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Agricultural Biotechnology Annual

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Report Highlights:
In the European Union (EU), governments, the media, non-governmental organizations, consumer groups, and industry associations remain conflicted about the use of agricultural biotechnology. Acceptance varies greatly among adopters, the conflicted, and opposed Member States (MS). EU and MS authorities have developed a complex and lengthy policy framework for plant and animal biotechnology that slows down and limits research, development, production, and imports. Nevertheless, the area planted to GE corn continues to expand in five MS, and the EU is a major consumer of biotech products, with millions of tons of GE soybean and corn products imported every year. The growing adoption of the technology by leading agricultural producer countries makes it increasingly difficult and expensive for EU companies to source non-biotech products and ingredients for food products that are labeled as 'non-GMO'.

SECTION I: EXECUTIVE SUMMARY

Until the 1990's, the European Union (EU) was a leader in research and development of genetically engineered (GE) plants, with both major public research institutions and private groups involved in agricultural biotechnology. EU and Member State (MS) authorities have developed a complex and lengthy policy framework, driven by well-orchestrated anti-biotech actions by non-government organizations (NGOs). As a consequence, research, development, and commercial production and imports of biotech products into the EU have been slowed and limited.

Despite the European Commission's priority for a sustainable bioeconomy in Europe that includes biotechnology, regulatory constraints and pressure by anti-biotech advocacy groups have significantly reduced research. Programs are often limited to basic research inside the laboratory in both plant and animal biotechnology and have discouraged open-field testing initiatives. In the past few years, several major private developers have left the EU to conduct experiments in other regions where their work is not in danger of being vandalized. Still, in 2013, open-field testing is being conducted in nine Member States on a variety of biotech crops.

Commercial cultivation of biotech crops is minimal in the EU, as a result of strong regulatory constraints. There are only two GE plants approved for cultivation, eight MS are currently imposing national ban on the GE corn approved, and most MS implement restrictive national coexistence rules and seed registration systems. Nevertheless, the GE corn approved for cultivation is being grown on 138,000 hectares in 2013, mostly in Spain, where it accounts for 30 percent of the corn area. Other producers include Portugal, the Czech Republic, Slovakia, and Romania. France, Germany, and Poland used to produce GE corn, as well, but have imposed national bans and production had dropped to zero. There are no GE animals commercialized in the EU, but cloned sport horses are being developed and produced by a French company in collaboration with the Italian industry.

The EU is a major importer of agricultural products derived from biotechnology, mainly for feed use. The EU is a major livestock producer and has a structural shortage of feed protein. The primary category of biotechnology-derived products imported consists of soybean products. About 70 percent of soybean meal consumed in the EU is imported and 80 percent of this meal is produced from GE soybeans. On average, EU imports of soybean meal and soybeans amount to $9 billion and $6.5 billion per year, respectively. The United States is the EU's second largest supplier of soybeans after Brazil and the third largest supplier of soybean meal after Brazil and Argentina.

The second largest category of products imported into the EU of a biotech origin is corn products. Unlike soybean products, the EU production is sufficient to meet most of its own corn consumption, with imports accounting for only 10 percent of total supply. Annual EU imports of corn products include $1.8 billion of corn, $151 million of corn planting seeds, and $87 million of dried distillers grains (DDGs). The United States used to be a major supplier of corn to the EU in the 1990's, but exports have collapsed since then. For significantly smaller markets, such as corn planting seeds and DDGs, the United States is a major supplier to the EU. The share of biotech in corn products imported from all countries is estimated at 25 percent.

Finally, the EU imports $59 million in bovine semen every year. A little more than half is supplied

by the United States with most of the remainder coming from Canada. These imports have the potential of being derived from cloned animal offspring.

Several policy factors are barriers to trade of biotech products entering the EU. The slow pace of approvals of new biotech products results in asynchronous approvals of products approved for commercial use outside of the EU but not within the EU. Currently, a 0.1 percent technical solution is used for the low-level presence in feed. The consideration of socio-economic criteria by biosafety authorities in MS when evaluating biotech products may also negatively impact trade, slowing the approval process further.

Another significant barrier to import of biotech products into the EU is the biotech labeling regulation in place since 2003. It requires that all food and feed produced from or containing biotech events be labeled as such. Conventional food and feed that contain over 0.9 percent of biotech events adventitiously must be similarly labeled. Many food manufacturers and distributors have reformulated in order to avoid such labeling, in fear of reduced purchases by consumers and negative publicity by NGOs. In addition, there are voluntary negative labeling (biotech-free" logos) initiatives in place in several MS. These include national systems in Austria, France and Germany, and private initiatives in a wider range of MS. Products involved include corn, soybean, meat, dairy products, and eggs.

There are three major categories of MS according to their acceptance the technology (see map in Part C). First, the "*Adopters*" include countries producing GE corn and MS who could be producers of GE crops, if the scope of crops approved for cultivation in the EU were wider and included crops with traits of interest for their farmers, industry, and/or consumers. Governments and industries in this group are generally pragmatic. Second, the "C*onflicted*" group includes countries where forces willing to adopt the technology (mainly the science community, farmers and the feed industry), are counterbalanced and usually out matched by forces rejecting it (consumers and governments, under the influence of active green parties and NGOs). Third, the "*Opposed*" group consists of MS where most stakeholders and policy makers reject the technology. Organic and products with geographical indications represent a significant part of food production in these countries. Market acceptance of animal biotechnology is low in the EU among policy makers, industry, and consumers, mainly due to ethical and animal welfare concerns.

Notes:

- Croatia joined the EU on July 1, 2013, and is the EU's 28th Member State. EU MS are mapped in annex 1.
- Reports referred to in this report and prepared by USDA/Foreign Agricultural Service Posts in the EU are listed in annex 2.

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Acronyms used in this report are the following:

CGF: Corn Gluten Feed
DDGs: Dried Distillers Grains
DGSANCO: EC's Directorate General Health and Consumers
EASAC: European Academies Science Advisory Council
EC: European Commission
EFSA: European Food Safety Agency
EGE: European Group on Ethics in Science and Technology
ENVI: European Parliament - Environment, Public Health and Food Safety Committee
EU: European Union
FAS: Foreign Agricultural Service (an agency of the U.S. Department of Agriculture)
GAIN: Global Agriculture Information Network
(a resource offered by USDA/Foreign Agricultural Service)
GE: Genetically Engineered (official terminology used by the U.S government)
GM: Genetically Modified
GMO: Genetically Modified Organism
(official terminology used by the EU, and used here when citing official references)
RACE: "GMO Risk Assessment and Communication of Evidence" research project
INRA: France's National Institute of Research in Agriculture
JRC: European Commission's Joint Research Center
LLP: Low Level Presence
MS: Member State of the EU
MT: Metric Ton
NGOs: Non-Governmental Organizations
NPBT: New Plant Breeding Techniques (terminology used in the EU)
OECD: Organization for the Economic Cooperation and Development
OIE: World Organization for Animal Health
RASFF: Rapid Alert System for Food and Feed
SCoFCAH : Committee on the Food Chain and Animal Health
TTIP: Transatlantic Trade and Innovation Partnership
UK: United Kingdom

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SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Europe has given rise to world-class public and private developers in agricultural biotechnology. On June 19, 2013, the World Food Prize was attributed to three distinguished scientists who developed the science of modern plant biotechnology, opening doors to improved agricultural crops that can feed the world more effectively and sustainably. One of the winners was Marc Van Montagu of Belgium. For more information, see here.

Major private European developers include BASF, BayerCropScience, KWS, Limagrain, Syngenta, and which conduct research for and supply genetically engineered (GE) seeds to markets outside 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 high costs and lack the procedural expertise needed to complete the European Union (EU) regulatory approval system.

- **EU Research Perspectives**

In April 2013, the European Commission's (EC) Joint Research Center (JRC) released a report named "Plant Breeding for an EU bio-based economy – The potential of public sector and public/private partnerships" (http://ftp.jrc.es/EURdoc/JRC80822.pdf), signed by several authors of the JRC and institutes based in several Member States (MS), i.e., **Belgium**, **France**, **Italy**, the

Netherlands, and **Spain**. The report concludes that "it can hardly be envisaged that in the current conditions of resources and funding the public conventional plant breeding sector could deliver the new varieties with the traits required for fulfilling the needs of the EU bioeconomy strategy 2020, for which private plant breeding is not investing enough. While the private plant breeding sector is concentrating on "cash crops" and is not investing enough on new varieties including traits required for fulfilling the needs of the EU bioeconomy strategy 2020, current public resources and capacities are too scarce to fully fill sectors not sufficiently covered by the private sector. However the new models of public/private partnerships aiming at covering all research and development stages (from genomics to variety release) are a positive development as they will help targeting breeding of minor crops and developing new traits of interest for which business opportunities are not (yet) established: public-private partnership to foster emergence of varieties that include new traits of interest."

This report follows the adoption by the European Commission of a Strategy for a Sustainable Bioeconomy in Europe in February 2012. See 2012 GAIN annual EU biotech report for more information.

- **International Projects:**

International Wheat Initiative:

The Group of Twenty (G20), created in 1999, is the premier forum for international cooperation on the most important issues of the global economic and financial agenda. Members of the G20 include 19 countries and the EU.

During France's Presidency of the G20 in 2011, the action plan of the G20 Agricultural Ministries created the Wheat Initiative (http://www.wheatinitiative.org). The Wheat Initiative is an international consortium gathering public institutions and private companies to coordinate global wheat research. European institutions and private companies are involved from **France**, **Germany**, **Italy**, **Spain** and the **United Kingdom (UK)**. On May 2013, the issued a vision document, paving the way for action. This document specifically indicates the use of biotechnology: "Increasing wheat production without agricultural expansion implies that we must increase wheat production on existing agricultural lands. This could be achieved partly by improving wheat yield genetic potential through a better understanding of the physiological traits involved and their interactions with the environment, and via their complementary introduction into new varieties by breeding and/or genetic manipulation."

International Barley Sequencing Consortium:

The International Barley Sequencing Consortium (IBSC), whose objective is to physically map and sequence the barley gene space, was founded in 2006. The European MS represented by the scientists involved include **France**, **Finland**, **Germany** and **the UK**. In October 2012, IBSC published "A physical, genetic, and functional sequence assembly of the barley genome" in the journal *Nature*.

International Peach Genome Initiative:

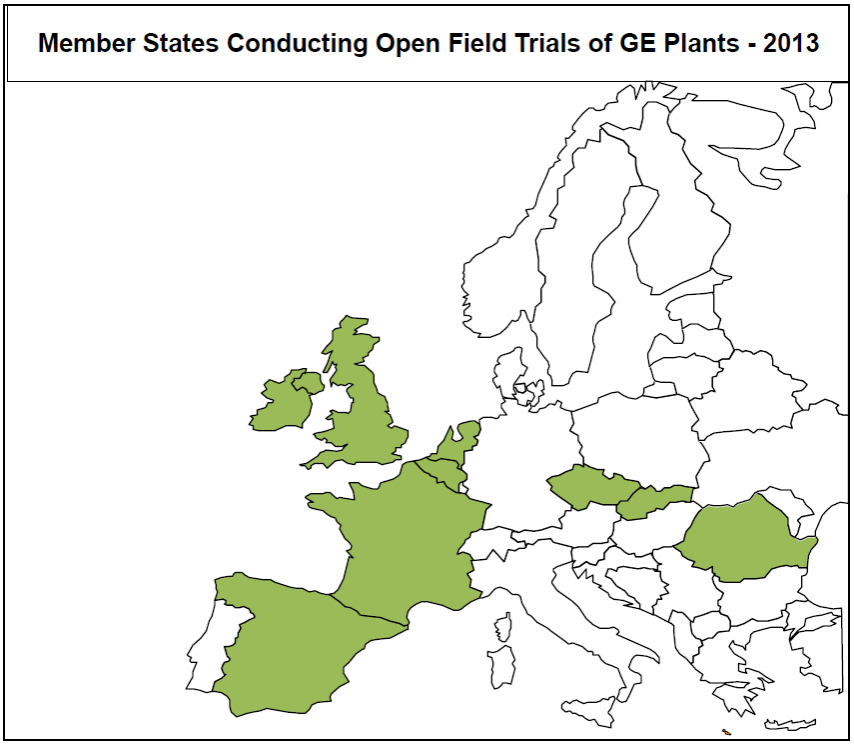
In March 2013, the International Peach Genome Initiative published the peach genome (see here for more information). This initiative is a consortium of international scientists from Universities and research centers located in five countries, including three in Europe: **France**, **Italy**, and **Spain**.

- **Open Field Testing**

The JRC maintains a list of the notifications by institute or company (by MS and by project) of the deliberate release into the environment of GE plants on this website: http://gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx. There may be fewer projects actually conducted in MS than those notified on this website.

Despite the vocal pressure of anti-biotech activists against transgenic plant development, nine MS conduct open-field testing on a variety of biotech plants: **Belgium, Czech Republic, France, Ireland, Romania, Slovakia, Spain, the Netherlands,** and **the United Kingdom** (see map below). Tested plants include barley, corn, cotton, flax, peas, plum, poplar, potato, sugar beet, tobacco, tomatoes, and wheat. For more information, see the annual biotech reports prepared by the countries aforementioned.

Portugal is a major producer of GE corn in the EU. Open field testing is permitted but there has been no notification since 2010.



