: import and uses in feed and industrial processing, not for cultivation.	Monsanto
3. Potato with altered starch composition Received by Sweden (C/SE/96/3501) Received by the Commission under Dir 90/220: 20.05.98 Favorable opinion of EU Scientific Committee 18.07.02 Received by the Commission under Dir 2001/18/EC: 24/01/03 Uses: for cultivation and production of starch, not for use as human food.	AMYLOGENE HB
4. Oilseed rape (Ms8, Rf3) Received by Belgium (C/BE/96/01) Received by the Commission: under Dir 90/220 16.01.97 Favorable opinion of EU Scientific Committee 19.05.98 Received by the Commission under Dir 2001/18: 5/02/03 Uses: import and cultivation in the EU, uses in feed and industrial processing.	Bayer CropScience
5. Maize MON 863 and MON 863 X MON 810 (protection against certain insect pests) Received by Germany C/DE/02/9 (6788-01-09) Received by the Commission under Dir 2001/18: 7/02/03 Uses: for import and use of grain and grain products, not for cultivation.	Monsanto
6. Maize herbicide and insect resistant (line 1507 – CRY1F) Received by the Netherlands (C/NL/00/10) under Dir 90/220/EC. Received by the Commission under Dir 2001/18 : 12/02/03 Uses: import and processing, not for cultivation	Pioneer/ Mycogen Seeds
7. Maize 1507 (or Bt Cry1F 1507) Received by Spain (C/ES/01/01) 11/7/2001 under Dir 90/220/EC. Received by the Commission under Dir 2001/18: 13/2/03 Uses: import, feed and industrial processing, and cultivation	Pioneer Hi-Bred /Mycogen Seeds
8. Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b) gene (Bt-11) Received by France (C/F/96/05-10) Received by the Commission under Dir 90/220: 12.04.99 and 03.05.99 respectively Favorable opinion of EU Scientific Committee 30.11.00 Received by the Commission under Dir 2001/18/EC: 16.6.2003 Uses: for cultivation, feed and industrial processing	Syngenta Seeds SAS

Product notification details	Company
9. NK603 Roundup Ready® maize Received by Spain (C/ES/03/01) Received by the Commission under Dir 2001/18/EC : 22/07/2003 Uses: import and use in feed and industrial processing, and for cultivation.	Monsanto
10. Rice tolerant to glufosinate-ammonium, event LLRICE62 Received by UK (C/GB/03/M5/3) Received by the Commission under Dir 2001/18/EC : 3/9/2003 Uses: import and use in feed and industrial processing, not for cultivation.	Bayer CropScience Ltd
11. NK603 X MON 810 maize Received by Spain (C/ES/04/01) Received by the Commission under Dir 2001/18/EC : 12/1/2004 Uses: import and use in feed and industrial processing, and for cultivation.	Monsanto
12. Cotton (281-24-236/3006-210-23), insect resistant Received by Netherlands (C/NL/04/01) Received by the Commission under Dir 2001/18/EC : 18/2/2004. Modified SNIF with reduced scope received 10/6/2004 Uses: import and use in industrial processing, not for cultivation, not for feed use.	Agrigenetics Inc. d/b/a Mycogen Seeds, c/o DowAgroSciences.
13. Carnation (Florigene Moonlite 123.2.38), modified color and herbicide resistant. Received by Netherlands (C/NL/04/02) Received by the Commission under Dir 2001/18/EC : 20/9/2004. Uses: import only, not for cultivation.	Florigene Ltd (Australia)

GM crops Banned by Member State Governments

A number of member states have invoked the “safeguard” clause of Directive 2001/18/EC and its predecessor law to justify national bans on some GM crops that have received European-level approval. As of April, 2005, the Commission has informed France, Austria, Luxembourg, Germany, and Greece that they lack scientific justification for those bans and therefore face legal action by the Commission. The Commission is still reviewing the more recent invocation of the safeguard clause by Hungary.

