USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 8/3/2012

GAIN Report Number: FR9105

EU-27

Agricultural Biotechnology Annual

Annual

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Report Highlights:
European governments, societies, and industries remain conflicted about the use of genetically engineered (GE) plants in agriculture and food production. Public perceptions, commercial use, research, and even regulatory approaches vary among the European Union's (EU) 27 countries. The EU approval system for GE crops remains politicized and operates at a slower pace than regulatory processes in GE producing countries. Imports of foods made from GE varieties not approved in the EU are banned, a problem that could grow as the use of the technology becomes more widespread globally. Seven EU countries, including leading crop producers France, Germany, and Hungary, have banned the commercial planting of GE corn. Others, such as Spain and Portugal, use it more freely. EU livestock producers face a structural shortage of feed protein and will remain dependent upon imports of 32 million metric tons of soy products annually, nearly all of which are sourced from biotech varieties in Argentina, Brazil, and the United States.

Section I. Executive Summary

Until the 1990's, the EU was a leader in research and development of genetically engineered (GE) plants, with both public research institutions and large private groups involved in agricultural biotechnology. EU and Member State (MS) authorities, however, have developed a complex and lengthy policy framework, driven by well-orchestrated anti-biotech actions by powerful non-government organizations (NGOs). As a result, and although agricultural biotechnology research is stated as a priority of the European Commission, a significant share of open-field research has disappeared. A recent and prominent example is the announcement in early 2012 by the German company BASF to relocate its biotechnology plant science headquarters to the United States. On the other hand, confined research continues to be intense in the EU, through institutions like the Joint Research Center of the European Commission, and in international programs like the tomato genome sequencing, which involves several MS.

The EU's lengthy, expensive, complex regulatory process and negative public opinion restrict the commercial cultivation of bioengineered crops to one trait, Monsanto's MON810 insect resistant corn. It is grown on approximately 100,000 hectares, mainly in Spain, Portugal, and the Czech Republic. This is a relatively old variety that has been replaced with by new technologies in corn production outside of Europe. With the development of stacked traits and other new technologies, the demonstration of the potential of biotechnology in Europe will remain limited.

Several types of trade barriers have been developed in the EU preventing GE products imports including: (1) delays in the approvals of new events has resulted in asynchronous approvals (i.e., the absence of approval in the EU of some bioengineered products already approved and produced in supplying countries); (2) the EU food industry and supermarket chains have reformulated to exclude potential GE ingredients since the EU regulation on traceability and labeling was implemented in 2003-2004, and non-GE labels are now used on some food products as a marketing tool in some MS, including France and Germany; (3) there is a growing consideration of socio-economic criteria in addition to scientific criteria to review GE products in the EU; and (4) EU-wide approvals for planting GE crops are circumvented by national bans in seven MS (Austria, Bulgaria, France, Germany, Greece, Luxemburg, and Hungary).

The EU is a major livestock producer that has a structural shortage of feed protein. Despite the controversy over the use of GE technology, the EU is expected to remain dependent upon soy imports annually, nearly all of it from biotech varieties produced in Argentina, Brazil and the United States. Every year, the EU imports approximately 20 million metric tons (MT) of soybean meal, 12 million MT of soybeans, and 500,000 MT of dried distillers grains (DDGs).

Within the EU, acceptance of agricultural biotechnology varies among and is reflected in differing MS policy, farmer, and industry approaches. This report classifies MS based on their level of acceptance and use. The first group includes MS most open to the technology. These MS include GE crop producers and those ready to adopt if EU approval is granted to locally cultivated crops. The second group includes MS hesitant to adopt the technology but where there are contradictory forces (such as their concern over GE crop compatibility with organic production). The third group includes MS the

most opposed to the technology (see map Section IV-on page 32).

Food security is a global challenge where the EU, as a leading agricultural producer, importer, and exporter, is playing a key role. In 2011, agriculture was set as one of the top priorities under France's presidency of the G20 for the first time in the history of the Summit. The G20 agricultural ministerial declaration stated that G20 members "recognize the need to increase sustainable agriculture production and productivity to improve food security, agree to strengthen agricultural research for development, and commit to enabling environment to encourage and increase public and private investment in agriculture." This conclusion and the commitment of the G8 in May 2012 on a "New Alliance on Food Security and Nutrition" may encourage the EU to incorporate agricultural biotechnology as a key research, development and innovation tool for achieving food security in the developing world.

There are no GE animals commercially produced in the EU. GE animals are principally used for research for medical and pharmaceutical applications. Animal biotechnology regulation in the EU parallels regulation of plant biotechnology and some MS do have specific regulations on animal biotechnology.

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Section II. Plant Biotechnology Trade and Production

a) Commercial Production of Biotechnology Crops

The two GE crops authorized for cultivation in the European Union (EU) are MON810 genetically engineered (GE) corn and the Amflora potato. Only GE corn, however, is commercially grown.

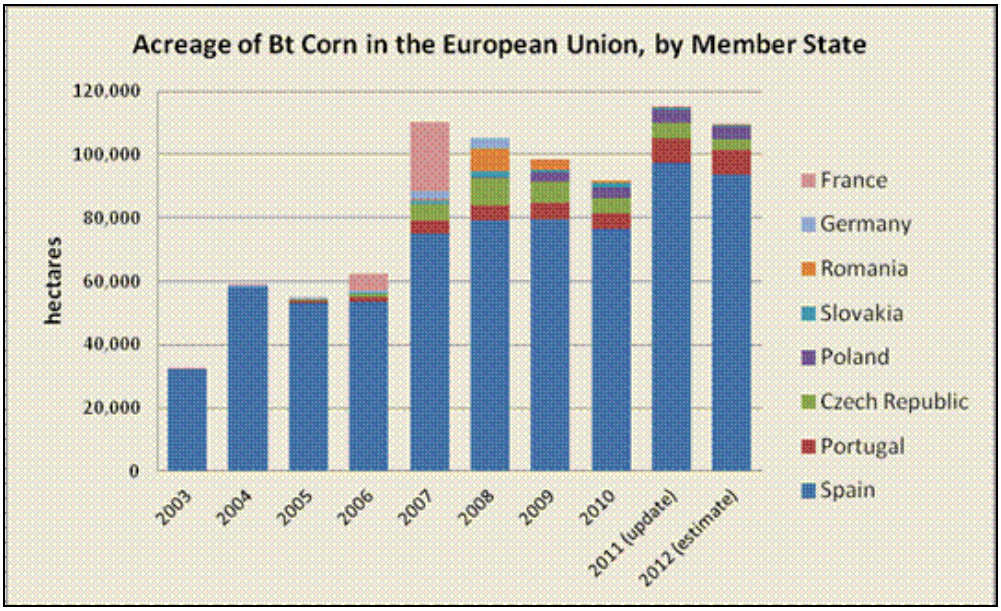
Since 2007, the EU acreage of GE corn has remained relatively stable, with fluctuations between 93,000 and 115,000 hectares (ha). **Spain** remains the leading GE corn producer, with 85 percent of the total acreage. In 2012, Spain's GE corn production is expected to decline due to the reduced total corn area anticipated as a result of lower water supplies. Nevertheless, the share of GE corn is expected to remain at similar levels as in previous years.

Other GE corn producers are **Portugal**, the **Czech Republic**, **Poland, Slovakia,** and **Romania**. In **Portugal**, planting area increased by nearly 60 percent to 7,724 ha in 2011 due to a rise in the overall corn area and an increase in insect pest pressure. In **Romania**, legislation requiring separate storage and handling for GE crops increases costs to farmers and is expected to reduce the area planted to GE corn. In the **Czech Republic** and **Slovakia**, the decline in GE corn acreage results from the demand for non-GE products from **Austria** and **Germany**.

GE corn is principally grown for domestic animal feed in Spain, Portugal and Poland. While in the Czech Republic and Slovakia, GE corn is used for small scale animal feeding and as a feedstock for the production of biogas.

EU-27 acreage of GE Corn by Selected Member States (in hectares)										
MS	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011 (update)**	**2012 (estimate)**
Spain	32,249	58,219	53,226	53,667	75,148	79,269	79,706	76,575	97,346	93,700
Portugal	0	0	730	1,254	4,199	4,856	5,094	4,869	7,724	7,700
Czech Republic	0	0	250	1,290	5,000	8,380	6,480	4,678	5,090	3,500
Poland	0	0	0	100	100	300	3,000	3,500	3,900	4,000
Slovakia	0	0	0	30	930	1,930	875	1,281	760	378
Romania	0	0	0	0	331	7,146	3,400	822	588	300
Germany	0	500	342	947	2,685	3,171	0	0	0	0
France	17	17	500	5,200	22,135	0	0	0	0	0
Total GE corn acreage	32,266	58,736	55,048	62,458	110,528	105,052	98,555	91, 725	115,408	109,578
Total Corn Acreage (1,000 ha)	9,138	9,677	9,169	8,492	8,444	8,854	8,284	7,984	8,750	9,200
Percentage of MON810 /Total Corn	0.3 %	0.6 %	0.6 %	0.7%	1.3%	1.2%	1.2%	1.1%	1.3%	1.2%

Source: FAS Posts



Source: FAS Posts

BASF's Amflora potato was approved for cultivation in the EU in March, 2010, and is estimated to have been grown on some 225 hectares in the **Czech Republic, Sweden**, and **Germany**. Amflora's cultivation has been controversial. In January 2012, BASF decided to stop commercialization and research activities on GE technology for the European market, including Amflora potato. It further announced the relocation of its biotech plant science headquarters from Germany to the United States.

EU-27 Acreage of GE Potato by Selected MS (in hectares)			
Member State	**2010**	**2011 (update)**	**2012 (estimate)**
Sweden	150	0	0
Czech Republic	147	0	0
Germany	15	0	0
Total Amflora Potato Acreage	225	20	0

Source: FAS Posts

b) Biotechnology Crops Under Development

Europe has given rise to world-class private developers of GE crops (e.g., Bayer CropScience, BASF, Syngenta, Limagrain, etc.) which conduct research for, and supply GE seeds to, markets outside of Europe. Basic research and very limited product development is also conducted at public research institutions and universities. In its current form, however, taxpayer-supported research is not likely to lead to short or medium term cultivation of GE crops in Europe. Very little emphasis is directed toward the product development end of the research 'pipeline.' Additionally, public researchers are generally unable to afford the costs and lack the procedural expertise needed to complete the EU regulatory approval system.

- *European Union Research Perspectives:*

In March 2012, the **Standing Committee on Agricultural Research** (SCAR) released a report on "Agricultural Knowledge and Innovation Systems in Transition – A Reflection Paper" encompassing the ways that agricultural innovations are transmitted to the field in the various EU Member States. The report found that extension services vary greatly among Member States and innovation developments are not transmitted in the same way to all European farmers.

The Paris-based Organization for Economic Collaboration and Development (OECD) also conducts work on Agricultural Knowledge Systems (AKS), on which a meeting ("Improving Agricultural Knowledge and Innovation Systems") was organized in June 2011, and where a number of American speakers covered plant biotechnology innovations and their use by farmers.

In February 2012, the **European Commissioner for Research, Innovation and Science** gave a press conference to announce that the European Commission adopted a strategy on "**Innovating for Sustainable Growth: A Bioeconomy for Europe**," described in a press release and memo. According to the memo, "the bioeconomy encompasses the sustainable production of renewable biological resources and their conversion and that of waste streams into food, feed, bio-based products such as bioplastics, biofuels, and bioenergy. It includes agriculture, forestry, fisheries, food and pulp and paper production, as well as parts of chemical, biotechnological and energy industries." The strategy document identifies three ways to meet the bioeconomy objectives: (1) investing in research, innovation and skills (increased public funding in food security and sustainable agriculture is specifically indicated as an example); (2) market development and enhanced competitiveness of bioeconomy sectors (for example, marketing new products with a direct benefit to citizens, such as food security and sustainable agriculture); and (3) stronger policy coordination and engagement with stakeholders.