Source: FAS Posts

b) COMMERCIAL PRODUCTION

The two genetically engineered (GE) crops authorized for cultivation in the EU are MON810 corn and the Amflora potato. Only GE corn, however, is commercially grown. It is a Bacillus thuringensis (Bt) corn resistant to the European corn borer (a pest).

Currently, there are five MS commercially cultivating GE corn: **Spain, Portugal, the Czech Republic, Slovakia,** and **Romania** (see map below). While MON810 corn is approved for commercial cultivation in the entire EU, several MS have implemented national bans on this product, including major corn producers. It is the case of **France** and **Germany**, both significant Bt corn producers in the past, but where production stopped when they implemented national bans. **Poland** was a producer of Bt corn until 2012, but banned cultivation in January 2013.

Austria, Hungary and **Italy** are also significant corn producers in the EU (see Eurostat map of corn production below) but have never commercially grown Bt corn, as they belong to the group of countries most opposed to agricultural biotechnology and as such, also implement national bans on MON 810 corn.

See Part F- Policy – Trade barriers section for more details on national bans, and Part G – Marketing – Public/Private opinions for more information on biotech acceptance across the EU.

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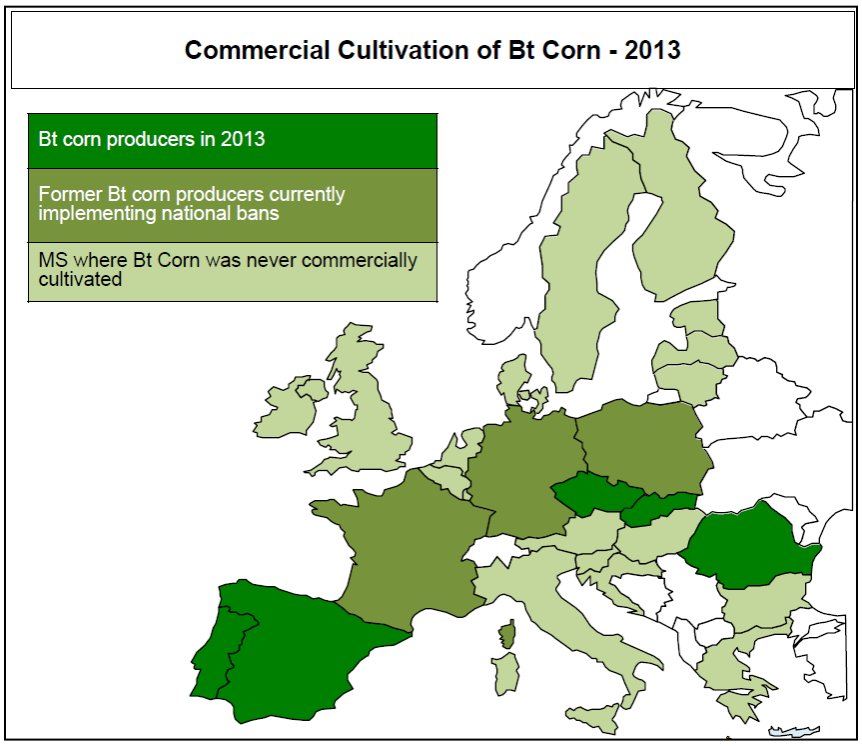
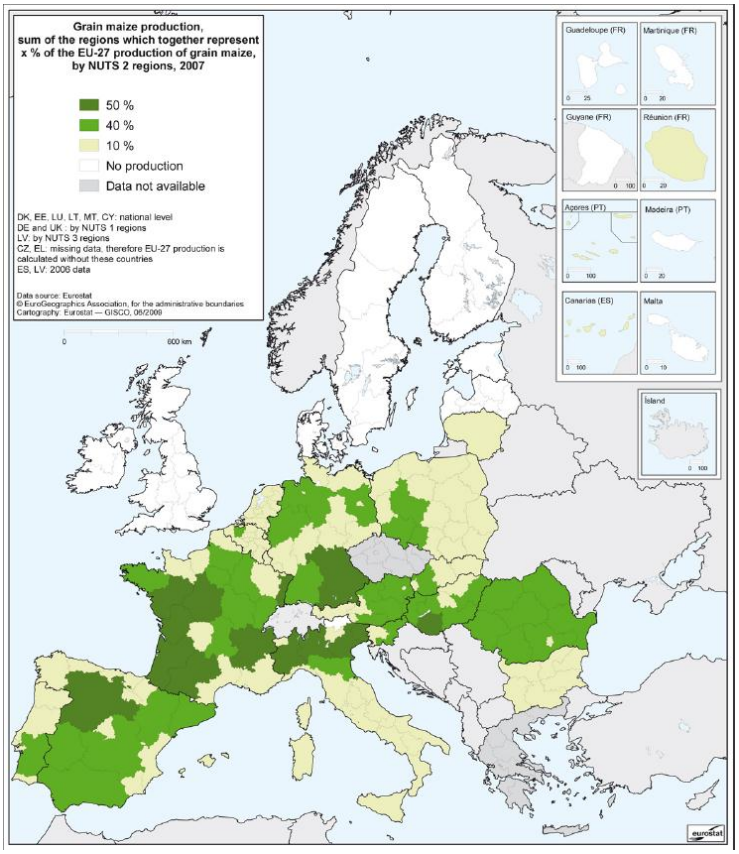


Source: FAS Posts



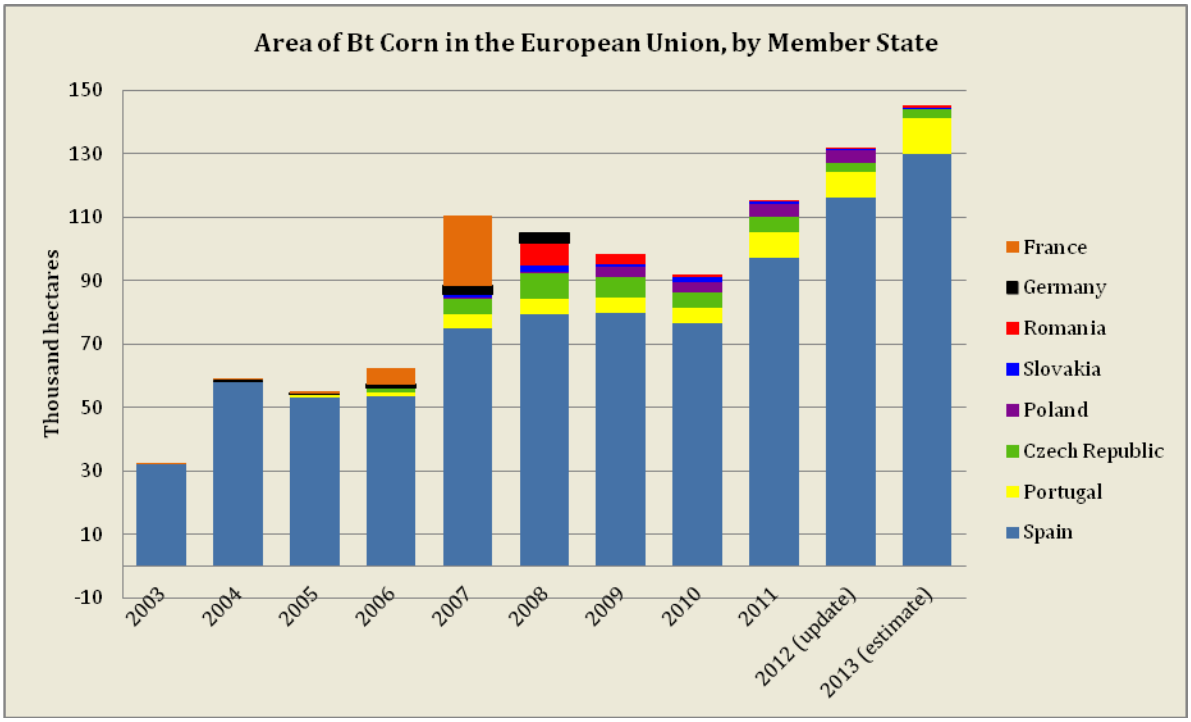
Source: Eurostat

Spain is the leading GE corn producer in the EU, with about 90 percent of the total area planted to Bt corn (see map and table below). While the Bt corn area is minimal in Europe, with less than two percent of the total corn area, it accounts for more than 30 percent of Spain's production. Record crops were grown in 2012 in Spain and **Portugal**, and further increases are expected in 2013 in both countries. For further explanation of cultivation trends by MS, please see country reports. **Poland** has stopped cultivating Bt corn in 2013, implementing a national ban on MON810. **Portugal**, the **Czech Republic**, **Slovakia** and **Romania** are the other producers of Bt corn in the EU.

EU-28 area on GE Corn by Selected Member States (in hectares)											
MS	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012 (update)**	**2013 (estimate)**
Spain	32,249	58,219	53,226	53,667	75,148	79,269	79,706	76,575	97,346	116,307	125,000
Portugal	0	0	730	1,254	4,199	4,856	5,094	4,869	7,724	7,700	10,000
Czech Republic	0	0	250	1,290	5,000	8,380	6,480	4,678	5,090	3,050	2,800
Poland	0	0	0	100	100	300	3,000	3,500	3,900	4,000	0
Slovakia	0	0	0	30	930	1,930	875	1,281	760	189	100
Romania	0	0	0	0	331	7,146	3,400	822	588	217	834
Germany	0	500	342	947	2,685	3,171	0	0	0	0	0

France	17	17	500	5,200	22,135	0	0	0	0	0	0
Total GE corn acreage	32,266	58,736	55,048	62,488	110,528	105,052	98,555	91,725	115,408	131,463	138,734
Total Corn Acreage (1,000 ha)	9,138	9,677	9,169	8,492	8,444	8,854	8,284	7,984	9,100	9,700	9,550
Percentage GE corn / Total Corn	0.35%	0.61%	0.60%	0.74%	1.31%	1.19%	1.19%	1.15%	1.27%	1.36%	1.45%

Source: FAS Posts



Source: FAS Posts

BASF's Amflora potato is the other GE plant approved for cultivation in the EU, since March 2010. It was grown on 225 hectares in the **Czech Republic, Sweden**, and **Germany** in 2010 (see following table), but 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, citing poor and deteriorating attitudes toward GE crops and poor marketing prospects in Europe. Please see Germany's 2013 annual GAIN biotechnology report for more information.

EU-27 Area of GE Potato by Selected Member States (in hectares)				
Member State	**2010**	**2011**	**2012 (update)**	**2013 (estimate)**

Sweden	150	0	0	0
Czech Republic	147	0	0	0
Germany	15	0	0	0
Total Amflora Potato Acreage	225	0	0	0

Source: FAS Posts

c) EXPORTS

The EU does not export GE crops/products. Each MS producing Bt corn uses it in its own domestic consumption, principally as animal feed (**Spain**, **Portugal**, **Romania**), and as feedstock for biogas production (**Czech Republic** and **Slovakia**).

d) IMPORTS

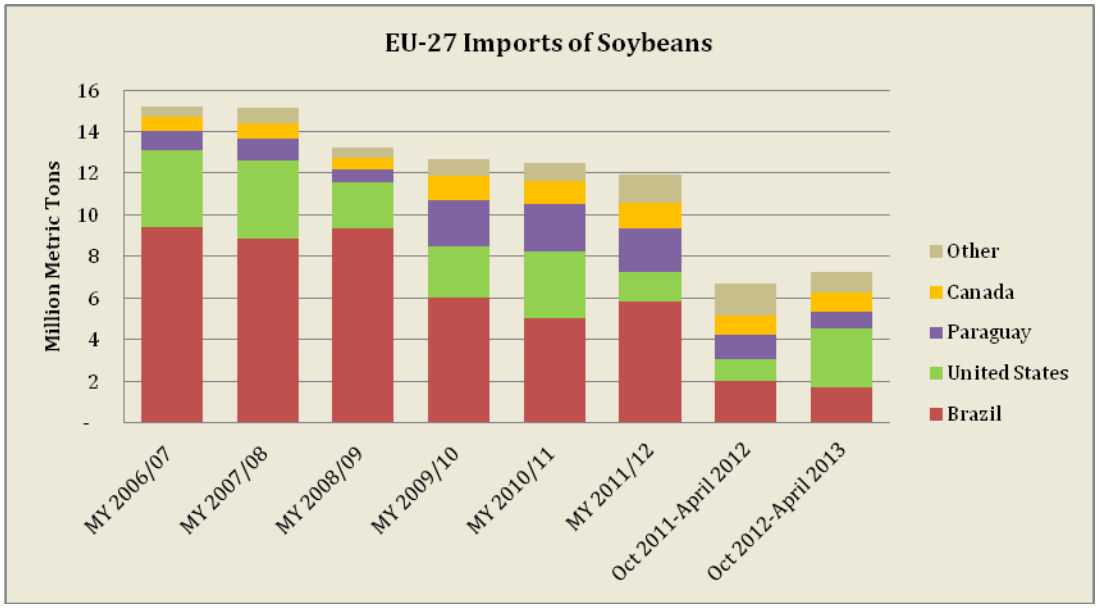
Most of the EU imports of biotech products consist of animal feed ingredients, mainly including soybean meal and soybeans.