TABLE 6: GM CROPS CURRENTLY BANNED BY MEMBER STATE GOVERNMENTS UNDER THE SAFEGUARD CLAUSE

AS OF 15 MARCH 2005

Member State and date of invocation	Product details and date of Scientific Opinion concerning original information to justify bans
1. FR (20.11.98)	Swede rape resistant to glufosinate MS1/RF1 Uses: cultivation for breeding activities (seed production) Product approval: 1996 Scientific Committee Opinion: 18.05.99
2. AU (14.02.97) 3. LX (17.03.97) 4. DE (28.02.00)	Bt-maize tolerant to glufosinate ammonium (Bt-176) Uses: All uses (cultivation, food and feed, processing) Product approval: 1997 Scientific Committee Opinions: 21.03., 10.04., 12.05.97 (AU); 09.11.00 (DE) EFSA: 08.07.04 (AU)
5. EL (05.11.98) 6. FR (20.11.98)	Swede rape tolerant to glufosinate (Topas 19/2) Uses: import, storage and processing (no cultivation) Product approval: 1998 Scientific Committee Opinion: 18.05.99 EFSA: 08.07.04 (EL)
7. AU (01.06.99)	Maize expressing the Bt cryIA(b) gene (MON 810) Uses: All uses (cultivation, food and feed, processing) Product approval: 1998 Scientific Committee Opinion: 24.09.99 EFSA: 08.07.04
8. AU (08.05.00)	Maize tolerant to glufosinate (T25) Uses: All uses (cultivation, food and feed, processing) Product approval: 1998 Scientific Committee Opinion: 30.11.00 (AU) replaced 20.07.01 EFSA: 08.07.04
9. HU (20.01.05)	Maize expressing the Bt cryIA(b) gene (MON 810) Uses: All uses (cultivation, food and feed, processing) Product approval: 1998 Scientific Committee Opinion: 24.09.99 EFSA: 08.07.04

Source: European Commission

2. CULTIVATION OF GM CROPS IN THE EU

Given EU consumer concerns and activist group resistance, including numerous incidence of crop vandalism, it is not surprising that few farmers in the EU grow approved GM crop varieties. Spain is effectively the only member state in the EU that is growing significant amounts of GM crops. In 2004, farmers in Spain planted 58,000 hectares of *Bt* maize, an 80% increase from the year before.[18] Spain accounts for 97% of all GM crops grown in the EU.

Very small quantities of GM crops are also grown in Germany and France. France has reduced the amount of GM crops from about 2,000 hectares in 1998 to less than 100 hectares in 2004. In 2004, almost 300 hectares were planted to GMO corn in Germany. About 100 German farmers registered fields for the planting of GM corn (Bt Corn) in 2005. Farmers have indicated intentions to plant nearly 1,000 hectares of GMO corn (principally varieties containing the Monsanto trait MON810).

The ten new member states of the EU are not presently cultivating significant quantities of GM crops. Those new States may prove to be more hospitable to GM varieties given the relative lack of political and popular opposition to GM foods and crops in the past. Romania, a country waiting for future admission to the EU, currently grows about 100,000 hectares of GM soybeans.

18 Clive James, Global Status of Commercialized Biotech/GM Crops: 2004, ISAAA (2004).

GM PLANTINGS IN THE EU 1998-2001 (HECTARES)

	1998	1999	2000	2001	2002	2003	2004
France	2,000	1,000	1,000	0	0	0	<100
Portugal	0	1,000	0	0	0	0	0
Spain	20,000	10,000	30,000	30,000	25,000	32,000	32,000
Germany	0	0	1,000	1,000	1,000	1,000	1,000
Total	22,000	11,000	32,000	31,000	26,000	33,000	33,100

Source: European Commission, Directorate-Gneral for Agriculture, World areas sown to GMOs by country