The **Joint Research Center (JRC)** of the European Commission is actively working on "**new plant breeding techniques**" (NPBTs) that are biotechnology techniques but differ from transgenesis. These techniques are described in a JRC document released in May 2011: "New Plant breeding Techniques - State of the Art and Prospect for Commercial Development." (See Section III-l for additional information)

Public research programs on biotech plants funded by European authorities are summarized in the 2010 document "A Decade of EU-Funded GMO Research (2001-2010)" published by the **Directorate General on Research and Innovation.** In this document, research programs are listed by category: environmental impacts, food safety, biomaterials and biofuels, and risk assessment and management.

- *Research Conducted by Member States:*

Confined Research:

With less strict regulations and little or no visibility for public opinion, there is confined research conducted by public entities.

On July 2012, a consortium of nine research centers, with the support of five companies and five Spanish autonomous communities, announced that they had sequenced the melon genome and obtained the particular genomes of seven melon varieties. The Melonomics project (http://melonomics.net/) was launched by the Spanish Genome Foundation.

In May 2012, the sequencing of the tomato genome was announced by an international consortium of 300 researchers and 14 countries (http://solgenomics.net), including six European Member States (France, Germany, Italy, the Netherlands, Spain, and the United Kingdom), where public research institutions and universities were involved.

Examples of confined plant biotechnology research projects include the following: **France**'s National Institute for Research in Agriculture (INRA) is strongly involved in the national program for research and higher education called "Invest for the Future" where various plant breeding programs are conducted with biotechnology tools on wheat, corn, rapeseed, sunflower seed, peas, sugar beet, miscanthus, sorghum, and aircraft biofuels. INRA also partners with private entities in research programs on crop genomics in the "Green Biotechnology" program. In **Germany**, four big research organizations (Max-Planck-Society, Leibniz Association, Helmholtz Association, Fraunhofer-Gesellschaft), universities, technical colleges, and non-academic research institutes play a central role in biotech development. In **Greece**, agricultural universities and the National Foundation carry out agricultural research. The Agricultural Research Foundation (NAGREF) operates under the umbrella of the Ministry of Agricultural Development and Food. The School of Agriculture at the Aristotelian University of Thessaloniki, Laboratory of Genetic Engineering and the University of Crete, Laboratory of Molecular Biology are considered to be the most progressive entities in the country on biotechnology. In **Hungary**, the main research institutes belong to the Hungarian Academy of Science, the Ministry of Rural Development, and universities. In **Poland**, plant biotechnology research is conducted by several research institutes, in some cases in cooperation with foreign companies or laboratories. The **Spanish** Technology Platform for Plant Biotechnology (Biovegen) is a cooperation network among R&D stakeholders from industry, academia and the farming community. There is also confined research reported in **Czech Republic, Denmark, Finland**, **Italy, Portugal**, **Slovenia, Sweden,** and the **United Kingdom**.

For more detailed information on these programs, please see country-specific reports prepared by FAS Posts in MS listed in Section V a).

Field Trials:

Biotech test plots - which are used both as a research tool and are a required part of the EU regulatory approval process - are routinely destroyed by activists in some Members States. As a result, the EU permit requests to conduct field trials have fallen dramatically since 2007.

Due to strict regulations and hostile public opinion, there are no field trials in **Austria, Bulgaria, France, Greece, Lithuania, Estonia, Latvia, Italy,** and **Slovenia,** and a limited number in **Belgium** (poplar, potato, and corn), **Denmark, Germany**, the **Netherlands**, **Slovakia,** and **Sweden**. In **Germany**, field trials have essentially ended in recent years, due to vandalism by anti-biotech activists, who, by law, have internet access to the exact location of any test plot.

There are more field tests than in the aforementioned countries in the **Czech Republic** (virus-resistant plum trees, glyphosate resistant corn and sugar beets), Ireland (late blight resistant potatoes), **Poland** (coexistence studies and effects of GE crops on non-target species), **Portugal** (corn), **Romania (**virus-resistant plum tree**), Spain** (corn, sugar beet, cotton, potatoes, tobacco and poplars), and the **United Kingdom** (nematode-resistant and blight-resistant potatoes, aphid-resistant wheat).

In the **United Kingdom**, Rothamsted Research has embarked on a field trial of Cadenza wheat, modified to produce a non-toxic odor - (E) beta-farnesene (EBF) (a naturally occurring chemical found in peppermint plants) that the wheat releases to act as an alarm signal to keep aphids away and attract their native predators, parasitic wasps (Braconidae). Rothamsted Research receives UK government funding via the Biotechnology and Biological Sciences Research Centre (BBSRC), with no links to the private sector. Despite action by protestors, which received significant media coverage in spring 2012, the trial continues amid tight security. The outreach by Rothamsted scientists, who have appealed via video, radio, and the internet for their work to continue, has been successful. In **Ireland**, open field test plots of a potato line with improved resistance to late potato blight were approved in July 2012 and for the next four years.

c) Imports

EU plant biotech trade consists mainly of soybean and corn products imported for use in animal feed, human food, and planting seeds.

Two Member States also have specific rules on the trade in GE seeds: **Poland** prohibits GE seed trade, and plans to implement a ban on GE feed by January 1, 2013, and **Bulgaria** prohibits trade in biotech seeds since 2010, even for research and development purposes.

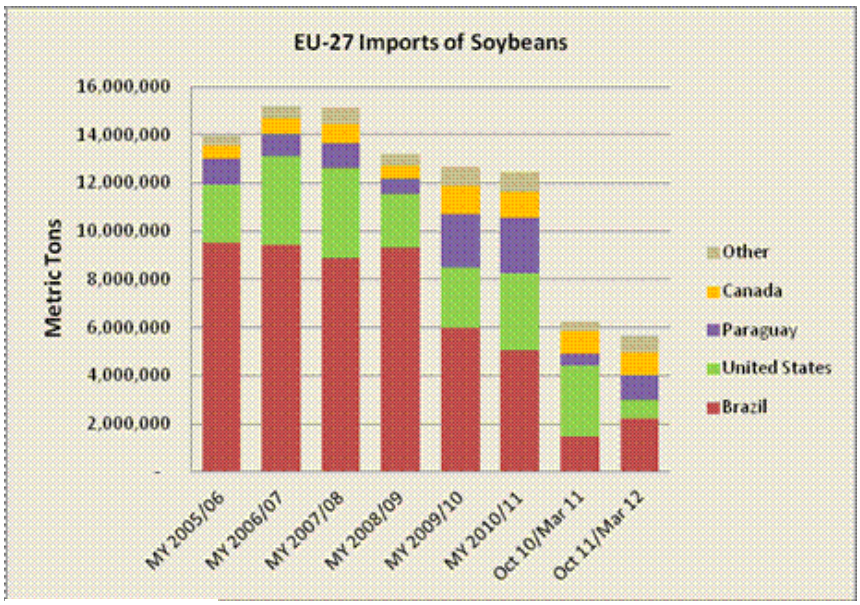
Soybean Products:

The largest category of GE products consumed by MS consists of soybean meal, which is the primary source of proteins for livestock. EU meat producers are dependent on imports of soybean and soybean meal from the Americas. Exports of these commodities from the United States to the EU have declined significantly since 1997. More specifically, U.S. exports of soybeans and soybean meal to the EU have averaged around $1 billion annually since 2006.

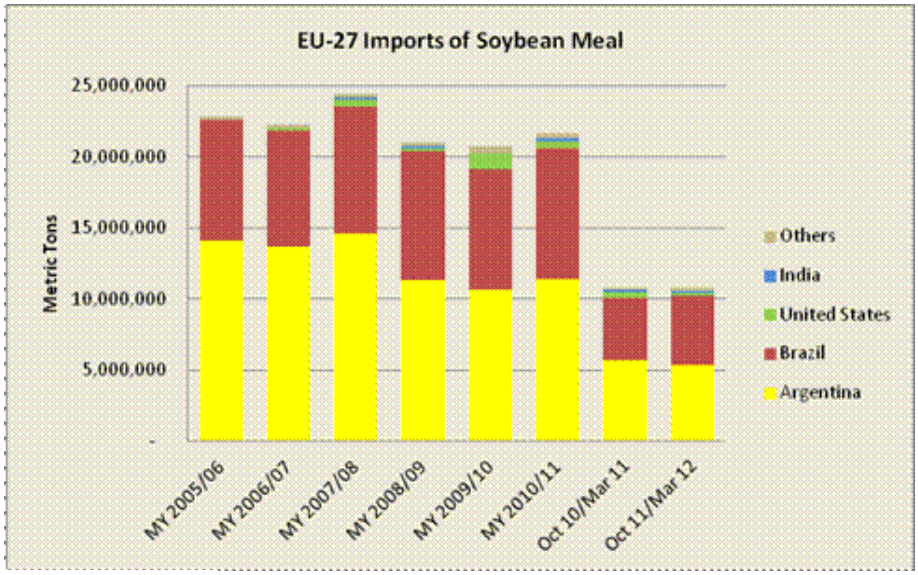
On average, 30 million metric tons (MT) of soybean meal are consumed annually (see 2012 annual EU-consolidated oilseeds GAIN report) in the EU, with soybean and soybean meal imports averaging 12 and 20 million MT, respectively. The largest users of soybean meal (**Spain, Germany**, **France**, **Italy,** and the **Benelux)** are also the major producers of livestock and poultry, with 65 percent of total EU consumption.

In the first half of MY 2011/12, EU imports of soybeans significantly declined, mainly from the United States, while imports of soybean meal remained stable. Reduced shipments of U.S. soybeans can be explained by the implementation of the European Renewable Energy Directive, which imposes certain

sustainability criteria on raw materials (such as soybean oil) used to process biofuels.



Source: Eurostat



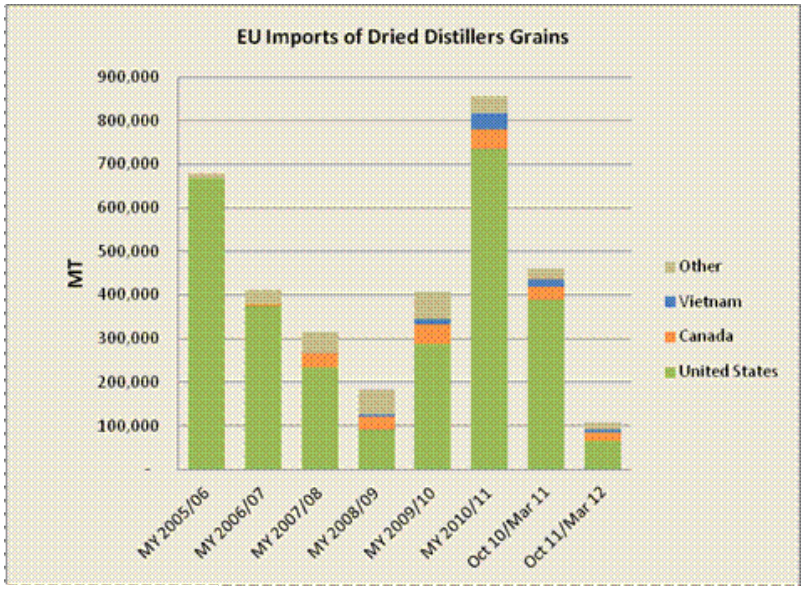
Source: Eurostat

According to the European feed industry association (FEFAC), non-biotech feeds account for less than 15 percent of total compound feed production in the EU. Poultry is the sector with the strongest demand for non-biotech feed, as a significant part of poultry meat is sold under quality and geographical indications that require animals to be fed on non-biotech feed.