- Soybean Products

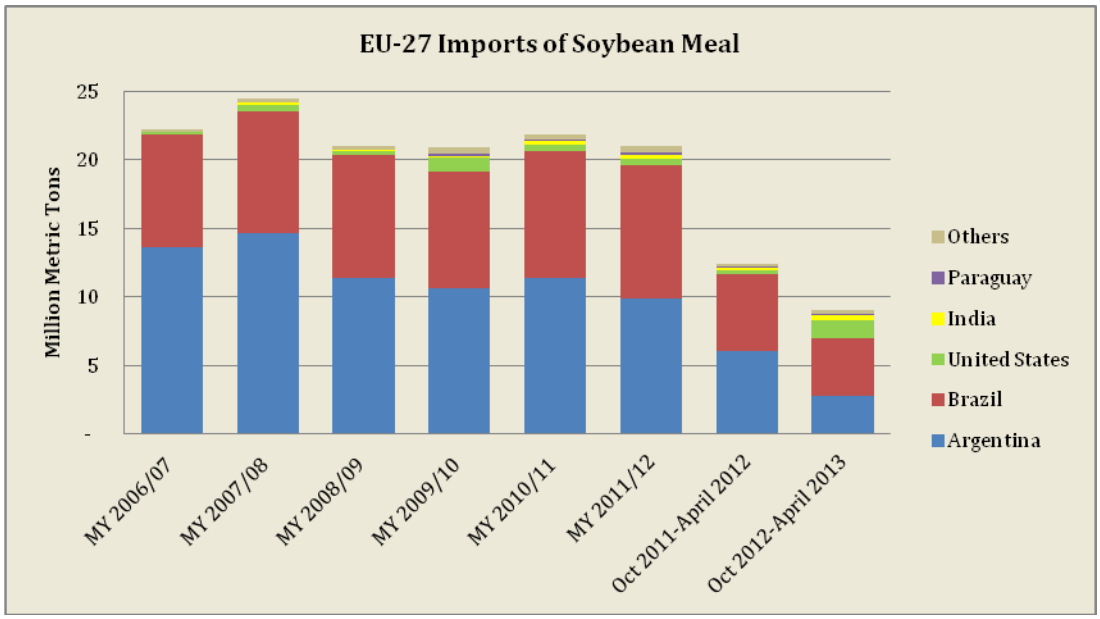
The largest category of GE products consumed by MS consists of soybean meal, which is the primary source of proteins for livestock. EU meat producers are dependent on imports of soybean and soybean meal from the Americas.

On average, 32 million metric tons (MT) of soybean products are consumed annually in the EU, with soybean and soybean meal imports averaging 12 and 20 million MT, respectively (see graphs below). 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. For more information on the EU oilseeds markets, see the 2013 annual EU oilseeds report AU13002.

The EU's leading suppliers of soybean products are also the world's largest producers of GE soybeans. The demand for non-biotech soybean meal in MS is estimated at 20 percent, but varies among MS and is mainly supplied by domestically grown soybean and imports from Brazil and India. India is a minor supplier of soybean meal to the EU compared to Brazil and Argentina. However, the EU has become one of India's top export destinations for soybean meal, mainly due to the high premium for non-biotech soybean meal, which is Euros 60-70 per MT or roughly a 13 percent premium to normal soybean meal prices.



Source: Global Trade Atlas



Source: Global Trade Atlas

- Corn Products

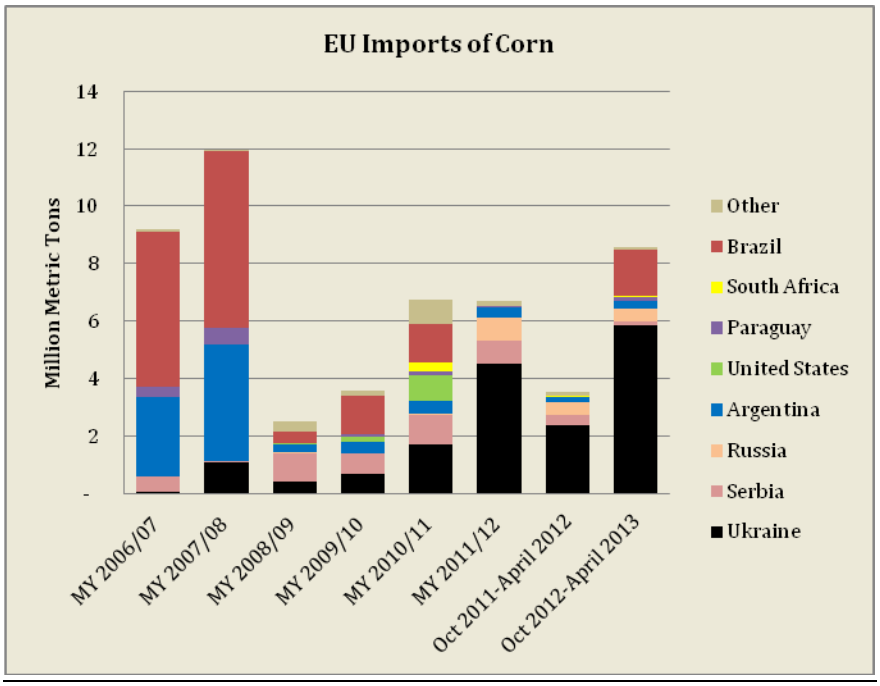
While the EU imports most of its demand for soybean products, it imports roughly 10 percent of its corn consumption. The annual EU corn consumption amounts to 62 million on average and more than 90 percent is supplied by local production. The share of GE products out of total corn consumption is estimated to be lower than 25 percent. Spain totals half of EU corn imports, followed by The Netherlands and Portugal. Please see Spain's 2013 annual GAIN biotech report for more information. While U.S. exports of corn to the EU fluctuated between two and four million metric tons (MMT) per year until 1997, they have been limited to a maximum of 400,000 MT

annually since then, except in 2010/11 (see graph below). The beginning of GE corn plantings in the United States caused a drastic decline in U.S. corn exports to the EU due to asynchronous approval (i.e., approvals in the U.S. occurring before approvals in the EU) of biotech events. The United States is no longer a major supplier of corn to the EU (see graph below).

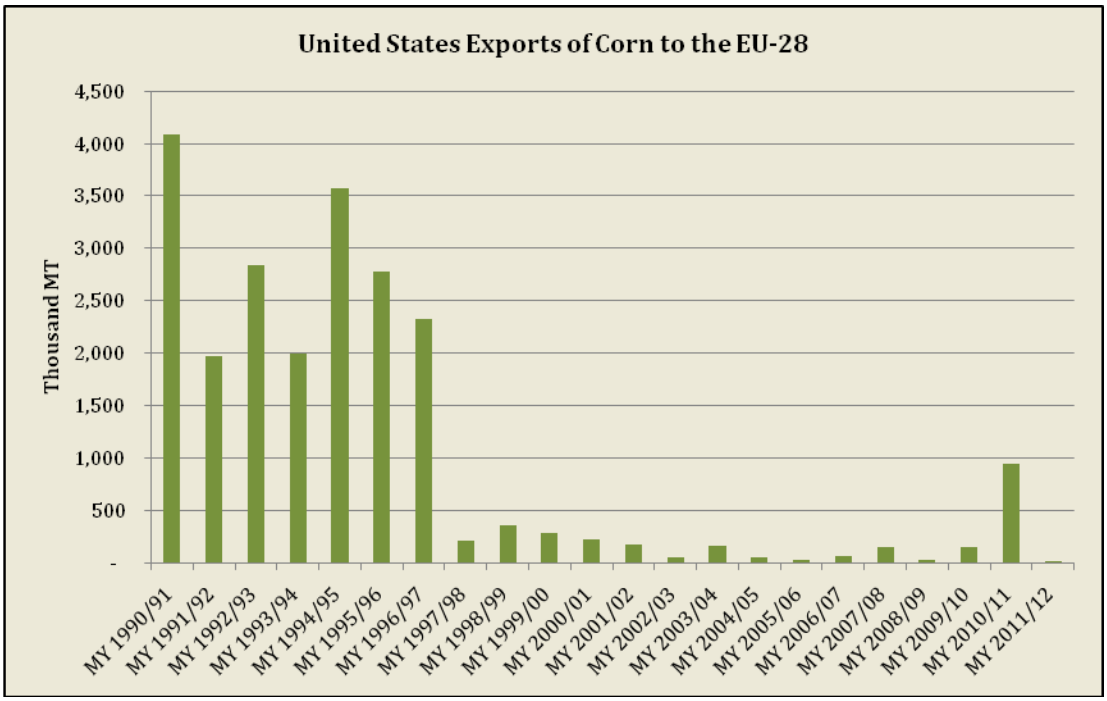
EU imports of dried distillers grains (DDGs) and corn gluten feed (CGF), mainly imported from the United States in the past, declined significantly with the growing share of biotech corn production in the United States and low tolerance of unapproved events in the EU. In marketing year 2011/12, high corn prices in the U.S. reduced competitiveness with products from other origins (see graphs below). The booming of Ukraine's market share in EU imports of corn and CGF has been remarkable in the past few years, resulting both from economic factors and their "non-biotech" image.

The United States remains a major supplier of all corn planting seeds to the EU. Its major competitors are Chile, Turkey and Serbia. In the EU, the leading producers of corn seeds for planting are **France** and **Hungary**, followed by **Austria**, **Bulgaria**, and **Romania**. All but Romania ban Bt corn for commercial production. Trade data don't differentiate between conventional and biotech corn seed varieties. The graph below therefore includes both categories.

EU imports of canned sweet corn are on the decline, in line with increasing domestic production. The United States is the EU's third largest supplier of canned sweet corn after Thailand and China (following graph). The implementation of biotech labeling in 2004 negatively affected U.S. exports of sweet corn to the EU, and led to **France**'s voluntary "non-biotech" labeling on canned sweet corn, for example (see Part B – Labeling for more information), aiming to "reassure" consumers on the absence of biotech corn in the product. Trade sources indicate that the low threshold (0.9 percent adventitious presence above which biotech labeling is compulsory, provided the biotech traits are approved in the EU) imposed by EU regulation has slowed down U.S. exports to the EU. Many food processors and distributers would not sell sweet corn labeled as sourced from or containing biotech products.



Source: Global Trade Atlas



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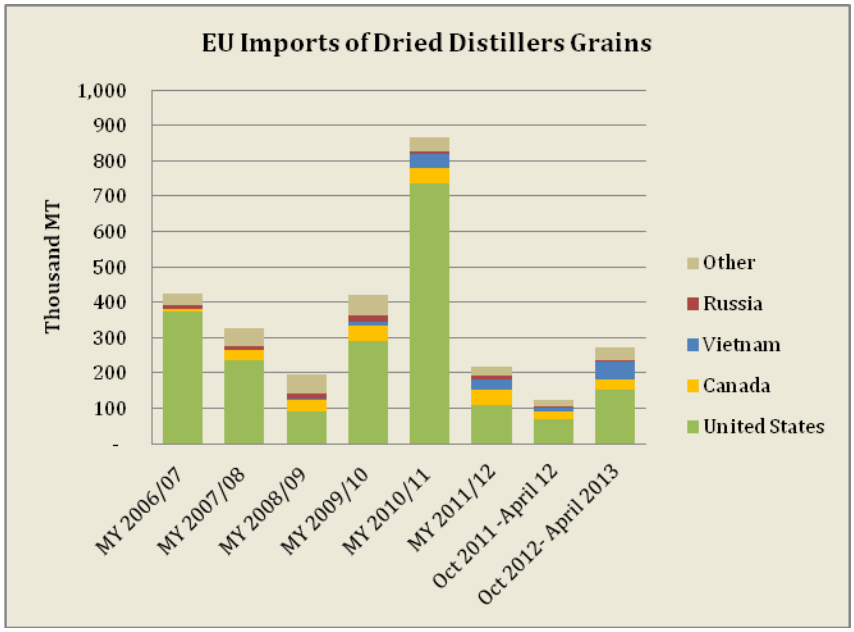