3. EU FIELD TRIALS AND GM CROP RESEARCH

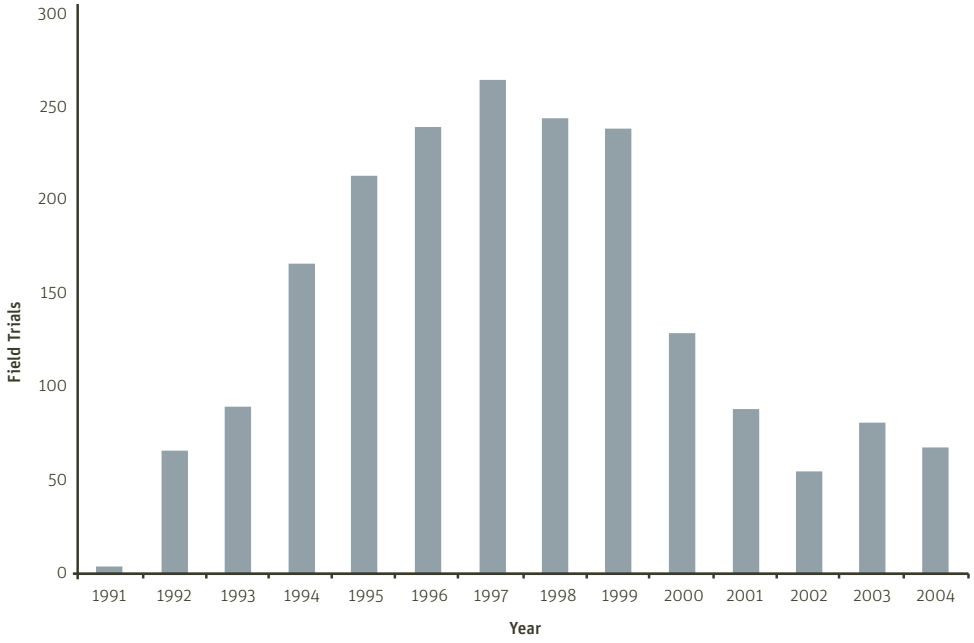
Though very few GM crops are cultivated commercially in the EU, and few products derived from GM crops are on the commercial market, some field trials and testing of GM crops and other plants and organisms have been conducted in the EU over the past 14 years. However, the pace of field trials has fallen considerably since 2000. From 1991 to 1999, field trials averaged about 169 a year; from 2000-2004, the rate of field trials was about half of that, at about 84 a year.

In a recent poll by Fraunhofer ISI, 39 percent of all institutions having projects on GM products in the EU have cancelled at least one project in the last four years. The poll also found that 21 percent of these institutions cited the unclear legal situation as the major factor for canceling their projects. The next highest reasons reported, were a feeling of low acceptance for GM products among European consumers (19%) and an uncertain market for GM products in the future (17%). The public sector (23%) was less likely to have cancelled GM research projects than the private sector (61%).

Between 1991 and December 2004 there were 1946 notifications of GM field trials taking place in the EU. France had the most notifications for field trials with 541, accounting for over one-quarter of all trials held. Six other member states held the bulk of the other notifications. These six member states, in descending order, were Italy (295 notifications), Spain (273 notifications), the United Kingdom (231 notifications), the Netherlands (151 notifications), and Belgium (130 notifications) and Germany (143 notifications).

These field trials consisted of various GM crops and organisms. The greatest number of trials included vegetables and grains (577 trials each), followed by food additive crops (421 trials), fruits (120 trials), non-food plants (88 trials), bacteria or viruses (83 trials), and trees/flowers (79 trials). Two or more subjects were concurrently tested in 24 of the field trials.

FIELD TRIALS OF GM IN THE EU BY YEAR



The most heavily field-tested grain was maize, with 520 trials. The other most tested grains were rice with 33 trials, and wheat with 31 trials. Less tested grains included barley (5 trials), alfalfa (2 trials), and rye (1 trial). Grains were combined in 17 field trials.

Sugar beets and potatoes were the most tested vegetables with 248 trials and 232 trials respectively from 1991–December 2004. Fodder beets were the next most heavily tested with 29 trials. Soybeans had 17 trials and eggplant 9 trials, lettuce had 8 trials, cauliflower and squash had 6 trials each and cabbage had 3 trials. Carrot and pumpkin were tested in 3 trials each, while turnips and peas had 2 trials each. GM radishes and zucchini each had a single trial. Vegetables were combined in 7 trials.

Tomatoes were the most tested fruit in this period with 75 trials. Melon had 8 trials as well as strawberries. Apples were tested in 7 trials, and grapes had 5 trials. Cherry and kiwi each had 3 trials, the olive had 2 trials, and orange, plum, raspberry, and watermelon each had a single trial.

Among plants from which food additives are derived, rapeseed was the most tested with 368 trials. Chicory was tested 31 times. The rest of the category consisted of Indian mustard (3 trials), swede (1 trial), and coffee (1 trial). Among non-food crops, tobacco was tested 56 times, and cotton was field tested 33 times from 1991 to December 2004.

SOURCES FOR APPENDIX F

European Science and Technology Observatory, European Commission Joint Research Center, Institute for Prospective Technological Studies Report, “Review of GMOs Under Research and Development in the Pipeline in Europe.”

GM Foods result Derived from the SNIF Database at the Robert Koch Institute Center for Gene Technology, Berlin, Germany. http://www.rki.de/

Clive James, “Global Status of Commercialized Transgenic Crops: 2004” ISAAA Brief No. 32

World Areas Sown to GMOs by Country 9/23/2002 European Commission Directorate-General For Agriculture.