Corn Products:

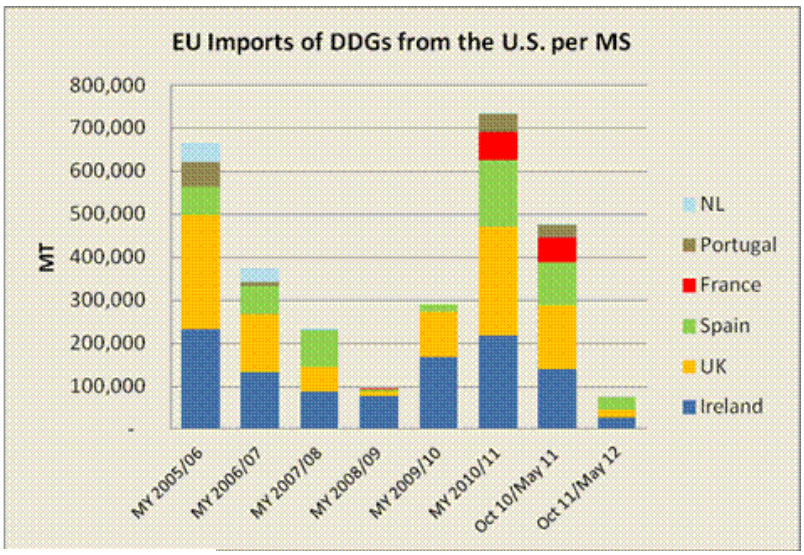
Corn and corn products, mainly dried distillers grains (DDGs), and to a lower extent, corn gluten feed (CGF), represent the second largest category of GE products used in animal feed. The annual EU corn consumption amounts to 62 million MT on average and more than 90 percent is supplied by local production, rather than by imports. The share of GE products out of total corn consumption is estimated to be lower than 25 percent.

EU imports of DDGs and CGF, mainly imported from the United States in the past, declined significantly with the growing share of biotech corn production in the United States and low tolerance of unapproved events in the EU. EU imports of DDGs bounced back in MY 2009/10 and MY2010/11, but were extremely low in the first half of MY 2011/12. The sharp decline can be attributed to the asynchronous approval of the MIR162 biotech event between the EU and the United States. It seems that higher quantities of domestically produced DDGs and grains have been incorporated by feed compounders to replace U.S. DDGs in animal feed rations.



Source: Eurostat

Within the EU, the largest importers of DDGs from the United States are **Ireland**, the **United Kingdom,** and **Spain**. EU imports of CGF from the United States have declined significantly over the past few years, while benefiting CGF from Ukraine. The main importers of CGF from the United States are traditionally **Belgium** and the **Netherlands**.



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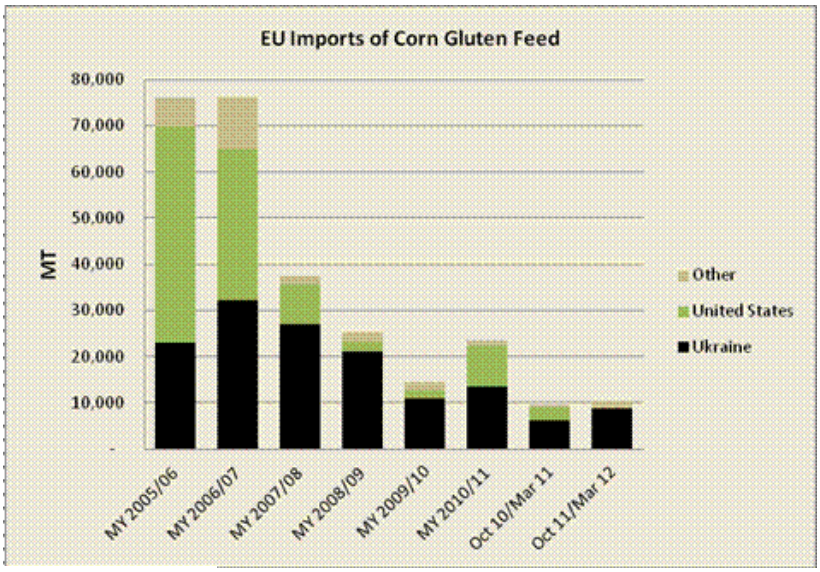


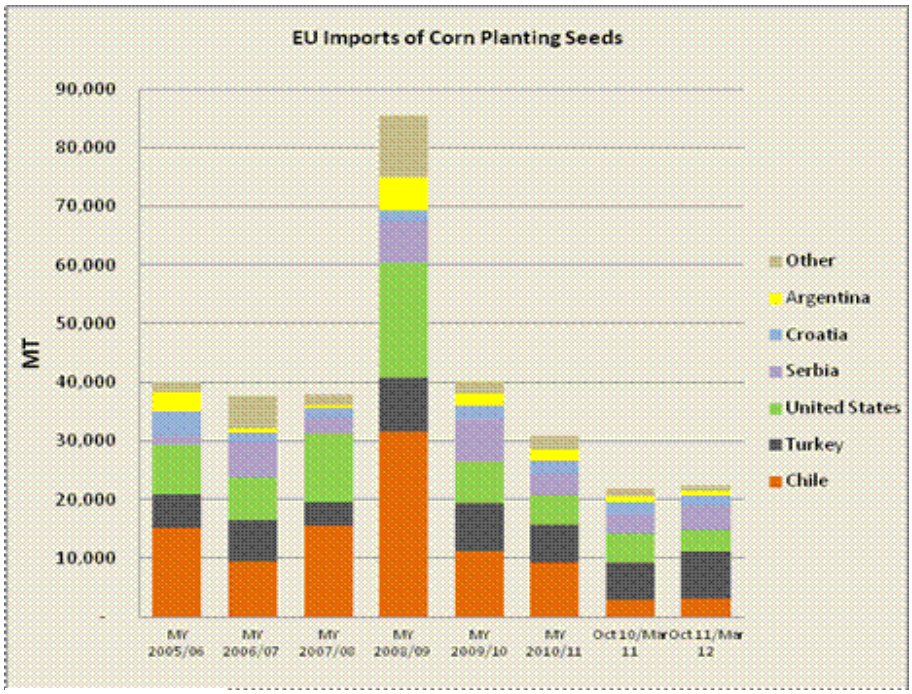
Source: Eurostat

Planting Seeds:

The percentage of GE corn out of the total corn grown in the European Union is limited. The leading producers of corn seeds for planting in the EU are **France** and **Hungary**. There is also production in **Austria**, **Bulgaria,** and **Romania**. In 2011, Romania produced its own biotech corn seeds for planting, while in Bulgaria, non-GE corn seeds are imported from other EU MS, Turkey, and the United States. **German** seed companies provide biotech seeds to U.S. farmers. These seeds, however, are not produced in Germany due to political opposition concerning the environmental release of GE crops. **Italy** applies a "zero tolerance" for adventitious presence of bioengineered seeds in conventional lots. **Portugal** sources GE corn seed directly from the United States and Chile, but the majority is U.S. produced seed imported after repacking. **Spain**, the leading EU GE corn producer, sources its GE seeds

from South Africa, Romania**,** and also produces some domestically. The United States is not a source of biotech planting seeds for Spain because of the low of tolerance for adventitious presence of unapproved events in planting seeds.

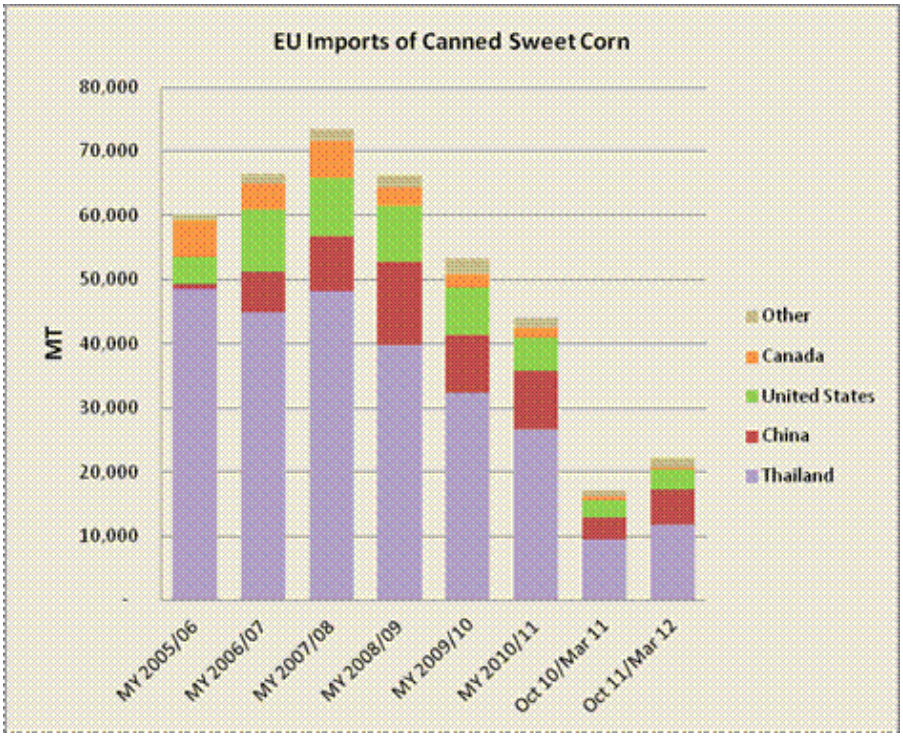
The United States remains a major supplier of corn planting seeds for the European Union but its market share has gradually declined in the past years, as did that of Chile, to the benefit of Turkey, Croatia, and Serbia, which are sources of non-GE products.



Source: Eurostat

Sweet Corn:

Total EU imports of canned sweet corn are on the decline, in line with increasing domestic production. The United States remains the EU's third largest supplier of canned sweet corn to the European Union after Thailand and China. The implementation of biotech labeling on food in 2004 negatively affected U.S. exports of sweet corn to the EU.



Source: Eurostat

d) Food Aid

The European Union is not a recipient of food aid, but does provide food aid to various countries, including mainly former colonies in Africa and Asia, where its political line is influential.

e) Production of Biotechnology Crop Developed outside of the United States

None.

Section III. Plant Biotechnology Policy

a) Regulatory Framework

i. *Responsible Government Ministries*

At the EU level, risk assessment and management are treated separately. The European Commission Directorate General (DG) responsible for risk management of bioengineered plants is DG Health and Consumers (SANCO). The European Food Safety Agency (EFSA) is responsible for risk assessment.

The Joint Research Center (JRC) and DG Research and Innovation conduct research programs on life sciences and biotechnology. A committee of Member States' experts and an Appeal Committee comprised of Member States' officials consider applications for specific products. Other decisions may be subject to review by the European Parliament and Council of the European Union (see Section III a) iv).