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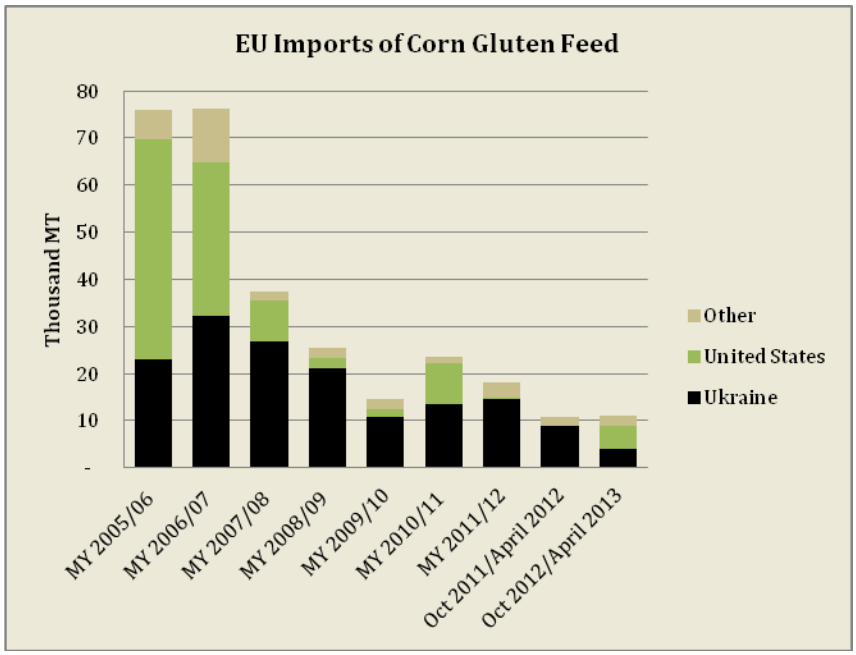
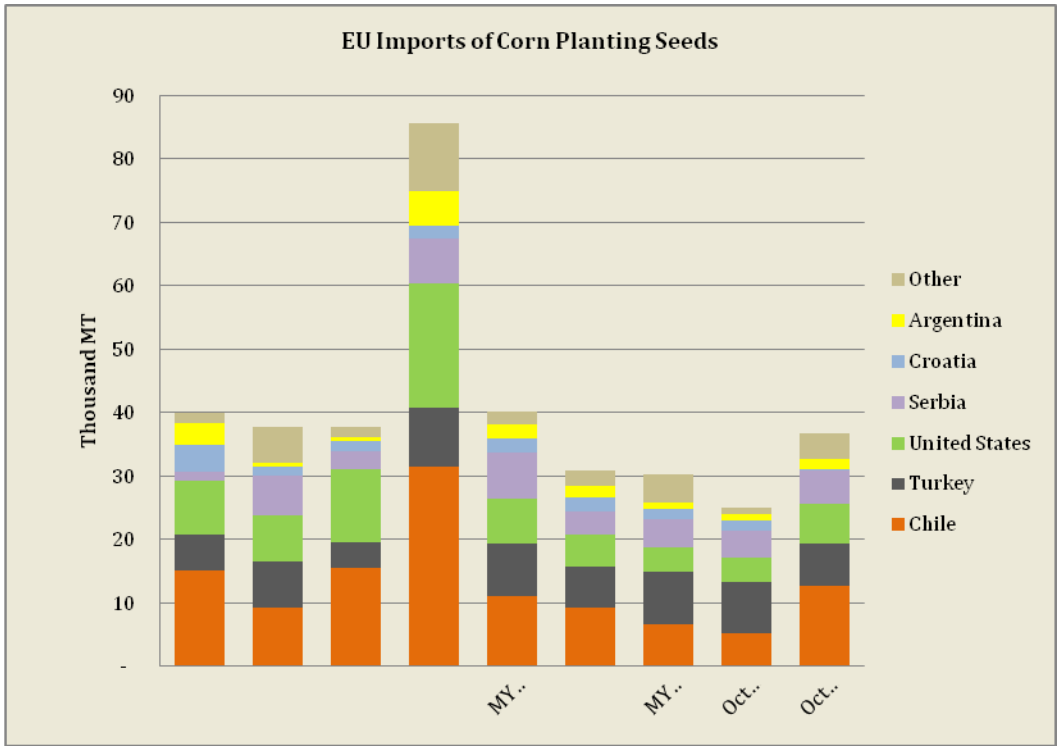


Source: Global Trade Atlas



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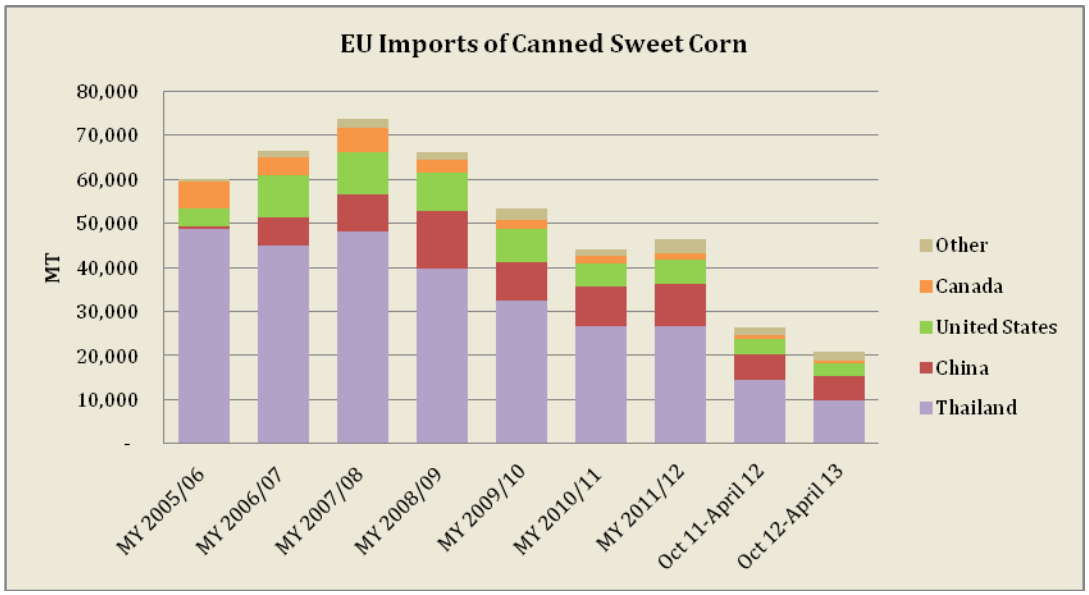


Source: Global Trade Atlas

e) FOOD AID

The EU is not a recipient of food aid, but does provide food aid to various countries, where its political positions are influential.

PART B - POLICY

a) REGULATORY FRAMEWORK

i. Responsible Government Ministries and role in the regulation of GE plants

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/Authority

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 related to plant biotechnologies

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 MS (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.

More recently, Professor Anne Glover, Chief Scientific Adviser to the European Commission, has been quoted as asserting that GE food and feed is no less safe than conventional food and feed. She has noted that **Austria** and **Luxembourg** have consistently voted against GE approvals whereas **the Netherlands** and **Sweden** have consistently voted for GE approvals. All four MS have been presented with the same scientific evidence. As such, Professor Glover has expressed her wish that

politicians who vote against GE food and feed admit that they do so for reasons other than science. 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

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, 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.

v. Legislations and Regulations with the Potential to Affect U.S. Exports

The European Commission asserts that Commission Implementing Regulation (EU) No 503/2013 published on June 8, 2013 "*on applications for authorization of genetically modified food and feed…*" clarifies the application for authorization procedure and should improve the process. However, it is unlikely that the Regulation will speed up the process, and the flexibility of risk assessors to adapt the approach used on a case-by-case basis will be reduced by imposing mandatory studies, (e.g. the 90 day rat study). An EFSA report questions the need to provide such studies for the risk of each application as follows: "*When 'molecular, compositional phenotypic, agronomic and other analyses have demonstrated equivalence of the GM food/feed, animal feeding trials do not add to the safety assessment*'". Furthermore, the additional burdens provided in the Regulation undermine the independence of EFSA, which had criticized the draft Regulation as previously mentioned.

U.S. exporters will face additional burdens, including a further unnecessary escalation in data requirements, many of which are not reflected in international agreements. Additionally, by making the requirements legally binding, additional complications can arise as the outcome of the risk assessment process is no longer purely based on scientific rationale, but now also on compliance with the law. EFSA guidance documents have been regularly fine-tuned and updated because of evolving scientific developments. The scientific relevance and technical feasibility of some of the new protocols and studies remains to be demonstrated. As such, further technical adjustments (e.g., allergenicity assessments, new statistical approaches) may be required, which is far more burdensome when legislative texts need to be amended.

vi. Timeline Followed for Approvals

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.

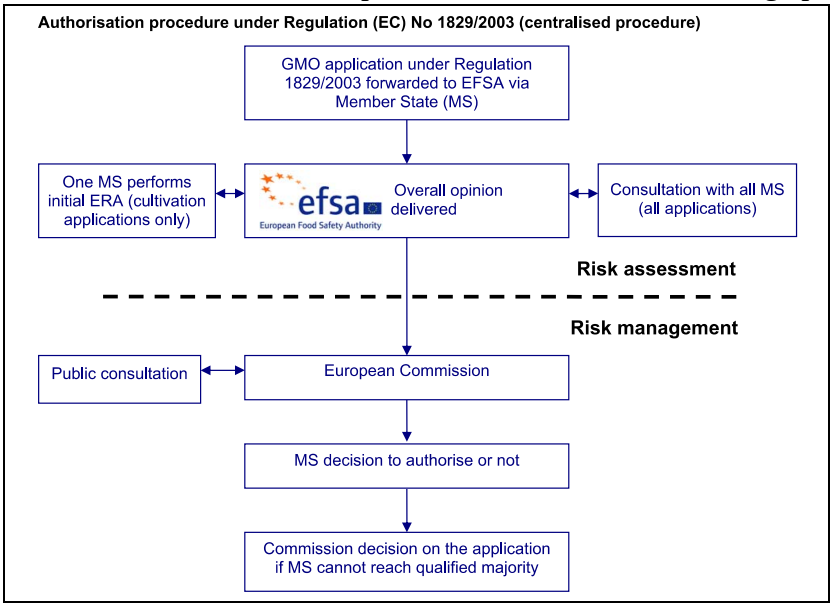
EU legislation therefore provides for the observance of the following timeline:

- 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.

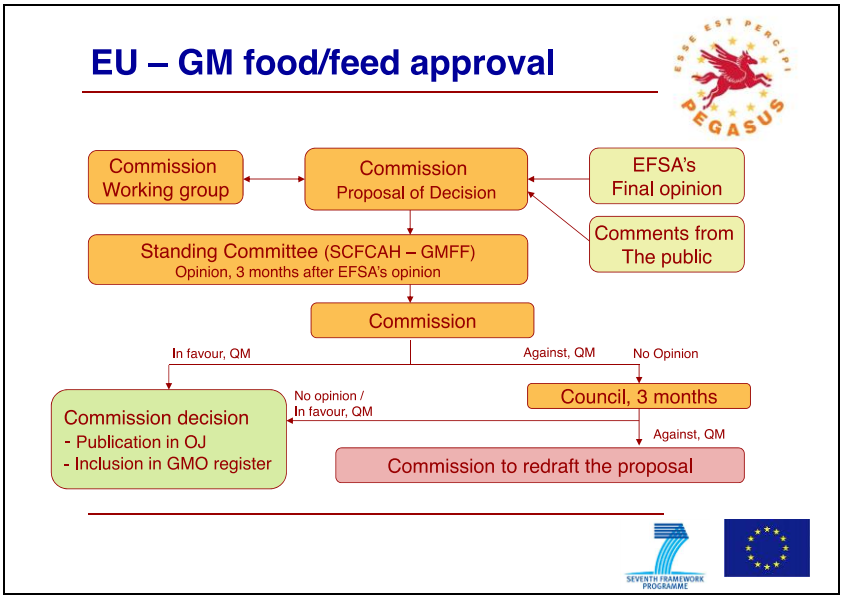
In practice, however, it takes an average of 46 months for a biotech product to be approved. Over one third of this time transpires after EFSA has issued its initial opinion which the European Commission puts into a draft decision for vote by the Member States. The Commission has waited 10 months on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

The EU-wide authorization procedure is described in the graph below.



Source: EFSA



Source: European Pegasus research project, Work Package 6

b) APPROVALS

- **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 MS. 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 MS 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.

[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.

- 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* 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.

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 the European Food Safety Agency's (EFSA) website.

- **Authorization for cultivation of biotech events**[3]

The appropriate competent authority of each MS 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

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

the MS 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 MS send to the Commission, within 30 days of receipt, a summary of each notification received.

- The Commission must forward these summaries to the other MS within 30 days following their receipt.

- Those MS may present observations through the Commission or directly within 30 days.

- The national competent authority has 45 days to evaluate the other MS 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.

- 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.

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.

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[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.

c) FIELD TESTING

The experimental release of biotech crops is 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 MS 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 MS 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) STACKED EVENT APPROVALS

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 provisions of Commission Implementing Regulation (EU) No 503/2013 which stipulate 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.

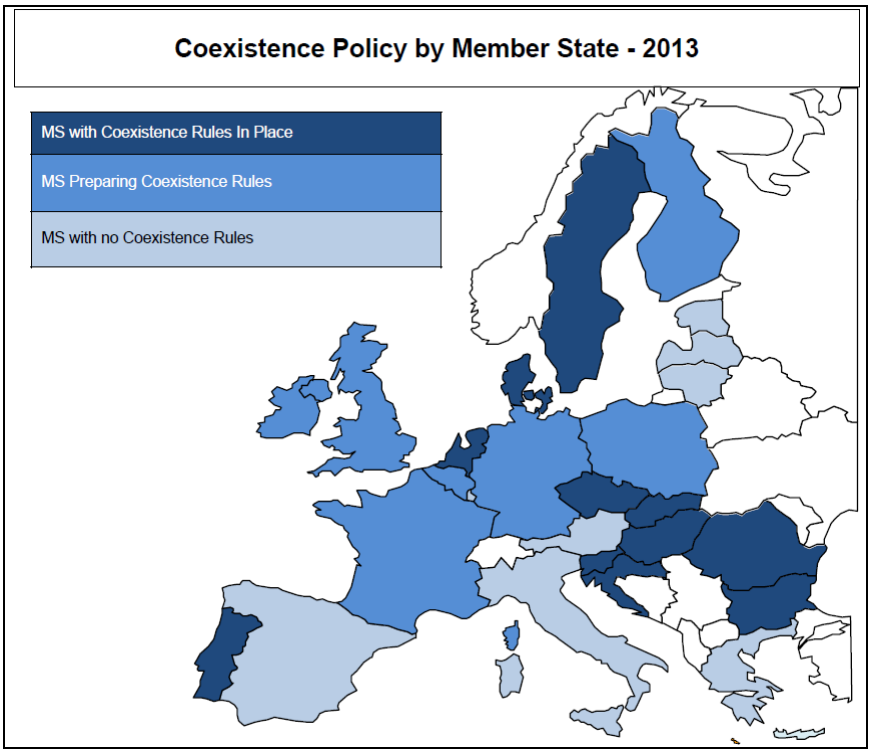
e) ADDITIONAL REQUIREMENTS – SEED REGISTRATION

In practically all MS, with the notable exception of **Spain**, farmers producing biotech crops must register their fields with government bodies. The specificity of these registration requirements varies greatly from country to country, and tends to discourage farmers from growing biotech crops, since the registration make fields easily identifiable and accessible by protestors. Please see individual MS 2013 annual biotech reports for more details.

f) COEXISTENCE

Coexistence rules of GE plants with conventional and organic crops are not set by EU authorities but by MS national authorities. The map below indicates that most MS have adopted or are preparing coexistence rules. Countries with coexistence rules in place include (1) GE crop producers (**Portugal, Czech Republic, Slovakia,** and **Romania**) and (2) MS opposed to agricultural biotechnology and where organic and agricultural production with geographical indications is significant (such as **Croatia, Hungary** and **Slovenia**).

MS without coexistence rules in place also include both categories. In **Spain**, which is the leading GE crop producer in the EU, coexistence is managed by good agricultural practices, but not by specific legislation. Major countries opposing the technology also don't have coexistence rules in place (**Austria, Greece, Italy,** and **Latvia**), as they don't anticipate growing biotech crops any time soon.



Source: FAS Posts

European coexistence research programs include the following:

- SIGMEA (2004-2007) focused on the sustainable introduction of biotech crops into European agriculture and proposed a toolbox for managing crop systems.
- COEXTRA (2005-2009) studied the coexistence and traceability of GE and non-GE supply chains and was a decision support system for the feed and food chains.

g) LABELING

- ***European Positive labeling:***

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)."

- ***Examples of National Voluntary Negative Labeling Systems:***

Austria: There are two Austrian voluntary labels for biotech free products issued by ARGE Gentechnik-frei (Platform for GMO-free Food Products) which follows the requirements for biotech-free food products laid down by the Austrian food codex. One label states "produced biotech-free" (gentechnikfrei erzeugt), the second label says "produced without biotech" (ohne Gentechnik hergestellt). The Austrian GE-free labels may only be used for meat and dairy products when derived from animals only fed by GE-free feed. Currently more than 1,500 products are labeled under this program. Major products are milk and dairy products, bread and bakery products, eggs, soybean products, meat, fruits and vegetables.

France: A biotech-free labeling system has been in place at the national level since July 1, 2012 (see explanations by the Ministry of Environment here). The system is based on a January 2012 decree, where (1) plant products can be labeled as "GMO-free" under the threshold of 0.1 percent; (2) animal products can be labeled "fed without GMOs" or "Sourced from animals fed without GMOs" under the 0.1 percent; (3) apiculture products can be labeled if biotech plants are not closer to the apiary than three kilometers. Although in place for a whole year, this labeling has only been used minimally, according to the leading consumer association.

Example of "fed without the use of GMO" logo on poultry products under the brand name "Loué."

Germany: In 2008, the German government legislated a voluntary "gene technology free" labeling program. In August 2009, the Ministry for Food, Agriculture and Consumer Protection introduced a national label to help consumers better identify products and to standardize the information consumers receive. The Ministry heavily promotes this label to the public.

- **Voluntary Negative Labeling: Private Labels**

In the **Czech Republic, Greece, Romania,** and **Slovakia,** some food manufacturers and retailers label products "GMO free" or "made from GMO-free corn/soybean," mainly on organic products.

France: There have been several voluntary initiatives put in place by the food industry and supermarket chains using "biotech-free" labeling. Canned sweet corn has been sold with a specific "biotech-free" logo since 2004, when the European traceability and labeling regulation for biotech products in food was implemented, in order to prevent sales from declining.

"This sweet corn is without GMO."

The supermarket chain Carrefour puts a "fed without GMO" logo on animal products sold under the Carrefour-branded name and using a 0.9 percent threshold.

Carrefour's "fed without GMO" logo

Germany: Food manufacturers can use an official label on their products only if they comply with strict documentation requirements. Eggs and cheese are the most popular products sold under this labeling scheme. Interestingly, the label may not be used for products for which no biotech varieties exist, such as oranges or basmati rice, among others. The administration of this program is largely entrusted to the "Verband Lebensmittel ohne Gentechnik e.V." (non-Biotech Foods Association). As of May 2013, the Association claims that 124 companies have a license to use the label.

Italy: The uncertainty around Italy's national biotech policy and the negative media has sharply

affect supermarket chain marketing strategies. Several private label brands have consistently marketed their products as 'GE-free'.

"Produced from milk obtained from non-GMO feed"

Poland: Below is an example of non-biotech labeling on eggs produced by Farmio Company, and a campaign conduced in national Polish TV and several private TV stations.

http://www.youtube.com/watch?v=UdJ3ZLCnpvo

Slovenia: Private voluntary labeling issued by the certification institute IKC UM

United Kingdom: The logo below can be found on the soybean milk for human consumption. See http://www.proterrafoundation.org/files/Press_Release_Alpro_ProTerra_on-pack.pdf for more information.

h) TRADE BARRIERS

Agricultural biotechnology is expected to be a key issue in the Transatlantic Trade and Innovation Partnership (TTIP) negotiations, starting this year between the United States and the EU. This results from the slow approval process of new GE products by European authorities and associated asynchronous authorizations and Low-Level Presence issues.

- ***Safeguard Clause:***

According to the Directive EC 2001/18, when a MS, 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 MS may invoke a safeguard clause on the biotech product the effect of which would be to 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.

The safeguard clauses currently in place in the EU are the following:

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
Hungary	Monsanto MON 810 corn	Cultivation	2005
	EH92-527-1 Amflora Potato	Cultivation/Feeding	2010
Luxemburg	Syngenta Bt176 corn	Cultivation	1997
	Monsanto MON 810 corn	Cultivation	2009
Poland	Monsanto MON810 corn	Cultivation	2013

Source: FAS Posts

- ***Delays in 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. 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 EU 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 European Authorities:***

See specific section on this issue below: section n)

- ***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 MS 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:

Socio-economic and ethical criteria are taken into account in the biosafety authority of several MS when evaluating biotech products, including **Bulgaria, Croatia, France, and Germany**. In **Austria**, **Germany,** and **Hungary**, the use of socio-economic criteria for the approval of agricultural biotech products is considered.

The **Czech Republic** and the **United Kingdom** don't consider including socio-economic criteria in their assessment of GE products. In **The Netherlands**, the former government supported the use of socio-economic criteria for the approval of producing GE products. The current government moved away from this position and has the standpoint that the approval process should only take the safety of the GE variety into account.

Spain actively participates at the technical level in the European GMO Socio-Economics Bureau discussions and considers positive to gain an increased knowledge of the impact of GE cultivation and imports. However, socio-economic criteria are not considered critical from the approval process point of view.

i) INTELLECTUAL PROPERTY RIGHTS

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

j) CARTAGENA PROTOCOL RATIFICATION

The Cartagena Protocol on biosafety to the Convention on biological Diversity is an international

agreement which aims to ensure the safe handling, transport, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, also taking into account risks to human health. It was adopted on January 29, 2000 and entered into force on September 11, 2003.

The sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (MOP 6) took place on October 1-5, 2012 in Hyderabad, India.

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.
Opening the meeting, Ms. Jayanthis Natarajan, Minister of Environment and Forests of the Government of India and incoming President of MOP 6 recognized the progress that had been made since the signing of the Cartagena Protocol in 2000. Following the adoption of the Nagoya – Kuala Lumpur Supplementary Protocol in 2010, greater consideration had been given to liability and redress within biosafety regulations. However, it was important to ensure that response measures did not become a barrier to innovation.

At the closure of the meeting, it was noted that progress had been made in discussions of the Guidance on Risk Assessment of Living Modified Organisms, and Parties were urged to consider using that Guidance. Requests for establishing ad hoc technical expert groups on risk assessment and socio-economic considerations were also welcomed. The focus on socio-economic considerations was seen as a significant step forward.

The seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol (MOP 7) will meet in 2014 or 2015.

k) INTERNATIONAL TREATIES/FORA

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

In 2011, France chaired the G20, and introduced agriculture among the top issues discussed at the ministerial level. A meeting of the agriculture ministers of the G20 countries took place in Paris in 2011, 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 (for more details, see FR9072).

The 2011 action plan of the G20 Agricultural Ministries created the Wheat Initiative, an international consortium gathering public institutions and private companies to coordinate global wheat research. A vision document was issued in May 2013. For more details, see Part A – Production and Trade a) Product Development.

l) RELATED ISSUES

- ***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 MON810 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 MS 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 MS 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.

- ***Legislation putting EFSA guidelines for authorization into legislation:***

Commission Implementing Regulation (EU) No 503/2013 *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* was published on June 8, 2013. The regulation 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 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.

It is unlikely that the Regulation will speed up the process, and the flexibility of risk assessors to adapt the approach used on a case-by-case basis will be reduced by imposing mandatory studies, (e.g., the 90-day rat study). An EFSA report questions the need to provide such studies for the risk of each application as follows: "*When 'molecular, compositional phenotypic, agronomic and other analyses have demonstrated equivalence of the GM food/feed, animal feeding trials do not add to the safety assessment*'". Furthermore, the additional burdens provided in the Regulation undermine the independence of EFSA which had criticized the draft Regulation as previously mentioned.

U.S. exporters will face additional burdens, including a further unnecessary escalation in data requirements, many of which are not reflected in international agreements. Additionally, by making

the requirements legally binding, additional complications can arise as the outcome of the risk assessment process is no longer purely based on scientific rationale, but now also on compliance with the law. EFSA guidance documents have been regularly fine-tuned and updated because of evolving scientific developments. The scientific relevance and technical feasibility of some of the new protocols and studies remains to be demonstrated. As such, further technical adjustments (e.g., allergenicity assessments, new statistical approaches) may be required which is far more burdensome when legislative texts need to be amended.

(See Section I "Plant Biotechnology", Part B "Policy", a) "Regulatory Framework", v) "Legislation and Regulations with the Potential to Affect U.S. Exports")

- ***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.

See Chapter 1, Part B, h) "Level of Tolerance of Unapproved Biotech Events by EU Authorities".

- ***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 technique that is 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 GE 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 EU, Japan, and South Africa.

In 2012, EFSA released two scientific opinions:

- On the safety assessment of plants developed through cisgenesis and intragenesis, available here. In this document, the EFSA panel on Genetically Modified Organisms concluded that "similar hazards can be associated with cisgenic and conventionally bred plants, while novel hazards can be associated with intragenic and transgenic plants."

- On the safety of plants developed using Zinc Finger Nuclease 3 and other site-directed nucleases with similar function, available here. This document concludes: "With respect to the genes introduced, the SDN-3 technique does not differ from transgenesis or from the other genetic modification techniques currently used, and can be used to introduce transgenes, intragenes or cisgenes. The main difference between the SDN-3 technique and transgenesis is that the insertion of DNA is targeted to a predefined region of the genome. Therefore, the SDN-3 technique can minimize hazards associated with the disruption of genes and/or regulatory elements in the recipient genome. While the SDN-3 technique can induce off-target changes in the genome of the recipient plant, these would be fewer than those occurring with most mutagenesis techniques. Furthermore, where such changes occur they would be of the same types as those produced by conventional breeding techniques."

- ***Research Program - GMO Risk Assessment and Communication of Evidence (GRACE):***

The European Commission has funded a three-year, 6 million Euro (US$7.8 million) project titled GMO Risk Assessment and Communication of Evidence (GRACE). The project will assess the effects of GE plants on human and animal health, the environment, and the economy and publish risk-benefit assessments for GE plants and derived food and feed. GRACE will perform an evaluation of existing studies, especially feeding studies, in a 'transparent manner and in accordance with clearly defined scientific quality criteria.' New feeding trials are also being performed. GRACE is being managed by Germany's Julius Kühn Institute (JKI).

GRACE is to conduct animal feeding trials and in vitro studies are analyzed with regard to the added value/necessity of 90-day feeding trials with whole foods. Feeding trials are compared with advanced state-of-the- art analytical, in vitro and in silico tools. The project will provide guidance for relevant, alternative in vitro cell-based approaches within the overall food and feed safety assessment.'

GRACE's desk research and feeding trial results will be reviewed by DG SANCO in 2015 or possibly 2016. At that time, it is believed that DG SANCO will review its stance on 90 day field trials being a required part of the EU's biotech approval process.