In the Member States, responsible government ministries include agriculture and food, environment, health, and economy.

ii. *Role and membership of Biosafety Committee*

The European Food Safety Agency's (EFSA) core task is to independently assess any possible risks of plants derived from genetic engineering to human and animal health and the environment. EFSA does not authorize GE products. Authorization is made by the European Commission and Member States as risk managers. EFSA's role is strictly limited to giving scientific advice.

iii. *Political factors influencing regulatory decisions*

EU Member States address the issue of biotechnology in various ways, both in terms of policy and marketing. This is due to industry needs and public opinions that are specific to individual Member States (see Section IV a). Negative public opinion initially developed in the late 1990s in response to various issues including "Mad Cow" disease (Bovine Spongiform Encephalopathy), asbestos and contaminated blood. These events led to significant distrust and public belief that companies and public authorities could disregard health risks in favor of protecting economic or political interests. Various anti-biotech NGOs took advantage of modern communication technologies to capitalize on public insecurity. Despite various factors discouraging plant biotechnology in the EU, many EU scientific researchers, farming groups, and industry sectors remain interested in using plant biotechnology because of the resultant benefits including higher yields, improved protection from pests, and cost savings.

iv. *Distinctions between regulatory treatment of the approval for food, feed, processing and environmental release*

- **Authorization Procedure:**

Plants derived from genetic engineering are subject to an onerous authorization procedure whether for import, distribution, processing, or cultivation for food or feed use in the EU. The steps necessary to obtain authorization for import, distribution, or processing are set out in Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Directive 2001/18/EC of the European Parliament and of the Council outlines the steps to obtain authorization for cultivation.

In both cases, the European Food Safety Authority (EFSA) must conclude that the product in question is as safe as a comparable conventional variety. Once EFSA issues a positive opinion, a political decision is taken by the Member States on whether or not the product should be authorized. This latter risk management phase of the authorization procedure is administered by the European Commission, which

submits the files to Member States' experts at the GE product Section of the Standing Committee on the Food Chain and Animal Health (SCoFCAH) or the Regulatory Committee (Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms) as appropriate.

Details of the procedures to be followed are set out below:

Authorization for placing biotech events on the market for food or feed use [1]

To obtain authorization for import, distribution, or processing biotech events:

- An application[2] is sent to the appropriate national competent authority of a Member State. That competent authority acknowledges receipt of the application in writing to the applicant within 14 days of receipt, and transmits the application to EFSA.
- EFSA informs other Member States and the European Commission of the application without delay, and makes it available. EFSA also makes the summary of the application dossier available to the public via the internet.
- EFSA is obliged to respect the time limit of six months from its receipt of a valid application to give its opinion. This six month limit is extended whenever EFSA or a national competent authority through EFSA requests supplementary information from the applicant.
- EFSA forwards its opinion on the application to the European Commission, the Member States and the applicant. The opinion is made available for public comment within 30 days from publication.
- Within three months after receiving the opinion from EFSA, the European Commission presents the SCoFCAH with a draft decision reflecting EFSA's opinion. SCoFCAH votes on the draft decision.
- Draft decisions that have been put to the SCoFCAH after March 1, 2011, are subject to the procedural rules outlined in the Lisbon Treaty. Under these rules, in the case of no qualified majority in favor of the draft decision, the Commission may either submit an amended draft to the Committee or submit the original draft to the Appeal Committee (comprised of senior officials from the Member States). If the Appeal Committee has neither adopted the draft decision nor opposed it by qualified majority within two months from the date of referral, it *may*

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council

[2] The application must include:

- Name and address of the applicant.
- Designation of the food, and its specification, including the transformation event(s) used.
- A copy of the studies which have been carried out and any other available material to demonstrate no adverse effects on human or animal health or the environment.
- Methods for detection, sampling, and identification of the event.
- Samples of the food.
- Where appropriate, a proposal for post market monitoring.
- A summary of the application in standardized form.

A complete list of accompanying information is provided in Regulation (EC) no 1829/2003, Article 5 (3) for food use, and Article 17 (3) for feed use.

be adopted by the European Commission. The post-Lisbon procedural rules give more discretion to the Commission. Previously, the Commission was obliged to adopt the draft decision. Under the new rules, the Commission has the option to adopt or not.

- Authorizations granted are valid throughout the EU for a period of ten years. They are renewable for ten year periods on application to the European Commission by the authorization holder at the latest one year before the expiry date of the authorization. This application for renewal of authorization must include, among other items, any new information which has become available regarding the evaluation of safety and risks to the consumer or the environment since the previous decision. Where no decision is taken on the renewal before the authorization's expiry date, the period of authorization is automatically extended until a decision is taken.

Authorization for cultivation of biotech events[3]

The appropriate competent authority of each Member State must provide written consent before an event can be commercially released.

The standard authorization procedure for pre-commercial release is as follows:

- The applicant must submit a notification[4] to the appropriate national competent authority of the Member State within whose territory the release is to take place.
- Using the information exchange system that has been set up by the European Commission, the competent authorities of the Member States send to the Commission, within 30 days of receipt, a summary of each notification received.
- The Commission must forward these summaries to the other Member States within 30 days following their receipt.
- Those Member States may present observations through the Commission or directly within 30 days.
- The national competent authority has 45 days to evaluate the other Member States' comments. If, as is typically the case, these comments are not in line with the national competent authority's scientific opinion, the case is brought to EFSA which has three months from receipt of the documentation to give its opinion.
- The Commission then presents a draft decision reflecting EFSA's opinion to the Regulatory Committee ("Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms") for vote.

[3] Directive 2001/18/EC of the European Parliament and of the Council

[4] The notification includes *inter alia*:

- A technical dossier supplying the information necessary for carrying out an environmental risk assessment.
- The environmental risk assessment and the conclusions, together with any bibliographical reference and indications of the methods used.

Complete details are provided in Article 6(2) of Directive 2001/18/EC.

- As is the case for placing biotech events on the market, draft decisions that have been put to the Regulatory Committee after March 1, 2011, are subject to the procedural rules outlined in the Lisbon Treaty. Under these rules, in the case of no qualified majority in favor of the draft decision, the Commission may either submit an amended draft to the Committee or submit the original draft to the Appeal Committee (comprised of senior officials from the Member States). If the Appeal Committee has neither adopted the draft decision nor opposed it by qualified majority within two months from the date of referral, it *may* be adopted by the European Commission. Post-Lisbon procedural rules give more discretion to the Commission. Previously, the Commission was obliged to adopt the draft decision. Under the new rules, the Commission has the option to adopt or not.

- **Timeline:**

In the past, applications for placing on the market and cultivating biotech events were submitted separately, and the respective authorization processes were carried out in parallel. It is now possible to submit both applications to EFSA for an integrated authorization process resulting in a single final decision.

EU legislation therefore provides for the observance of the following timeline:

- Upon receipt of a positive EFSA opinion, the European Commission has three months to secure a vote at the Standing Committee.
- If the Member States do not achieve a qualified majority for or against the approval, which is typically the case, the Commission is obliged to submit the approval proposal to the Appeal Committee within two months of the vote.

In practice, however, it takes an average of 46 months for a biotech product to be approved. Over one third of this time transpires after EFSA has issued its initial opinion which the European Commission puts into a draft decision for vote by the Member States. The Commission has waited 10 months on average as opposed to the prescribed three months before requesting Member States to vote.

Each year, more biotech applications have been submitted than authorization decisions made, creating a growing backlog both in EFSA and at the Commission. The slow pace of authorizations coupled with the absence of a commercially viable low level presence (LLP) policy creates problems even for traders exporting conventional products to the EU. Exporters have little confidence to trade because shipments could contain trace amounts of a biotech product, which had been approved in the country of origin, but not yet approved in the EU. In such cases, the shipment would be stopped at the EU border to prevent it from entering the EU market (see Section III j).

- **Evaluation of EU biotech legislation**

EU legal acts are typically reviewed and evaluated every five years to ensure their effectiveness. An evaluation of the biotech legislation on cultivation under Directive 2001/18/EC and food and feed under

Regulations (EC) No 1829/2003 and 1830/2003 was made between 2009 and early 2011. The resultant reports conclude that there is continued support for the principal objectives of the legislation: protection of health and the environment and the creation of an internal market for the sector. However, adjustments are needed to implement the existing legislation more effectively. The suggested adjustments include:

- More scope for Member States to decide whether to allow cultivation within their individual territories.
- The European Commission to table draft Decisions in a timely fashion.
- An effective means to address the adventitious and technically unavoidable presence of unauthorized biotech material. The reports note that maintaining a "zero tolerance" policy leads to more LLP incidents as the global use of biotech crops increases. In addition, notifying these incidents under the Rapid Alert System for Food and Feed, which is designed to be used for safety-related incidents, is seen as inappropriate by some stakeholders.

The response by Health and Consumer Policy Commissioner John Dalli to the reports' conclusions demonstrates that the problems in the EU on the rate of approvals are not caused by the way the legislation is written. He noted that the reports, "*…confirm that the problems of implementation of the GMO legislation do not stem from its design or its objectives…but rather from the way these sensitive issues are handled at a political level."*

Implementation of the legislation is a problem because risk assessments conducted by EFSA are not supported by all decision makers and influencers in Brussels and the Member States. The voting patterns of some Member States on biotech issues are not based on scientific evidence regarding the protection of health and the environment but on perceived political necessities. The results are inconsistent policy implementation and a prolonged decision making process.

The evaluation and a WTO panel ruling in 2006 against the EU concerning the *de facto* moratorium on biotech products would have reasonably prompted the EU to address some of the problems by amending the biotech legislation. However, as noted in the reports, the first preference for those most impacted at industry level by the slow rate of approvals is for the existing legislative framework to be implemented as drafted rather than be amended. Legislative amendments would be subject to agreement by the EU Parliament and the Member States in the EU Council. In the current environment, opening up the existing legislation would also reopen the debate with uncertain results.

Given these constraints, the Commission has chosen to introduce minor reforms that use other non-fundamental legislation or which are designed to minimize any changes to current law. Examples of this approach, which are addressed in more detail elsewhere in this report, include:

- The Commission's package presented in July 2010 designed to allow Member States to decide whether or not to cultivate approved biotech crops in their individual territories.
- The "technical solution" for LLP which defined "0" as "0.1 percent" in an amendment to other legislation that falls under Commission competence, and is not subject to co-decision by the Council and Parliament.
- The Commission's proposal in January 2012 to put EFSA's guidance on authorization

applications into binding legislation.

b) Biotechnology Crops Approved for Commercial Use

i. *Food, Feed, Processing*

A variety of biotech events are approved in the European Union for feed and food use under Regulation EC 1829/2003. The full list of approved products is available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

The list of biotech products pending renewal authorization under Regulation EC 1829/2003 is available on DG Health and Consumers' website. Review by the European Food Safety Authority may be searched from its website.

ii. *Environmental Release*

The full list of approved products is available on the European Commission's website at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

For the list of pending authorizations for environmental release under Directive 2001/18, see EFSA's website.

c) Field Testing of biotechnology Crops

The experimental release of biotech crops are subject to the provisions of Directive 2001/18/EC.

A separate application must be submitted for each field trial, and every approval is contingent on a comprehensive environmental safety assessment. The assessment considers the plant, the novel trait and the ecosystem in which the field trial takes place. Authorization is granted when current knowledge of the biotech plant cannot indicate any environmental risk.

When more experience with a particular biotech plant has been acquired, one application can cover field trials at more than one location. Under certain conditions, further test sites in other EU Member States can be reported without the need to authorize each individually, referred to in legislation as the "differentiated procedure."

An application for a field trial must be submitted to the competent national authority for the Member State in which the trial is set to take place. The accompanying documents must substantiate that the field trial does not threaten the environment and the surrounding ecosystem. The national authority decides whether or not to allow the field trial within 90 days of submission.