In 2011, USDA's Agricultural Research Service entered into a non-funded cooperative agreement to supply experimental biotech potatoes to JKI for the GRACE program's animal feeding trials. However, U.S. regulatory agencies are not convinced about the value of the GRACE approach for

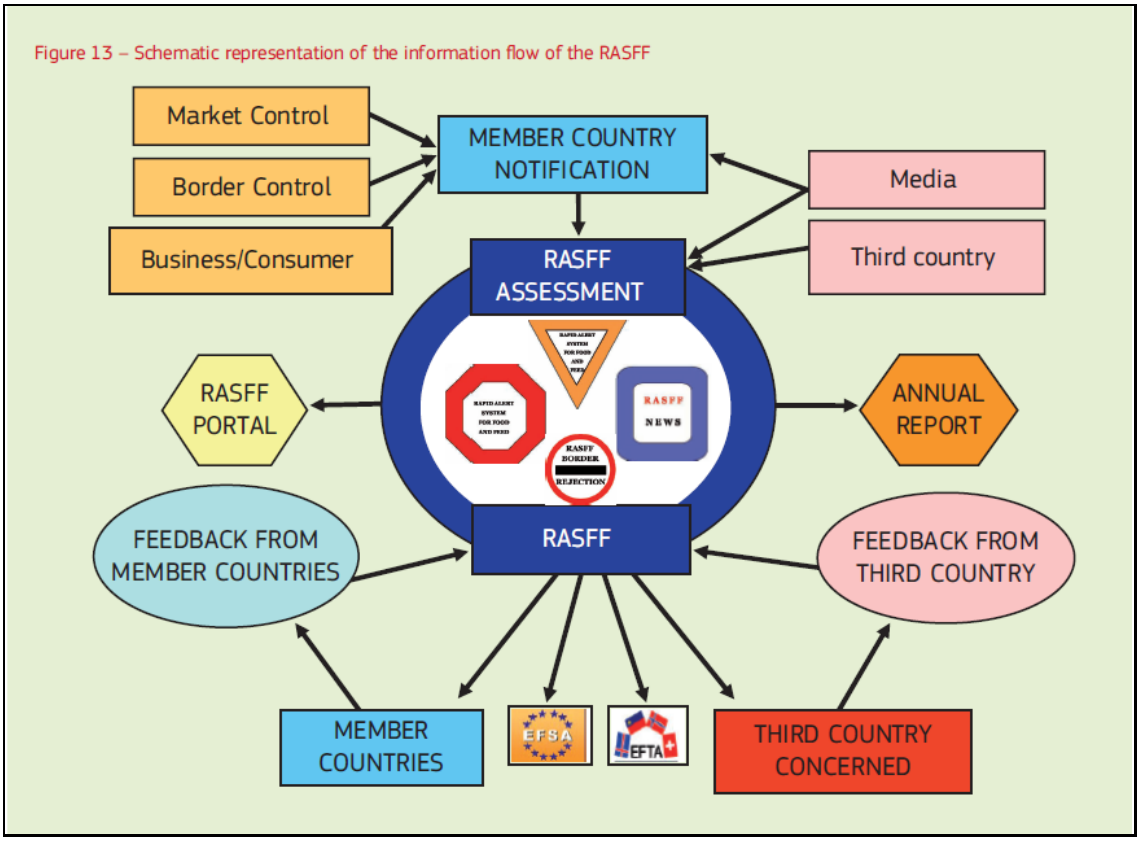
making safety assessments. Instead, FDA supports the approach of the international standard setting body Codex Alimentarius for a more focused, multi-disciplinary approach to evaluate the safety of foods from genetically engineered plants. The cooperative agreement was terminated by the Agricultural Research Service on March 29, 2013.

m) MONITORING AND TESTING

In the EU, the Rapid Alert System for Food and Feed (RASFF) is used to report food safety issues to consumers, trade, and Member States authorities. RASFF's annual report released in June 2013 revealed, "Of the 3,516 original notifications transmitted in RASFF in 2012, 332 concerned feed (9.4%) and regarding food contact materials, 299 notifications were counted (8.5%)."

The general functioning of the RASFF is illustrated in the graph below:

Figure 13 – Schematic representation of the information flow of the RASFF



Source: RASFF 2012 annual report

More specifically relative to the detection of unapproved biotech products in food, RASFF's annual report indicates the following: "Following the repeated RASFF notifications of genetically modified rice from China, unauthorized in the European market, the EU implemented a new Regulation concerning rice from China, replacing decision 2008/289/EC (Bt63 rice). Decision No. 2011/884/EU which is in force since January 11th, 2012, requires systematic screening for genetic modifications of rice products from China that are intended for the European market. This explains the top ranking of GMO findings in the category cereals and bakery products from China in *(the following)* table."

According to the report, the categories and countries most notified for unapproved GE products in food in 2012 were the following:

Product Category	Country of Origin	Number of Notifications
Cereals and Bakery Products	China	39
Fruits and Vegetables (papaya)	Thailand	10
Cereals and Bakery Products (basmati rice)	Pakistan	5
Other Food Product/Mixed	China	2
Cereals and Bakery Products	Argentina	1
Cereals and Bakery Products	Czech Republic	1
Cereals and Bakery Products	Hungary	1
Cereals and Bakery Products	India	1

Finally, RASFF's 2012 annual report indicates that the presence of unapproved GE products in feed was marginal relative to other notifications in feed in 2012, mainly concerning mycotoxins and pathogenic microorganisms.

Croatia, which has accessed the EU on July 1, 2013, started regular testing for GE products in 2004 and 2005 when the government randomly tested foods and seeds. Several products had to be withdrawn from the market due to a lack of proper biotech labeling. There is now regular biotech testing at the border and in the market. The testing is performed in accordance with annual inspection plans for Sanitary Inspection and is dependent on the financial resources for the fiscal year.

n) LOW-LEVEL PRESENCE POLICY

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. The Commission has undertaken to announce possible policy options as a function of

the data received and will then open up a three month comment period. After a DG SANCO Advisory Board has analyzed and evaluated the comments, an Impact Assessment Board made up of officials from various DGs will examine the DG SANCO evaluation. Stakeholders, including non-EU countries, will have the opportunity to submit comments. The Commission will decide on which option to propose. 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. For the measure to be put into Community law, the Council cannot have a qualified majority against and the Parliament cannot have a simple majority against the proposal. There is no deadline for the publication of the Impact Assessment, but it is understood that the request for comments should be published soon. It seems unlikely that Impact Assessment will be published until next year. The Commission has asserted that a "step-by-step" approach will be taken on LLP. Since a technical solution for feed has already been introduced, the next step would be for the EU to consider a technical solution for food, after which an LLP for seed would be considered, probably in the form of a technical solution. The Commission has asserted that the seed issue is even more sensitive than food. Clearly, it should be recalled that the faster the rate of authorizations, the less need there is for LLP. At this time there are no signs that the rate of authorizations is speeding up.

PART C – MARKETING

a) MARKET ACCEPTANCE

There is an overall reluctance in public opinion regarding GE products in food, due to various factors including the lack of objective sources of information. Therefore, the public mainly hears extreme pro and con sources. Public opinion generally expresses distrust of private international biotech companies, especially those that are the most visible. Academic and public research efforts both exist but are less visible to the public, even though they are considered these entities more credible and neutral than NGOs and private companies.

- ***Demand for non-biotech products***

As indicated in the g) section on labeling, there are several initiatives across the EU to label the absence of GE products in food production. It is the case of the organic sector and of some products sold under Geographical Indications.

The "Danube Soya" Association was created with the support of the Austrian government to promote the production and processing of non-biotech soybeans in the Danube river region. It is a non-governmental association, whose members are farmers, traders, feed companies, retailers, and

green organizations of nine countries: **Austria, Bavaria, Bosnia and Herzegovinia, Croatia, Hungary, Romania, Serbia, Slovenia, and Switzerland**. The association estimates the production potential for soybeans in the Danube region at 4 MMT. (see 2013 annual EU oilseeds GAIN report and the aforementioned country reports for further information).

As the global cultivation of GE crops expands, it is increasingly difficult for European importers to source non-biotech products, and especially soybean products, for which the EU is a net importer (see Part A – Imports, for more information). The availability of non-biotech products is gradually declining, while their prices are on the rise. European demand for non-biotech soybean products is mainly supplied by domestic production and imports from Brazil and India.

France is a major market for non-biotech soybeans and meal, due to demand for non-biotech animal feed for products sold under Geographical Indications (mainly poultry, meat and dairy products), which usually restrict or prohibit GE products even in feed use. The premium for non-biotech soy meal is currently estimated at 60-70 Euros per MT, or roughly a 13 percent premium over normal soybean meal prices. India has become an alternate to Brazil in supplying non-biotech soybean meal to the EU and almost half of its exports to the EU go to France.

The growing adoption of the technology by leading agricultural producer countries makes it increasingly difficult and expensive for EU companies to source non-biotech products and ingredients, especially those needed for organic products, specialty products, and products with geographical indications that have extensive predetermined standards.

In May 2013, the **German** association for the animal feed and nutrition sector and several German food retailers signed a declaration calling for Brazil to supply more of GE-free soy to European consumers. For more information, see Brussels Soy Declaration.

In the **United Kingdom**, several supermarket chains announced in April 2013 that their poultry and livestock supply chains could no longer source efficient quantities of non-biotech animal feed at a reasonable cost. See United Kingdom 2013 annual biotechnology GAIN report for more details.

b) PUBLIC/PRIVATE OPINIONS

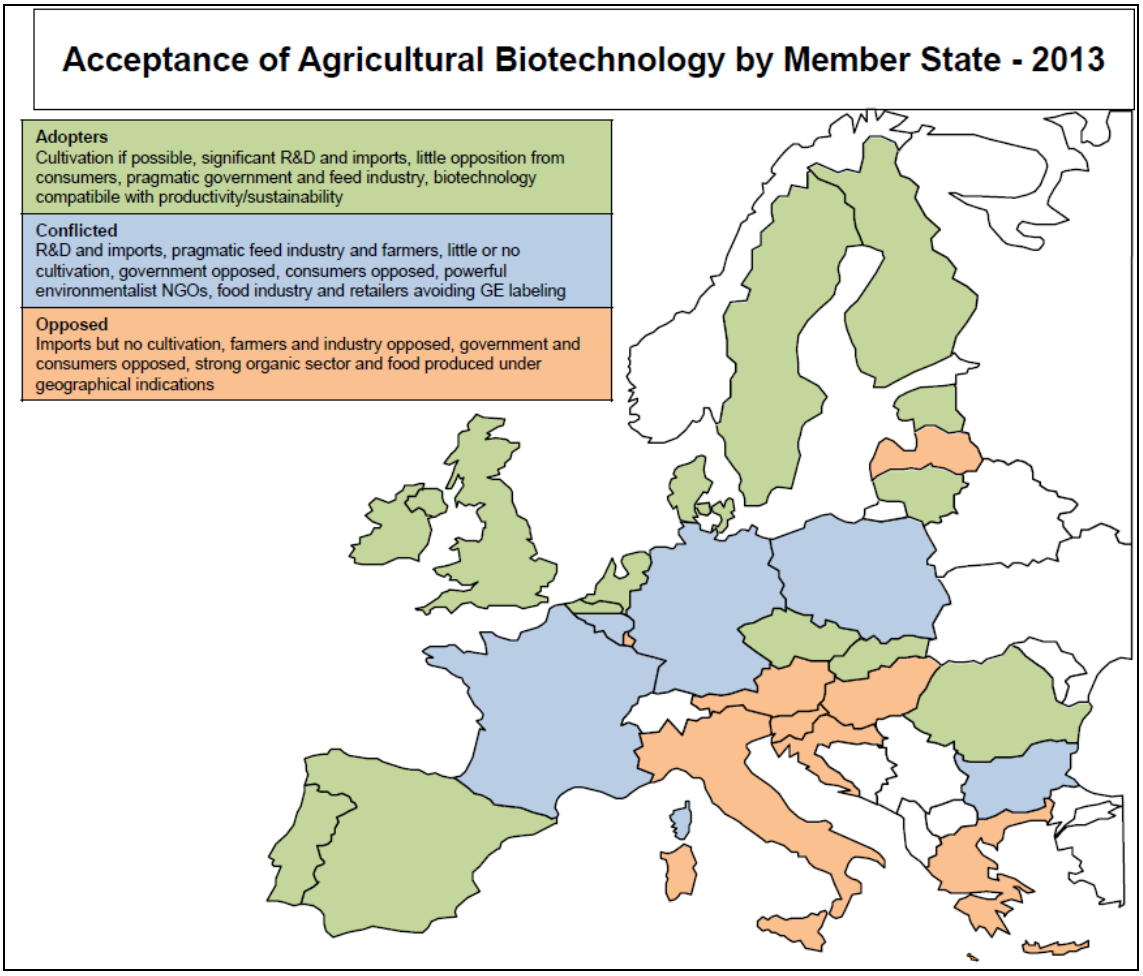
There are three major categories of MS depending on their acceptance of plant biotechnology, illustrated in the map below.

- The "*Adopters*" include producers of Bt corn (**Spain, Portugal, Czech Republic, Slovakia**, and **Romania**) and MS who could be producers of GE plants if the scope of approved products for cultivation in the European Union was wider and included crops with traits that would present a benefit to farmers and industry in these countries. The latter include **Northern Belgium – Flanders-, Denmark, Estonia, Finland, Ireland, Lithuania, the Netherlands, Sweden,** and the **United Kingdom**. The "Adopters" are characterized with pragmatic governments and industry, generally open to the technology. For example, the government of the **United Kingdom** has openly taken position in favor of adopting

biotechnology in agriculture in the past few months. As for **Romania**, despite the fact that the Ministry of Agriculture signed the Danube Soya Declaration, which sent a negative signal towards farmers and industry, the Government strongly opposed the recent Parliament initiative to prohibit cultivation and import of biotech crops.

- The "*Conflicted*" group includes MS where there are groups willing to adopt the technology (mainly the science community, farmers, feed industry) and others that reject it (consumers and governments, under the influence of active Green parties and environmentalist non-governmental organizations). In this group, **France, Germany,** and **Poland** all used to cultivate Bt corn but have implemented national bans. Southern **Belgium** (Wallonia) and **Bulgaria** are under the influence of the other countries of this group, especially France.

- The "O*pposed*" group consists of MS where most stakeholders and policy makers reject the technology. Most of these countries are located in Central and South Europe (**Austria, Croatia, Greece, Hungary, Italy,** and **Slovenia**) with the exception of **Latvia**. In all cases, organic food and products sold under Protected Geographical Indications represent a significant part of the farm and food production, and there are fears that biotech crop cultivation could not coexist with these other types of agriculture. A minority of farmers is supportive of growing biotech crops in these countries.



Source: FAS Posts

c) MARKET STUDIES

- ***Eurobarometer:***

The most recent Eurobarometer survey dates back from 2010 and is available at here.
The attitudes of European consumers to biotechnology show 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 and want more information, especially information about the safety of biotechnology, but have no ultimate opinion on the topic. The latest Eurobarometer survey has shown that a majority of Europeans are optimistic about biotechnology (53 percent) and 20 percent say "don't know".

The survey shows also differences among MS regarding the support for food derived from biotechnology. During the 1996-2010 period, there was 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 support. Member States where GE crops are grown were more supportive.

- ***Consumerchoice Project:***

This study, funded by the European Commission (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 MS – 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.

PART D - CAPACITY BUIILDING AND OUTREACH

a) ACTIVITIES

In the EU, USDA's Offices of Agricultural Affairs work to facilitate knowledge and understanding between the United States and Member States by maintaining a close dialogue with public authorities, farmers, and industry groups. In 2012 and 2013, country-specific biotech outreach

activities were conducted in several MS. For more details, see separate biotech GAIN reports of the various MS listed in annex. The meetings, visits, and seminars for U.S. visitors (government, industry, farmer groups, and research scientists) with European officials are aimed at facilitating bilateral information flow and understanding.

For example, the FAS/Paris website includes events organized on biotechnology since 2010 here and multi-year newsletters here since 2006.

b) STRATEGIES AND NEEDS

- ***Plant Biotechnology to Boost Agricultural Productivity:***

In most MS, plant biotechnology is generally perceived by scientists, farmers and the farm industry as a tool to increase productivity of the farm sector. And, there are concerns among these groups that the competitiveness of agriculture in Europe is in jeopardy as long as biotechnology is not adopted.

- ***Plant Biotechnology to Address Agriculture Sustainability:***

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. For information, see GAIN reports "Using 'Sustainability' to Market U.S. Foods in Europe" and "France's Sustainable Agriculture Initiatives." However, plant biotechnology is not a tool usually considered, either by policy makers or the public, to address this issue. Organic agriculture is often considered the only way to make agriculture more sustainable, especially in the group of European countries most opposed to the technology, as defined in Part C) Market Acceptance section above.

In a report of European Academies Science Advisory Council (EASAC) released in June 2013, "Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture," EASAC considers that "novel agricultural technologies such as improved GM crop varieties do not negate the necessity for good agricultural practices but should be incorporated in integrated pest management and Integrated Weed Management programs. When used incorrectly GM crops, like other agricultural technologies, can result in adverse environmental and agricultural impacts such as the development of resistant pests and weeds."

- ***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 EU when developing their regulatory requirements. According to EASAC's report of June 2013 referenced above, "Evidence indicates that EU policy, practices and perspectives have sometimes constrained the use of crop genetic improvement technologies in African countries, creating difficulties for scientists, farmers and policy-makers."

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."
Using biotechnology as a tool to address world food security is a concept that some are familiar with in the EU but it does not have wide support. The media and public are generally uninformed of the benefits of biotech crop production in emerging and developing countries, and it is not a significant area of discussion or debate in the EU.

CHAPTER 2 – ANIMAL BIOTECHNOLOGY

PART E – PRODUCTION AND TRADE

a) BIOTECHNOLOGY PRODUCT DEVELOPMENT

The International Swine Genome Sequencing Consortium, launched in 2003in **France**, and led by American and European researchers, conducted the most thorough genomic study yet conducted of the domestic pig and its wild boar counterparts. A new genomic analysis reveals some new, unexpected and potentially beneficial similarities between pigs and humans, along with a few distinct differences. A report of the study appears in the journal *Nature* on 15 November 2012. For more details, see http://presse.inra.fr/en/Resources/Press-releases/Pig-Genome

The MS where genetic engineering is used in animals include **Austria, Belgium, the Czech Republic, Denmark, France, Germany, Hungary, Italy, the Netherlands, Poland, Slovakia, Spain,** and **the United Kingdom**. Most of these countries develop GE animals for medical purposes (including Alheimer's disease, xenotransplantation). Some MS use animal biotechnology for breeding (high yielding sheep, dairy cows and swine genomics, resistance to avian flu).
A company in the **United Kingdom** is developing GE insects to address human health issues (e.g., mosquitoes developed to prevent the dissemination of dengue), and agricultural issues (e.g., olive flies developed to protect olive trees from insect infestation).

b) COMMERCIAL PRODUCTION

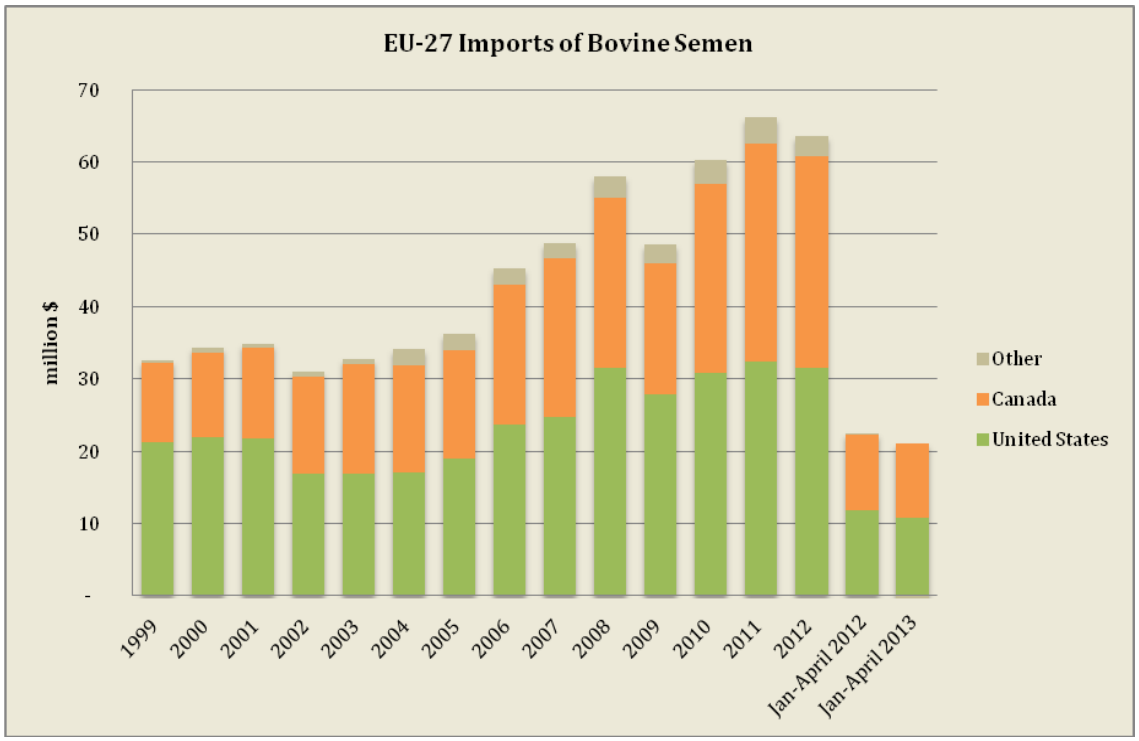
There is no GE animal commercialized in the EU. A **French** company clones sport horses, in collaboration with **Italian** industry. Cloned animals are elite breeding horses.

c) BIOTECHNOLOGY EXPORTS

N/A

d) BIOTECHNOLOGY IMPORTS

The United States is the EU's leading supplier of bovine semen, sharing the bulk of the market in almost equal proportions with Canada. These imports have the potential of being derived from cloned animal offspring.



Source: Global Trade Atlas

PART F – POLICY

a) REGULATION

i) Responsible Government Ministries

The three European entities regulating animal biotechnology are the following:

- European Commission – Directorate General Health and Consumers (DGSANCO)
- Council of the EU, after Member State (MS) experts' approval in the Standing Committee

on the Food Chain and Animal Health (SCoFCAH)
- European Parliament - Environment, Public Health and Food Safety (ENVI) Committee

ii) Political Factors Influencing Regulatory Decisions

- NGOs for animal welfare
- Small farmer and local food groups
- Biodiversity activists
- Consumer groups

iii) Legislations and Regulations with the Potential to Affect U.S. Trade

- *GE Animals:*

The EU regulatory framework for GE animals is the same as for GE plants. The EU has established a legal framework regulating GE food and feed derived products, as well as the release of living biotech products into the environment, in order to ensure a high level of protection of human and animal health and the environment. 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 release into the environment.
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 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 GMO 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.

EFSA has developed guidance documents for future applications for authorization for import, distribution, or processing, as well as for authorization for release into the environment of GE animals. Two working groups have been set up for this reason within EFSA:
- Working group of the biotech Panel that developed guidance for (1) food and feed safety risk assessment of products derived from GE animals, and (2) environmental risk assessment for GE fish, insects, mammals and birds;
- Working group from the Animal Health and Welfare (AHAW) Panel that developed guidance for animal health and welfare aspects.

EFSA has set up a webpage on Genetically Modified Animals that keeps track of the progress of the work on GE animals, as well as provides the relevant documents and reports.

On May 23, 2013, EFSA published its "Guidance for the Environmental Risk Assessment (ERA) of Living GE Animals to be Placed on the EU Market." It provides guidance for assessing potential effects of GE fish, insects, mammals and birds on animal and human health and the environment and

the rationales for data requirements for a comprehensive ERA. In accordance with Directive 2001/18/EC, EFSA lists the six steps for the ERA of GE animals as: (1) problem formulation including hazard and exposure identification; (2) hazard characterization; (3) exposure characterization; (4) risk characterization; (5) risk management strategies; and (6) overall risk evaluation. Under annex 2 of the same Directive, the seven areas of potential risk applicants must consider are: 1) persistence and invasiveness of the GE animal, including vertical gene transfer; (2) horizontal gene transfer; (3) interactions of the GE animal with target organisms; (4) interactions of the GE animal with non-target organisms; (5) environmental impacts of the specific techniques used for the management of the GE animal; (6) impacts of the GE animal on biogeochemical processes; and (7) impacts of the GE animal on human and animal health.

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." 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 of the public consultation on the draft Scientific Opinion for this guidance was published February 2012.

The publication of both guidance documents opens up the way for approval applications for GE animals. To date, EFSA has not received any applications on GE animals.

- *Animal Cloning:*

Currently, food derived from cloned animals, but not from their offspring, is regulated by Novel Foods Regulation (EC) No 258/97. After a 2008 proposal to revise Novel Foods Regulation 258/97 failed to be approved in March 2011 (see GAIN report EU Novel Foods Proposal failed to win Approval), the Commission started work to launch a new legislative proposal to regulate animal cloning and its offspring, as well as their products. The goal is to launch this new proposal together with a new proposal on novel foods and the proposal will separate the approval of animal cloning and its products from the Novel Foods regulation. After several delays, the Commission is planning to launch this proposal in late 2013, but informally officials familiar with the dossier do not expect the proposal to be ready before the spring of 2014 at which time the current European Parliament is halting work as it faces elections in May 2014.

Since the entry into force of the Lisbon Treaty, the standard procedure for adopting legislative proposals is the "ordinary legislative procedure". Under this procedure, the European (EP) Parliament and Council must jointly adopt Commission proposals for new or amended framework legislation. For more information on the EU decision-making procedures see GAIN report "Adopting EU Framework Legislation on Cloning – How does it work?" This report explains the different stages and key actors in the development of new framework legislation on animal cloning for food production, from the Impact Assessment to the final phase of the ordinary legislative procedure.

In preparation of its new proposal on animal cloning, the Commission asked EFSA for an update on its scientific opinion and ordered an impact assessment. EFSA published an update of its opinion in

July 2012: Update on the state of play of Animal Health and Welfare and Environmental Impact of Animals derived from Somatic Cell Nuclear Transfer (SCNT) Cloning and their Offspring, and Food Safety of Products Obtained from those Animals.

For the assessment on animal cloning, which must assess the economic, social and environmental impact of a legislative initiative, a "roadmap" outlining five policy options was published in February 2012. A public consultation which is also part of the IA ran from May until September 2012. The work on the impact assessment is still ongoing.

Original EU Risk Assessment of Animal Cloning:

For the 2008 proposal for reviewing the Novel Foods regulation, the European Commission ordered a risk assessment of animal cloning for food purposes. The risk assessment consisted of two parts: the scientific element was performed by the European Food Safety Authority (EFSA), while the European Group on Ethics in Science and New Technologies to the European Commission (EGE) was tasked with the assessment of ethical aspects of animal cloning for food purposes.

European Food Safety Authority (EFSA) studies:

- EFSA 2008 Study on Animal Cloning: EFSA released its draft report followed by public consultation. The final report was adopted on July 15, 2008. While the report found no issues with animal cloning from the perspective of food safety, it highlighted concerns about animal welfare of cloned animals.