For every authorized field trial, the national authority provides the European Commission with a

summary communicating the most significant information in the application. The summary document is then made public. The public must be informed of all field trials and may comment in the decision within identified time frames.

d) Regulatory Treatment of multi-trait "stacked" events

In the EU, stacked events are also subject to risk assessment. The approval process is the same as for single events. Risk assessment of stacked events follows the principles provided in EFSA's Guidance Document, which stipulates that where all single events have been assessed, the risk assessment of stacked events should focus mainly on issues related to a) stability, b) expression of the events, and c) potential interactions between the events. EFSA will not review single events and stacks comprised of those events concurrently.

e) Additional Product Registration Prior to Use - Field Register

In **Austria, Belgium, Bulgaria, the Czech Republic, Denmark, France, Germany, Greece, the Netherlands, Portugal, Romania, Slovakia,** and **Slovenia,** farmers producing biotech crops must register their fields with governmental bodies. The specificity of these registration requirements varies greatly from country to country, and tends to discourage farmers from growing biotech crops, making fields easily accessible by protestors.

Despite the ongoing internal discussions there is no commercial GE crop field register or coexistence regulation enforced in **Spain**. Information available about commercial GE crops planting in Spain is the total area at the regional and national levels, which is calculated based on biotech seed sales records. It is publicly available at the Ministry of Agriculture, Food and Environment website.

f) Coexistence Policy

- *Member States with Coexistence Rules in Place: Austria, Bulgaria, the Czech Republic, Hungary, Portugal, Romania, Slovakia, and Sweden*

MS with GE crop cultivation and coexistence rules are the following:

The **Czech Republic** recently updated coexistence rules to remove administrative duplicities and add rules for future situations, such as growing GE soybeans. **Portugal** was one of the first countries to create legislation that recognizes the right of farmers to voluntarily associate and establish both GE Production Zones and GE-Free Zones. In **Romania**, co-existence rules between biotech, conventional and organic crops have been in place since 2006. Farmers take measures to avoid cross-breeding of GE plants with non-GE plants (with minimum isolation distance, separate storage, cleaning of machinery and transportation means). The coexistence rules in **Slovakia** require the farmers to notify neighboring farmers within the radius of minimal isolation distance of intent to cultivate GE plants in order to avoid

seed contamination between GE, conventional, and organic crops.

MS not producing GE crops but with coexistence rules are the following:

In **Bulgaria**, the major biotech law from 2010 imposes strict coexistence distances, prohibiting cultivating GE crops in all protected areas, and leaving no available place in the country for field trials or commercial production. In 2005, **Denmark** was the first EU MS to impose coexistence rules. In **Hungary** the 2006 Coexistence Regulation requires prior written consent requirements of all landowners and land users of the neighboring parcels and big isolation distances required between biotech and conventional or organic crop fields. In **Slovenia** there is a national coexistence law requiring farmers in GE production zones to fulfill legal obligations related to farming GE varieties (including training and notifying the State and adjacent farmers about their GE crop farming intentions). The **Swedish** Government adopted in 2007 its national framework for coexistence measures, detailed in June 2008 by the Board of Agriculture.

- *Member States Preparing Coexistence Rules: Belgium, Finland, France, Germany, Luxemburg, the Netherlands, and Poland*

The two **Belgium** regions, Flanders and Wallonia, are responsible for formulating and implementing coexistence policies. The regulations contain possibilities to impose "biotech free" zones, and a liability fund paid by the farmer planting GE crops. Sector sources believe that the combination of restrictions will practically ban the cultivation of GE crops in Wallonia. The approach of the **Luxembourg** Government towards the use and cultivation of biotech crops is as least as restrictive as the regulations imposed by the Walloon Government. **Finland** is currently preparing national legislation on coexistence.

France's High Council on Biotechnology, released its conclusions regarding biotech and non-biotech coexistence in December 2011, and a draft decree of the various Ministries involved was transmitted to the European Commission in January 2012, but no feedback was reported. There are records of many years of research on the conditions of biotech and non-biotech coexistence in France, which were the basis for the commercial cultivation of Bt corn until 2007. **Germany**'s approach to coexistence is complex and changing. German federal and local governments have put into place an assortment of planting bans, segregation distances, and other requirements. In June 2012, the Federal Ministry for Agriculture announced that it is planning to give the German Laender (regions) more competence for the planting of biotech crops, which could be the preliminary end for the planting of biotech crops.

In November 2004, the **Dutch** agricultural sector and NGOs jointly presented their coexistence agreement to the Ministry of Agriculture. An agreement on the scope of a compensation fund for possible damage to conventional and organic crops and a monitoring system in the field still needs to be reached. A compensation fund for potatoes has been established, but not yet for corn and sugar beets. Wageningen University is reportedly working on a monitoring protocol. Some sector sources believe that the combination of restrictions will practically ban the cultivation of GE events. **Poland** is proposing restrictive coexistence measures on the crops under new legislation, which is expected to be completed by early 2013.

- *Member States with no Coexistence Rules: Greece, Italy, Spain, and the United Kingdom*

This group is diverse, as it includes the strongest opponents to the technology (Austria, Greece, and Italy), the largest producer of Bt corn in Europe (Spain), and the MS the most ready to adopt the technology (the United Kingdom).

Austria has no federal coexistence law but all nine provinces implement precautionary bills that include coexistence regulation. Currently, coexistence is of little relevance to **Greek** farmers: the government has banned all GE crop events approved by the EU authorities, and most regions have declared themselves GE-free. In **Italy**, neither the central government nor the regions have established coexistence legislation. The issue is the subject of a seven-year series of legal battles.

To date, coexistence in **Spain** has been managed following the good agriculture practices promoted by the National Association of Seed Breeders (ANOVE), published on a yearly basis. This guide includes practical tips to facilitate production traceability, labeling, and coexistence. There are no coexistence rules in the **United Kingdom.**

g) Labeling for Packaged Food or Feed

- *EU Legislation:*

EU legislation requires all food and feed produced from or containing biotech events to be labeled as such.

Conventional food and feed that contains over 0.9 percent of biotech events adventitiously must be similarly labeled.
Regulation (EC) no 1830/2003 provides: *"…for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on the label*." For non-pre-packaged products, those words must appear on, or in connection with, the display of the product.

Regulation (EC) No 1829/2003 requires food and feed which contains in excess of 0.9 percent biotech events adventitiously to be labeled "*genetically modified*" or "*produced from genetically modified (name of ingredient).*"

- *Implementation by Member State:*

Member States implement aforementioned EU Regulations. The food industry and supermarket chains have generally reformulated to exclude potential GE ingredients (such as corn starch, soy lecithin or soy oil), and almost no foods have been sold at retail level labeled as GE products, due mainly to the worries of processors and distributors that they might be targeted by anti-biotech activists. Animal products

like meat, dairy and egg products derived from animals fed on GE ingredients are not required to be labeled by the EU legislation, despite the fact that imported biotech soybean meal is a major feed ingredient for most livestock and poultry. For example, most media and even anti-biotech groups are realizing that most typical **Italian** Protected Designation of Origin (PDO) products, come from animals fed with GE soybean meal.

Several Member States have put in place specific labeling rules in addition to the EU requirements. **Bulgaria**'s Food Law, amended in 2010, requires special labels on biotech enhanced foods when the threshold exceeds 0.9 percent with a clear identification of the exact quantity and type of the bioengineered event. This marking should be not less than 25 percent of the package, in capital letters and in contrast color.

- *Examples of Non-GE Labeling:*

France and **Germany** are now implementing specific non-biotech labeling. In **France**, voluntary "GMO-free" labeling has been implemented since July 1, 2012 (see France's Ministry of Economy website). The threshold of 0.1 percent is used for plant products under which they can be labeled as "GMO-free." For animal products (such as dairy, meat, fish, and egg products), two thresholds are set in the decree: 0.1 percent and 0.9 percent, to be indicated on the label, under which "Sourced from animals fed without GMOs <0.1%" or "Sourced from animals fed without GMOs <0.9%" can be labeled.

Prior to the implementation of this new biotech-free labeling, there has been several voluntary initiatives in the past, including Carrefour-branded products. Canned sweet corn has been sold with a specific "biotech-free" logo in order to prevent sales from declining, as consumers connected all corn with biotechnology).

Carrefour supermarket chain "fed without GMO, guaranteed at 99.1 percent" logo:

"Sweet corn without GMO" label on canned sweet corn sold in France:

Germany: In August 2009, the Ministry for Food, Agriculture and Consumer Protection introduced a

standard label to help consumers to better identify products and to standardize the information consumers receive. Food manufacturers can now use an official label on their products if they comply with strict requirements. The administration of this program is largely entrusted to the "Verband Lebensmittel ohne Gentechnik e.V." (non-Biotech Foods Association). As of May 2012, the Association claims that 103 companies are using the label. A private example for the use of non-biotech labeling as a marketing tool is "Landliebe" (Landlove), a popular German brand of dairy products sold by Campina GmbH. Campina, while targeted in the past for sourcing milk from farmers using biotech feeds, is now making biotech-free claims with its Landliebe milk, cream, butter, and yoghurt using its own label. Many other dairy products sold by Campina do not make biotech-free claims.

"Non biotech" label as introduced by German Ministry in 2009:

h) United Nations Cartagena Protocol on Biosafety under the UN Convention on Biological Diversity

The sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (MOP 6) will take place on October 1-5, 2012 in Hyderabad, India. See http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4715.

On June 11, 2012, the EU Environment Council adopted conclusions on the EU position for the October meeting. The Council stressed the importance of the full and effective implementation of the Cartagena Protocol on Biosafety by all parties. It also reaffirmed its support of the previously agreed means to achieve implementation of the Cartagena Protocol.

i) Position in Other International Treaties, Conventions or International Fora

Individual Member States generally express similar position on biotechnology in international fora.

In 2011, **France** chaired the G20, and took the initiative to introduce agriculture among the top issues discussed at the ministerial level. The Government of France had not considered food security as a strategic necessity until the G8 food security initiative in 2008. A meeting of the agriculture ministers

of the G20 countries took place in Paris and their conclusions were taken into account in the final meeting of the heads of state in Cannes in November 2011. The ministerial declaration adopted unanimously by the ministers of agriculture of the G20 called for "improved agricultural technologies" and "innovation in plant breeding" to "increase the agricultural production and productivity." Although not specifically indicated, plant biotechnology is part of these tools.

j) Trade Barriers Negatively Impacting U.S. Exports

- *Safeguard Clause:*

According to the Directive EC 2001/18, when a Member State, as a result of new information, has detailed grounds for considering that an approved biotech event constitutes a risk to human health or the environment, the Member State may invoke a safeguard clause on the biotech product; provisionally restrict or prohibit use on its territory.

The MS must ensure that in the event of a severe risk, emergency measures (including suspension or termination of the placing on the market, and provision of appropriate information to the public) are applied. The MS must immediately inform the Commission and the other MS of actions taken and give reasons for its decision. The MS must provide its review of the environmental risk assessment, indicate whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

Detailed Safeguard Clause by MS and by Event Banned			
Country	**Event Banned**	**Scope**	**Date of Ban**
Austria	Bayer T25 corn,	Cultivation	2000 (Amended 2008)
	Monsanto MON 810 corn	Cultivation	1999 (Amended 2008)
	Monsanto GT73 rapeseed	Import/Processing	2007 (Amended 2008)
	Monsanto MON 863 corn	Import/Processing	2008
	Bayer Ms8 rapeseed	Import/Processing	2008
	Bayer Rf3 rapeseed	Import/Processing	2008
	Bayer Ms8XRf3 rapeseed	Import/Processing	2008
	BASF EH92-527-1 potato	Cultivation	2010
Bulgaria	Monsanto MON810	Cultivation	2010
France	Bayer Rapeseed Topas 19/2	Import/Processing	1998
	Bayer MS1XRf1 rapeseed	Import/Processing	1998
	Monsanto MON 810 corn	Cultivation	2008, 2012
Germany	Syngenta Bt176 corn	Cultivation	2000
	Monsanto MON 810 corn	Cultivation	2009
Greece	Bayer Rapeseed Topas 19/2	Import/Processing	1998
	Syngenta Bt176 corn	Cultivation	1997

	Monsanto MON 810 corn	Cultivation	2001
	Bayer T25 corn	Import/Processing	1997
	Bayer MS1XRf1 rapeseed	Import/Processing	1998
	Monsanto MON810 corn	Cultivation	2010
Luxemburg	Syngenta Bt176 corn	Cultivation	1997
	Monsanto MON 810 corn	Cultivation	2009
Hungary	Monsanto MON 810 corn	Cultivation	2005
	EH92-527-1 Amflora Potato	Cultivation/Feeding	2010

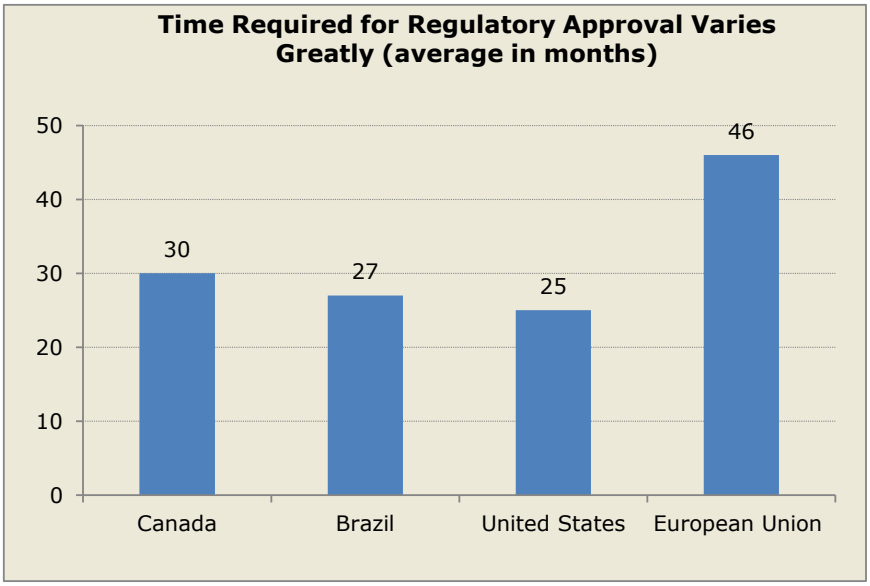
Source: FAS Posts

France's ban on MON810 has been challenged several times both by scientific (European Food Safety Agency - EFSA) and legal organizations (European Court of Justice). In November 2011, the French high administrative authority, Conseil d'Etat, lifted the ban imposed in 2008, based on the conclusions of the European Court of Justice. Nevertheless, the Government of France reinitiated the ban in March 2012, early enough to prevent farmers from planting, and only a few weeks before the presidential election. Many farmers were disappointed by this decision, as they enjoyed both agronomic and economic benefits from this commercial production before the ban.

The **Italian** Region Committee (representing Italy's 22 regions and autonomous provinces) recently requested the Ministry of Agriculture to invoke the safeguard clause to ban the cultivation of EU-approved GE crops in Italy. This is the second time the Regions have called on the Ministry to impose a full moratorium on biotech cultivation. The former Minister of Agriculture approved the first request and committed himself to invoke the safeguard clause, but did not follow through.

- *Delays in the EU Approvals of New Events, Resulting Asynchronous Approvals:*

The EU regulatory procedures for approving biotech plants take a significantly longer time than those in supplier countries. The EU takes 46 months on average for an import approval.



Source: EuropaBio

Differences in the speed of authorizations continue to lead to situations where products are approved for commercial use outside the EU but not within the EU. These asynchronous approvals result in severe risks of trade disruption since the EU applies close-to-zero tolerance for the presence of unauthorized biotech events in food and feed. Shipments of agricultural commodities destined for the EU have been rejected when minute traces of such events were detected at the point of entry. As a result, the EU animal sector is disadvantaged when not receiving much needed, low cost, high quality vegetable protein.

Delays in EU approvals of new events restrict the scope of biotech events present in feed and food products, and commercially grown products. The slow pace of approvals restricts the right for the industry to use the technology, and only exacerbates the polarization on one single product.

- *Level of Tolerance of Unapproved Biotech Events by EU Authorities:*

In the fall of 2009, shipments of around 180,000 metric tons of U.S. soy were denied entry into the EU because they contained traces of three biotech corn types that had not been approved by the EU but were approved in the United States. The situation prompted the European Commission to propose a 0.1 percent threshold for as yet EU unapproved biotech events in feed be allowed. In effect, this "technical solution" implied that the Commission chose not to introduce a practical policy that addressed the issue of LLP of unapproved biotech events in the EU, but rather to maintain its position on zero tolerance. The move allowed the EU to appear to tackle the issue without amending the basic legislation. The fact that the measure is limited to 0.1 percent renders it commercially unviable.

The resultant Regulation, Commission Regulation (EU) No 619/2011 which entered into force on July 20, 2011, is limited to feed material authorized for commercialization in a non-EU country and for which an EU authorization request for the biotech event in question has been lodged with EFSA for at least three months or for which the authorization has expired.

The European Commission committed to evaluate the impact of the "technical solution" on the food and feed chain, and received data from various stakeholders with a view to extending its scope to include food. A proposal that simply replaces "feed" in the existing legislation with "food and feed" would clearly result in the same constraints that currently apply to feed also applying to food.

- *Reformulation:*

Since the European regulation on biotech traceability and labeling for food and feed has been implemented in the EU, the food industry and supermarket chains have reformulated to exclude potential GE ingredients (such as corn starch or soy lecithin or soy oil), in order to avoid compulsory labeling.

- *Consideration of Socio-Economic Criteria:*

EU Authorities:

As requested by the Environment Council of December 2008, the European Commission reported to the European Parliament and Council in 2011 on socio-economic implications of biotech plant cultivation on the basis of Member States' contributions. This inconclusive report notes that, in general, the contributions reflect polarized opinions built upon a limited fact-based background, and influenced by the initial positive or negative perception of contributors. The core of the discussion demonstrates a wide range of different views on matters including the co-existence between biotech and conventional or organic approaches, impact on biodiversity, modification of farming practices, and marketability of products. Perhaps the most significant conclusion drawn from the report is that the present or future socio-economic impacts of biotech plant cultivation in the EU are often not analyzed in an objective manner.

In view of this, the Commission recommended that a methodological framework should be built to define the precise socio-economic indicators to be monitored and to establish appropriate rules for data collection. The Institute for Prospective Technical Research (IPTS) of the Commission's Joint Research Center (JRC) was requested to review for policy makers the main findings of scientists who are active worldwide in the field of socio-economic assessment. To respond to this request, the "International workshop on socio-economic impacts of genetically modified crops" was co-organized by the JRC-IPTS and Food and Agriculture Organization of the United Nations (FAO) in November 2011.

The resultant June 2012 report on socio-economic impacts of GE crops underlines that "the sustainability of the benefits over time will depend on the adoption of 'best agricultural practices,' either for conventional or GM crops, in particular to prevent the advent of any kind of resistance on weed or pests that will make technology fail." The report also concludes that "case studies covering different GM crops and countries indicate that the biotechnology sector captures 30 to 60 percent of the created benefits in developed countries. However, in countries with a lower degree of patent protection farmers capture 80-90 percent of the benefits." On coexistence costs, the report highlights that "the costs and feasibility of coexistence depend to a large extent on the threshold set for adventitious presence of GM

crops in non-GM production."

Member States:

The **Dutch** Government supports the use of socio-economic criteria for the approval of producing GE products for a more inclusive legislation. **France**'s High Council on Biotechnology includes two committees of equal importance when reviewing biotech products and issues: the socio-economic and ethics committee, and the scientific committee. This organization slows down significantly the reviewing process, as the committees usually disagree in their conclusions and recommendations on the biotech products they are in charge of reviewing. In practice, their diverging approaches are often difficult to reconcile.

k) Legislation in Place Addressing Intellectual Property Rights Issues in Case of Commercially Planted Biotechnology Crops

Biotech plants may be patented under **Directive 98/44/EC on the legal protection of biotechnological inventions.** The Directive has been implemented by all Member States since 2007.

The International Seeds Federation (ISF)'s position on intellectual property is that the most effective Intellectual Property (IP) system should balance a) protection as an incentive for innovation and b) access to enable others to further improve plant varieties. ISF's preferred form of protection for varieties is through Plant Breeders Rights (PBR).

The European Seeds Association (ESA) supports the co-existence of all IP rights. ESA asserts that the European Patent Convention (EPC) and Directive 98/44/EC stipulate that plant varieties as well as essentially biological processes for the production of plants are excluded from patentability and fully supports these exclusions.

l) Agenda on Biotechnology Issues: European Union specific legislation/registration requirements

Proposal to allow Member States to "opt out" of cultivating EU approved biotech crops:

EU legislation allows for MS to ban biotech products for scientific reasons in the "safeguard clause" of the legislation. Austria, France, Germany, Greece, Luxembourg, Bulgaria and Hungary have invoked a safeguard clause provided in EU legislation to impose national cultivation bans on MON 810 corn (see Section III j). However, EFSA has determined that these bans are not justified by scientific evidence, which is a precondition of using the safeguard clause. The EU has allowed the bans to continue despite the EFSA determinations.

As a response to this unsatisfactory situation and coupled with the aim of encouraging Member States to approve biotech products, in July 2010 the European Commission presented a package designed to allow MS to decide whether or not to allow the cultivation of approved biotech crops in their individual territories. The package consists of a "fast solution" and a proposal for a legislative amendment to the governing legislation. The "fast solution" essentially implies new guidance on isolation distances recommended to ensure co-existence between GE and conventional crops. Those MS that do not wish to cultivate GE crops are, in practice, able to use the new guidance to impose isolation distances which would effectively preclude the possibility of GE crop cultivation. As this does not imply legislative amendments, the Council and the European Parliament are not required to approve the measure which was applicable immediately. The proposal for a legislative amendment would allow a Member State to "opt out" of GE crop cultivation and requires approval by the Council and the Parliament. To date, no common position has been agreed between the Council and the Parliament.

Proposal to put EFSA guidelines for authorization into legislation:

On January 12, 2012, the European Commission presented a draft implementing Regulation to the Member States *on applications for authorization of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council.* The proposal is intended to be the basis upon which companies submit applications for biotech authorization and MS and EFSA assess the environmental risk of biotech plants. Although the Commission asserts that this draft regulation aims to reflect the existing guidelines for applications and assessments, there are significant differences that could create additional difficulties for the applicants and challenges the system itself.

Adventitious Presence for Seeds:

The EU has yet to establish or propose an adventitious presence (AP) threshold for seeds despite the fact that AP or technically unavoidable presence has always been a feature of conventional agriculture and is practically unavoidable. Low levels of seed of other crops or seed of plants from another variety have always been accepted in seed batches. AP of biotech seeds can occur in conventional seeds in the same way.

Beyond Recombinant DNA Technology: New Plant Breeding Techniques

The processed based nature of the EU's approach to biotechnology regulation requires the approval of each new novel plant breeding techniques that are currently being adopted. In its report, New Plant breeding Techniques - State of the Art and Prospect for Commercial Development, the European Commission's Joint Research Centre (JRC) Institute for Prospective Technological Studies (IPTS) notes, "Biotechnology companies and plant breeders are particularly concerned about the legislative uncertainty of the GMO classification of new plant breeding techniques" (NPBTs).

A working group established by the European Commission in 2007 is currently evaluating whether

certain new techniques constitute techniques of genetic modification and, if so, whether the resulting organisms fall within the scope of the EU biotech legislation. The group is discussing the following eight new techniques:

- Zinc finger nuclease (ZFN) technology (ZFN-1, ZFN-2 and ZFN-3)
- Oligonucleotide directed mutagenesis (ODM)
- Cisgenesis and intragenesis
- RNA-dependent DNA methylation (RdDM)
- Grafting (on GM rootstock)
- Reverse breeding
- Agro-infiltration (agro-infiltration "sensu strict," agro-inoculation, floral dip)
- Synthetic biology

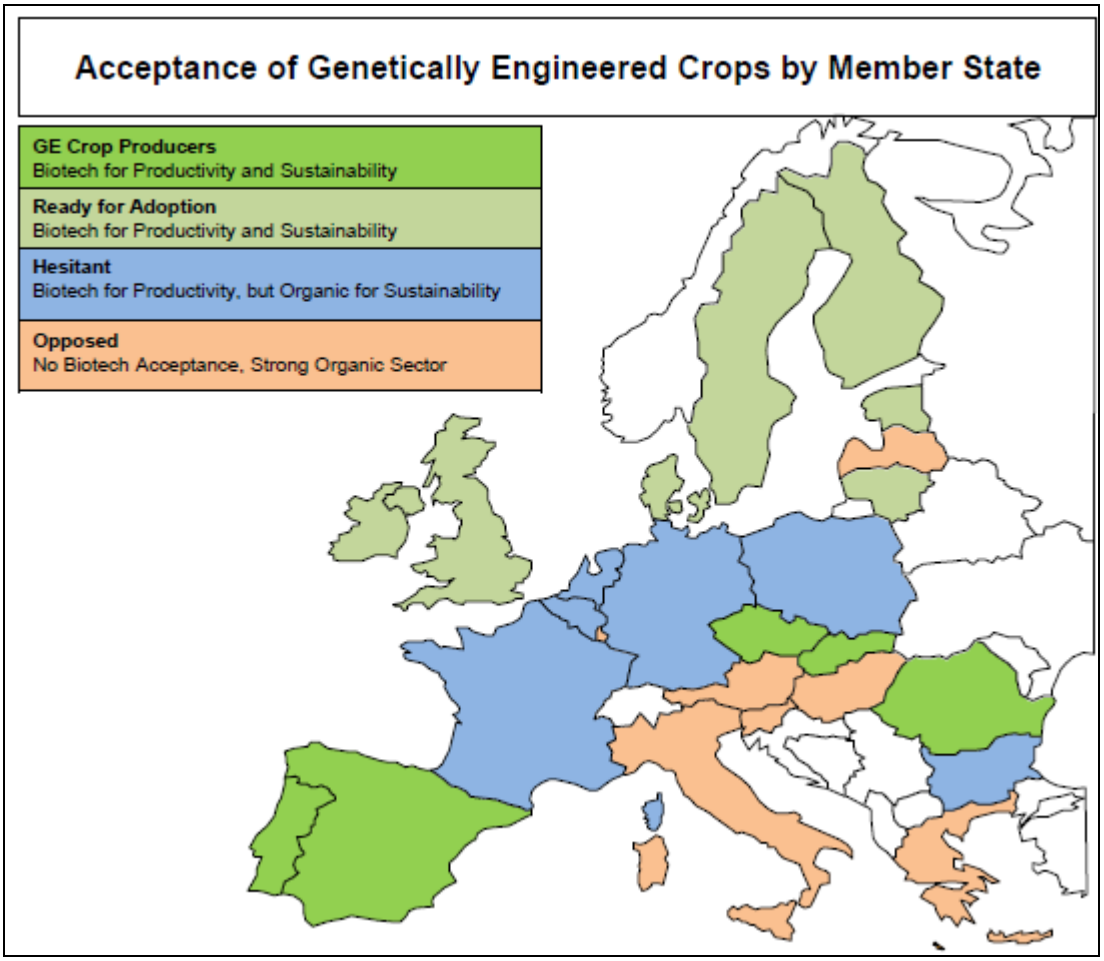
Should these or other new technologies be classified as 'GMO' it would further limit the technology options open to European farmers and would potentially disrupt EU trade with early technology adopters. The JRC organized a workshop on NPBTs in September 2011 in Seville, **Spain**, on the "Comparative Regulatory Approaches for New Plant Breeding Techniques" where approaches to these techniques by various countries were compared, including Argentina, Australia, Canada, the European Union, Japan, and South Africa.

Section IV. Plant Biotechnology Marketing Issues

a) Market Acceptance

Market acceptance of plant biotechnology varies among Member States and often suffers from the polarization of the public opinion on the single product currently commercially grown and one single company producing it. Undoubtedly, a wider range of biotech events approved would reduce the pressure on the product, now outdated by more modern technology using stacked events for example. In addition, a wider diversity of GE crops allowed for commercial cultivation in the EU would show a variety of possibilities of use of the technology on a more species than just corn, providing a wider range of characteristics than just insect resistance, and created by several private companies (including European ones) and public research organizations.

There are three categories of MS according to their domestic policy, farmer and industry approaches, and public opinion on biotechnology.



Source: FAS Posts

Group A – Countries considering biotech plant production contributes to increasing agriculture productivity and sustainability

Subgroup 1 – GE producers, most open to the technology:

This group includes the countries commercially producing biotech crops (Bt corn) in the European Union. **Spain** remains the leading producer, with a government open to the technology and a favorable public opinion. **Portugal, the Czech Republic,** and **Slovakia**, the second, third and fourth largest producers of Bt corn, have a pragmatic approach on biotech crop cultivation and research. **Romania** has a positive experience of growing GE soybean prior to accession to the EU, and acceptance remains wide among farmers, industry and policy makers.

Subgroup 2 – MS ready for adoption: Positive perception by the industry and non-opposition by the public opinion

Since a new government was formed, **Ireland** is now more on the same line as the **United Kingdom** regarding acceptance of agricultural biotechnology, and was changed from group B to Group A since

last year's report. Other MS belonging to this subgroup include **Denmark**, **Estonia, Finland**, **Lithuania,** and **Sweden**, which would all produce GE plants if authorized in the EU and if species and traits make sense to be grown in these countries.

Group B – Countries considering biotech plant production contributes to increasing agriculture productivity, and who favor organic agriculture to address agriculture sustainability

This group includes European countries where farmers and the industry are open to plant biotechnology, but where legislation is too restrictive and public opinion too hostile for adoption. The **Flanders region of Belgium** as well as the **Netherlands** are the most receptive to plant biotechnology in this group. In **Poland**, the government is increasingly opposed, and biotechnology is perceived as unhealthy, although there is unregulated production of Bt corn. In **Bulgaria** and **France,** farmers and the industry welcome plant biotechnology to increase their productivity, but face opposition against international agro-food companies in line with an anti-globalization sentiment, and governments hostile to agricultural biotechnology. In, **Germany** acceptance of the technology is shrinking, with the termination of all open field test plots, the leading agrochemical company BASF delocalizing its biotech activities out of the country, and plant science education narrowing to conventional breeding exclusively.

In all these MS, the opposition to biotechnology is generally connected to the acceptance and development of organic agriculture, perceived by consumers as the opposite of agriculture using biotechnology. As both biotech and organic agriculture aim to reduce pesticide inputs while maintaining high productivity, reconciling both types of practices into good agricultural practices would contributes greatly to making agriculture production more sustainable.

Group C – Countries with the strongest opposition to biotechnology

Organic agriculture looks like the main opponent to biotechnology in this group of countries, not only for consumers and government, but also for farmers, who choose organic agriculture in order to obtain public subsidies from the European Union.

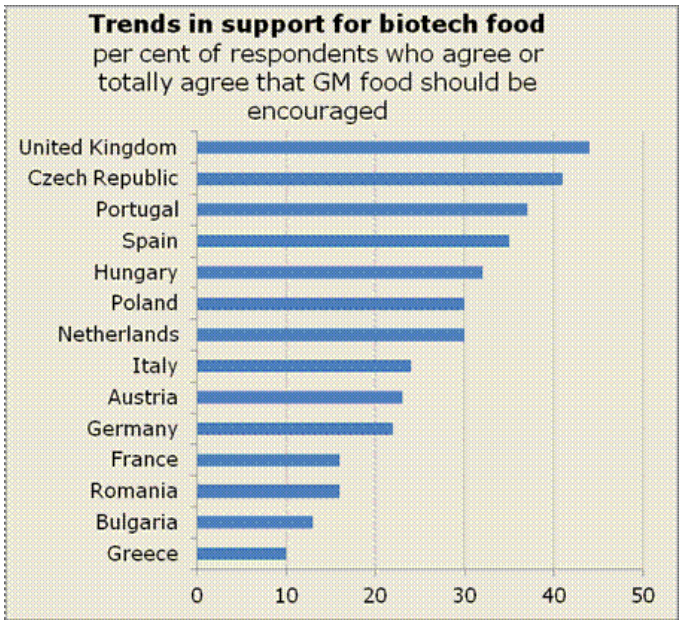
In these countries, the debate has been framed to oppose organic agriculture with agricultural biotechnology. **Austria** is a leading organic producer in Europe, and also the leading anti-biotech MS, where the government considers that small-scale organic farming must be protected. Austria's firm position against agricultural biotechnology has impacted **Hungary** and **Slovenia**. In 2011, Hungary became the second leading opponent to agricultural biotechnology, imposing private companies to destroy thousands of hectares of Bt corn. A patriotic, anti-globalization approach exacerbates anti-biotech perception in Hungary. Other members of this group include the **Wallonia region** of **Belgium**, **Luxemburg**, **Greece**, **Italy**, and **Latvia**.

b) Country-Specific Studies on the Marketing of Biotechnology Products

Eurobarometer:

The attitudes of European consumers to biotechnology show a great variation across MS. The European Commission, as well as national institutes and agencies, regularly conduct polls in order to assay the general tendencies of consumers. Polls show that many European consumers are skeptical but they have no ultimate opinion on the topic but demand for information, especially information about the safety of biotechnology. The latest Eurobarometer survey has shown that a majority of Europeans are optimistic about biotechnology (53 percent; 20 percent say "don't know").

The survey shows also differences among Member States regarding the support for food derived from biotechnology. Across the period of 1996-2010, there is a downward trend in the percentage of supporters. In 2010 the EU average opponent outnumbered supporters by three to one, and there was no country with a majority of supporters. The **United Kingdom** and **Czech Republic,** who showed the most support, are as much exceptions as **Greece** is at the bottom of the list. Generally, countries with a ban on GE crop plantings showed low values of support. Member States where GE crops are grown were more supportive.



Source: Eurobarometer

Consumerchoice Project:

This study, funded by the European Commission (and more specifically, the EU Framework Programme for Research) and coordinated by King's College London, UK, was conducted in 2006-2008. It was reported in the joint JRC/FAO report on socio-economic impacts of GM crops, released in June 2012. It addressed the question of whether consumers in the EU buy GE-foods when they are available on the shelves of grocery stores. The study involved ten Member States – the Czech Republic, Estonia, Germany, Greece, the Netherlands, Poland, Slovenia, Spain, Sweden and the UK – together with participation from organizations taking an EU-view both from consumer and industry perspectives. The study concluded that European consumers buy GE foods - when they have the opportunity.

Section V. Plant Biotechnology Capacity Building and Outreach

a) U.S. Government, USDA funded and Private Sector Capacity Building/Outreach Activities

In the European Union, FAS offices believe it is crucial to facilitate mutual knowledge and understanding between the United States and Member States by maintaining a close dialogue with public authorities, farmers, and industry groups. In 2011 and 2012, country-specific biotech outreach activities were conducted in **Bulgaria**, the **Czech Republic**, **France**, **Germany**, **Italy**, **Ireland**, **Romania**, and the **United Kingdom**. The meetings, visits and seminars for U.S. visitors (government, industry, farmer groups, research scientists) with European officials were aimed at facilitating bilateral information flow and understanding.

For example, soybean farmers traveling under the aegis of the International Soy Growers Alliance (ISGA) visited Brussels, Berlin, London and Paris in June 2012 to discuss the future of biotechnology with industry and Government representatives. ISGA represents the interests of soybean farmers from Argentina, Brazil, Paraguay, the United States, and Uruguay. In meetings with national interlocutors, the ISGA farmer representatives illustrated how their cultivation practices, combining no-till, crop rotation, and biotech seeds, have reduced environmental impact while contributing to increased productivity and exports. ISGA farmers expressed concerns about the EU's slow approval process of new biotechnology products, while the diversity of biotech soybean varieties is expanding.

For more information regarding these activities, please see the specific reports prepared by FAS offices in MS listed in the table below as well as FAS websites in MS. For example, the FAS/Paris website with events organized on biotechnology since 2010: http://www.usda-france.fr/biotechnology-437263-en.htm.

Reports Prepared by Member States Within the Past Year			
Member State/EU	**Date**	**Report Number**	**Title**
Austria	8/29/2011	AU1106	New Corn Parent Seed Facility
Belgium-Luxembourg	6/15/2012	BE2006	Agricultural Biotechnology Annual 2012
Czech Republic	6/15/2012	EZ1204	Agricultural Biotechnology Annual
EU-27	10/28/2011	E60060	Commission sets out working definition for nonmaterial
	7/10/2012	FR9102	Biotechnology – Food Security – Sustainability

France			in the Americas
	6/15/2012	FR9096	Agricultural Biotechnology Annual
	2/21/2012	FR9091	Non-Biotech Labeling Rules in Place and Proposed Rules on Coexistence
	2/9/2012	FR9089	Incentives and Plant Breeding Breakthroughs to Reduce Soy Imports
	1/30/2012	FR9081	2011 Biotech Outreach Program - Lessons Learned
	8/18/2011	FR9073	Agricultural Biotechnology Annual
	7/18/2011	FR9072	Paris - Innovation and Plant Biotechnology to Address Food Security
Germany	6/21/2012	GM12012	Agricultural Biotechnology Annual 2012
	12/14/2011	GM1029	Agricultural Biotechnology Annual 2011
Italy	7/9/2012	IT1224	Biotechnology in Italy in 2012
	7/6/2012	IT1223	Say Yes to GMOs or Italian Agriculture will suffer
	6/1/2012	IT1213	European Court Likely to Rule Italy's Biotech Authorization is Not Legal
	4/20/2012	IT1211	Regions Want Italy to Invoke the Safeguard Cause
	4/20/2012	IT1210	Italian farmer on trial for planting GM corn
	9/2/2011	IT1137	Italian Ministry of Agriculture Tests Seeds for GMOs
	8/22/2011	IT1131	Agricultural Biotechnology Annual
	7/11/2011	IT1127	Italy Intends to Invoke Safeguard Clause

Netherlands	6/11/2012	NL2017	Agricultural Biotechnology Annual
	8/15/2011	NL1014	Agricultural Biotechnology Annual
Poland	6/15/2012	PL1212	Agricultural Biotechnology Annual
Romania	6/20/2012	RO1214	Agricultural Biotechnology Annual
	8/22/2011	RO1006	Agricultural Biotechnology Annual
Slovakia	6/20/2012	LO1202	Agricultural Biotechnology Annual
	7/21/2011	LO1101	Agricultural Biotechnology Annual
Spain	6/21/2012	SP1221	Agricultural Biotechnology Annual
	10/11/2011	SP1119	MON810 Corn Area Reaches Record Level on the Iberian Peninsula
	9/8/2011	SP1116	Agricultural Biotechnology Annual
Sweden	5/29/2012	SW1202	Agricultural Biotechnology Annual

Note: all FAS GAIN reports are available on line at:
http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx

In addition, since 2006, FAS/Paris has published a multi-year newsletter of the United States and Agricultural Biotechnology, disseminated to approximately 400 contacts in France and internationally. This newsletter focuses on U.S. policy, economics, and science and is available at: http://www.usda-france.fr/biotechnology-437293-en.htm.

b) **European Union-Specific Needs or Strategies**

Plant Biotechnology to Boost Agricultural Productivity:

Plant biotechnology is generally perceived by scientists, farmers and the farm industry as a tool to increase productivity of the farm sector. There are many who point that the competitiveness of agriculture in Europe is in jeopardy as long as biotechnology is not adopted. For example, wheat yields in the EU are reportedly stagnating. All MS do not share this productivity objective for agriculture, but, as indicated in Section IV, a), MS with the largest share of EU agricultural production consider that plant biotechnology as a tool to boost agricultural productivity.

Plant Biotechnology to Address Agriculture Sustainability:

While governments, industry and consumers in the EU are increasingly sensitive to agricultural

sustainability, and measures are taken both by EU and MS authorities to make agriculture more sustainable (including good agricultural practices, reduced pesticide use, reduced pollution and green house gas emissions, renewable energies, organic), plant biotechnology is not a tool usually considered neither by policy makers nor by the public to address this issue. In fact, organic agriculture, which is often opposed to biotechnology agriculture (see Section IV, a), is often considered in the EU as the only way to make agriculture more sustainable.

Plant Biotechnology to Address Food Security:

Due to the history of European colonization and current patterns of trade, many countries in Africa look to the European Union when developing their regulatory requirements.

The OECD-FAO Agricultural Outlook 2012-2021, released in July 2012, considers plant biotechnology in its chapter "Achieving Sustainable Agricultural Productivity Growth" and states that "biotech crops can on the one side help farmers reduce the use of other inputs, thereby reduce input costs, and through increased productivity and predictability, improve farmers' output and incomes. On the other side, they can increase the cost of seeds and reduce the seed capital value of farmers. Since plant biotechnology is generally scale-neutral, the benefits may be more accessible to developing countries and smallholders in general."

The G20 conclusions in 2011 under France's presidency, as well as the commitment of the G8 in May 2012 on a "New Alliance on Food Security and Nutrition" may encourage EU countries to incorporate agricultural biotechnology as a key research, development, and innovation tool for achieving food security in the developing world.

Biotechnology to address world food security is an approach that many understand in the European Union, and are sensitive to. The media, the public, and sometimes, policy makers, are generally uninformed of the benefits of biotech crop production in emerging and developing countries and are eager to know more about it. Programs organized by FAS Posts in the EU linking plant biotechnology and food security have been a success. Biotechnology's benefits as a tool to addressing global food security have been diminished by the anti-biotech lobby which uses contrary messaging.

Section VI. Animal Biotechnology

I. Development and Use

a. *Use of Animal Biotechnology*

In several MS genetic engineering is not used in animals, while for the other MS, genetic engineering is used for medical or pharmaceutical applications.

In **Belgium,** GE animals are authorized for use as laboratory animal for medical research at universities and academic hospitals.

In **Denmark**, transgenic pigs have been developed at Aarhus University to be used in research on Alzheimer's disease. The pigs have been genetically modified to function as animal models for Alzheimer's disease. Thereafter, the pigs are cloned with the use of these somatic cells.

In **France**, animal biotechnology is mainly used by INRA in its Animal Genetics unit. The programs are conducted on the following three main themes: study of the structure of the genome, analysis of the phenotypic variability, and methods of population management. In January 2012, INRA published a report on its action on animal genetics improvement, describing the status of the current knowledge of animal genetic improvement on animals and its perspectives. In less than a decade, genetic animal breeding has significantly improved as a result of genomic selection.

In **Germany**, animal biotechnology is made only on basic science level, in "closed system" laboratories.

In **Austria**, scientific projects for pharmaceutical applications of animal biotechnology are carried out in closed systems. GE animals are authorized for use as laboratory animal for medical research at universities and academic hospitals.

In the **Netherlands**, 15 to 20 licenses are granted annually. The largest group of genetically modified animals is mice. The livestock sector does not keep genetically modified animals nor do agricultural research institutes for research purposes.

Genetic engineering for the development of farm animals is not being used in the **Nordic countries**.

Genetic engineering of farm animals is still at the development stage in **Poland**. Research on GE animals is very limited, and carried out in three research centers: Institute of Animal Breeding in Balice (Krakow), Institute of Animal Genetics in Jastrzebiec (Warsaw) and Agricultural University (Poznan). The leading animal GE laboratory of the National Institute of Animal Breeding in Balice near Krakow concentrates on production of animal (swine) for xenotransplantations. Most of the work concentrates on reduction of species-specific immunological difference and decrease of risk of xenograft rejection. Polish scientists from Balice produced a transgenic boar, TG 1154.

In **Spain,** there is no known research of development of GE animals for the food market. The Ministry of Environment and Rural and Marine Affairs keeps track of the GE animals used in confined facilities and publishes a complete list on their website. GE animal research since 1992 consists on mice, hogs and fish for medical purposes. Research in this field is carried out by both public and private research centers.

In the **UK,** the universities of Cambridge and Edinburgh announced in early 2011 that they had created a biotech chicken that will not pass on the avian influenza virus to other birds, thereby preventing outbreaks spreading through poultry flocks. The researchers also claim that if introduced into commercial poultry flocks, the trait has the potential to increase the production of poultry meat and eggs by protecting the health of the birds. The study was published in the journal *Science* and publicly

funded by the Biotechnology and Biological Sciences Research Council (BBSRC).

b. *Commercial Production*

There is no GE animal commercially produced in the European Union.

II. Regulation

On January 26, 2012, EFSA published its "Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects[5]." This document provides guidance for the risk assessment of food and feed containing, consisting of or produced from GE animals, as well as for the health and welfare assessment of these animals, within the framework of Regulation (EC) No 1829/2003 on GE food and feed. The outcome[6] of the public consultation on the draft Scientific Opinion for this guidance was published February 2012.

EFSA is still working on a similar guidance document on the risk assessment relating to the safety of releasing GM animals bred for food and feed purposes into the environment.

EFSA has set up a webpage on Genetically Modified Animals[7] that keeps track of the progress of the work on GE animals, as well as providing the relevant documents and reports. To date, EFSA has not received any applications on GE animals.

III. Stakeholder/Public Opinion

There is little visibility of animal biotechnology in the public opinion, which generally considers it as a non-issue.

IV. International Organizations

N/A.

V. Outreach, Needs and Strategies

There have been no recent activities conducted on animal biotechnology in the European Union.

[5] http://www.efsa.europa.eu/en/efsajournal/pub/2501.htm
[6] http://www.efsa.europa.eu/en/supporting/doc/226e.pdf
[7] http://www.efsa.europa.eu/en/topics/topic/gmanimals.htm