- The EFSA report: Food Safety, Animal Health and Welfare and Environmental Impact of Animals Derived from Cloning by SCNT and their Offspring and Products Obtained from Those Animals:

- Outcome of Public Consultation on the EFSA Draft Animal Cloning, 2008

- EFSA's most recent study is Further Advice on the Implications of Animal Cloning. In this study, EFSA focused on the health and welfare of animal clones during their productive life and natural life span. The recommendations related to the investigation of the causes of pathologies and mortality observed in clones during the gestational and postnatal periods and those observed at a lower frequency in adulthood were also observed. Additionally, EFSA expanded the scope of the assessment to the extent of how the current knowledge applies to cloning of sheep, goats, and chicken.

The European Group on Ethics (EGE) in Science and New Technologies to the European Commission released a report in 2008 named Ethical Aspects of Animal Cloning for Food Supply, 16 January 2008.

b) LABELING AND TRACEABILITY

Food from GE animals will need to be labeled according to Regulation (EC) No 1829/2003. Depending on whether food from cloned animals is considered different than food from classically bred animals, Novel Foods Regulation 258/97 may require specific labeling.

c) TRADE BARRIERS

The main trade barriers are the societal and political opposition to animal biotechnology, due to ethical and animal welfare concerns.

The same legislative framework applies for GE animals as for GE plants. No application has been brought to EFSA for GE animals.

Products from cloned animals are subject to an approval under the Novel Foods regulation.

d) INTELLECTUAL PROPERTY RIGHTS

The same legislative framework applies for GE animals as for GE plants. □

e) INTERNATIONAL TREATIES/FORA

The European Union is a party to the Cartagena Protocol on Biosafety□
Under the 7th Framework Program (FP), the European Commission is funding an integrated project, titled Pegasus, which aims to provide policy support regarding development, implementation, and commercialization of GE animals, derivative foods, and pharmaceutical products. The Pegasus project includes eight Work Packages. More information about the Pegasus project is available at: http://www.pegasus.wur.nl/UK/.

As part of the Pegasus, research project, Vazquez-Salat N, et al, published "The current state of GMO governance: Are we ready for GM animals?" Biotechnol Adv (2012), available here. This paper describes international organization approaches to animal biotechnology as follows: the Organization for the Economic Cooperation and Development (OECD) and the Codex Alimentarius Commission have working groups and develop guidelines on biotech animals. For example, the CAC developed a "Guideline for the Conduct for Food Safety Assessment of Foods Derived from Recombinant-DNA Animals." The World Organization for Animal Health (OIE) has no specific guidelines on GE animals, but on the use of cloned animals. France hosts both OECD and the OIE.

PART G – MARKETING

a) MARKET ACCEPTANCE

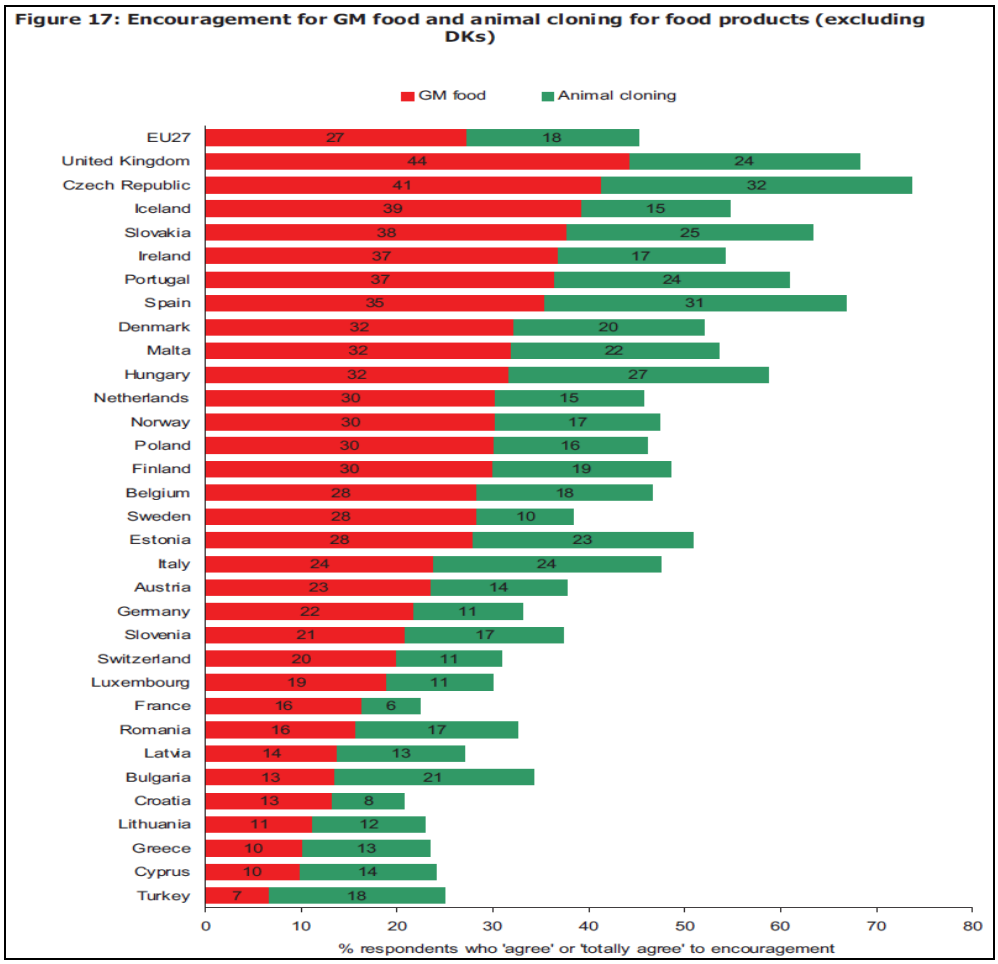
Market acceptance of animal biotechnology is low in Europe among policy makers, industry, and consumers, mainly due to ethical and animal welfare concerns. It is generally a controversial issue that is not widely discussed and sometimes a non-issue. It could remain so if implemented for medical purposes rather than for animal agriculture.

b) PUBLIC/PRIVATE OPINIONS

The EU livestock industry is hostile to commercializing cloned or GE animals but is interested in animal genomics and Marker Assisted Selection for animal breeding.
There is little visibility of animal biotechnology in the public opinion, which is generally more hostile to it than to plant biotechnology, for ethical concerns.

c) MARKET STUDIES

The European Commission released a report in 2010 named "Europeans and Biotechnology: Winds of Change?" that includes the following graph. It reflects the combination of consumer acceptance of food derived from GE plants and animal cloning in each MS.



PART H – CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES

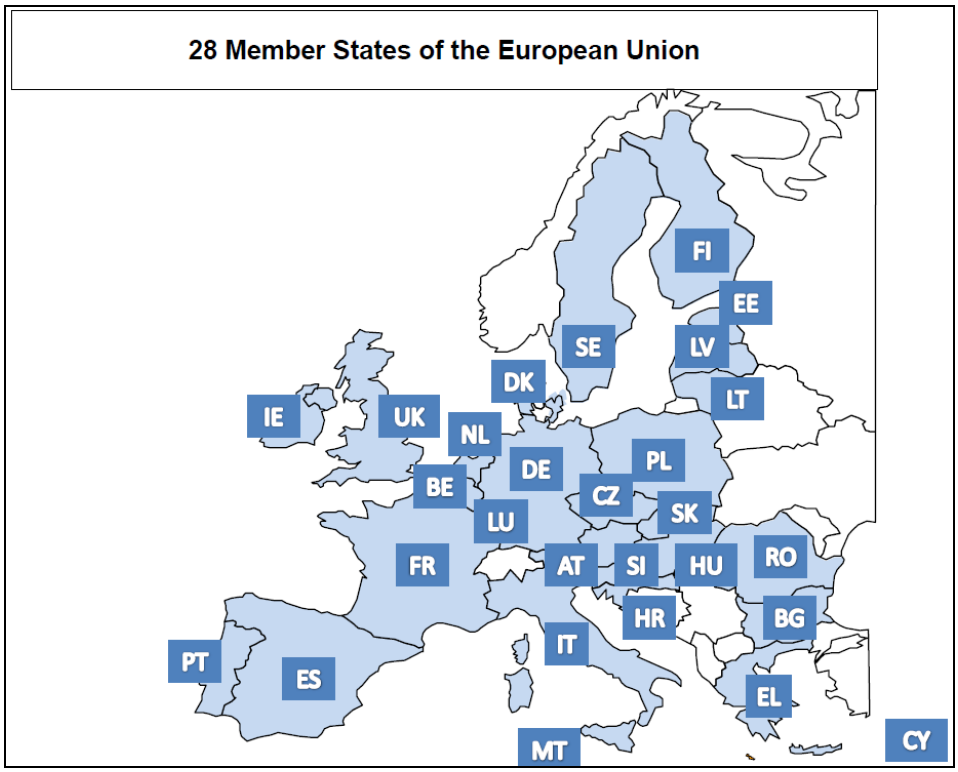
Activities across the EU include sharing information with European and Member States authorities relative to commercial and regulatory practices in the U.S. relating to animal biotechnology, in the form of seminars, visits and meetings. For more detailed information, see separate reports prepared by FAS Offices in Member States.

b) STRATEGIES AND NEEDS

Overall, many stakeholders in the EU would welcome more information on regulation and use of animal biotechnology in the United States and other countries. Increasing dialogue would help mutual understanding and move away from the generally emotional approach of the technology in the EU.

ANNEX 1 – 28 MEMBER STATES OF THE EUROPEAN UNION

As of July 1, 2013, the 28 Member States of the European Union are the following:



Austria (AT)	Italy (IT)
Belgium (BE)	Latvia (LV)
Bulgaria (BG)	Lithuania (LT)
Croatia (HR)	Luxembourg (LU)
Czech Republic (CZ)	Malta (MT)
Cyprus (CY)	The Netherlands (NL)
Denmark (DK)	Poland (PL)
Estonia (EE)	Portugal (PT)
Finland (FI)	Romania (RO)
France (FR)	Slovakia (SK)
Germany (DE)	Slovenia (SI)
Greece (EL)	Spain (ES)
Hungary (HU)	Sweden (SE)
Ireland (IE)	United Kingdom (UK)

ANNEX 2 – RELATED REPORTS

USDA Offices of Agricultural Affairs in the European Union prepared the following reports for the EU and its Member States:

Year	Date	Country	Title
2013	June 17	Czech Republic	Agricultural Biotechnology Annual
	June 17	Romania	Agricultural Biotechnology Annual
	June 17	Germany	Agricultural Biotechnology Annual
	June 14	United Kingdom	Agricultural Biotechnology Annual
	June 12	Netherlands	Agricultural Biotechnology Annual
	June 12	Romania	Romanian Senate rejects Proposal to Prohibit Biotech Products
	June 11	Italy	Agricultural Biotechnology Annual
	June 11	Spain	Agricultural Biotechnology Annual
	June 10	France	Agricultural Biotechnology Annual
	June 4	Hungary	GMO Investigation Launched
	April 22	UK	UK GE Plants and Animals Report
	April 19	France	France and the Bioeconomy or Green Economy
	April 5	EU	Annual EU-27 Report – Oilseeds and Products Ample Soybean World Supplies to Boost EU-27 Soybean Meal Consumption
	April 17	EU	Adopting EU Framework Legislation on Cloning – How does it work
	March 13	EU	GM-Free Labeling Conference in the European Parliament

	March 1	Romania	Romania Proposes to Prohibit Import and Cultivation of Biotech Products
	February 8	Romania	Romania's Farmers Ignored, Agriculture Minister Endorses the Danube Soya Declaration
	February 5	Romania	Will Romania change its stance on the Danube Soya Declaration?
	January 24	Romania	Romania Reaffirms Role of Scientific Opinion for not Supporting Danube Soya Declaration
	January 15	France	France Chooses Agro-Ecology for a More Sustainable Agriculture
2012	December 17	France	Ag Biotech Policy – Emotion Takes Precedence Over Science
	November 30	Hungary	Government Sponsors Road Show Criticizing Use of Technology in Agriculture
	November 9	France	France's Sustainable Agriculture Initiatives
	November 2	EU	Using 'Sustainability' to Market U.S. Foods In Europe
	October 25	France	France Takes Tough Position on GE Crops Based on Flawed Study
	October 16	Hungary	Agricultural Biotechnology Annual
	October 11	Germany	Parliamentary Question Reveals Support for GE Crops
	October 9	France	International Scientists Respond to Uncritical Media
	October 1	Germany	German Risk Assessor Finds Flaws in Seralini Study
	October 1	Spain	MON810 Corn Area Hits New Record in the Iberian Peninsula
	August 8	EU	EU-27 Agricultural Biotechnology Annual
	August 2	Portugal	Portugal Biotech Standing Report

	July 26	Austria	Agricultural Biotechnology Annual
	July 13	EU	EFSA Confirms Opinion on Safety of Animal Cloning
	July 10	France	Biotechnology – Food Security – Sustainability in the Americas
	July 9	Italy	Biotechnology in Italy 2012
	July 6	Italy	Say Yes to GMOs or Italian Agriculture will Suffer
	July 5	Italy	Agricultural Biotechnology Annual
	June 21	Spain	Agricultural Biotechnology Annual
	June 20	Romania	Agricultural Biotechnology Annual
	June 15	Croatia	Agricultural Biotechnology Annual
	June 15	France	Agricultural Biotechnology Annual

All these reports are available on the USDA/ FAS website at http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx