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Biotechnology and Other New Production Technologies

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Report Highlights:
In the European Union (EU), governments, the media, non-governmental organizations, consumers, and industry associations remain conflicted about the use of agricultural biotechnology. Acceptance varies widely across countries. A complex policy framework developed under pressure from anti-biotech activists has limited research, development, and production. The EU produces very few genetically engineered (GE) plants and animals but, with the growing adoption of biotechnology around the globe by leading agricultural producers, it imports millions of tons of GE soybean and corn products every year. Recent developments include a political agreement that allows Member States to ban cultivation of GE crops in their territories for non-scientific reasons, a move that may increase the pace of regulatory approvals, and a legislative proposal on animal cloning.

Section I. Executive Summary:

Until the 1990's, the European Union (EU) was a leader in research and development of biotech plants. Under the pressure from anti-biotech activists, EU and Member State (MS) authorities have developed a complex policy framework that has slowed down and limited research, development, and commercial production of biotech products. Due to repeated destruction of test plots by activists, programs are often limited to basic research inside laboratories and, in the past few years, several private developers have left the EU to conduct experiments in countries, such as the United States, where their work is not in danger of vandalism. Still, in 2014, open-field testing is being performed in 12 MS on a variety of biotech crops, and a new public-private partnership is planning to invest in research and innovation to fulfill the needs of the EU bioeconomy.

Commercial cultivation of genetically engineered (GE) crops is minimal in the EU, as a result of strong regulatory constraints. The only GE plant approved for cultivation, a corn variety, is grown on around 130,000 hectares, mostly in Spain, where it accounts for 30 percent of the corn area. The EU does not export any GE products, but it is a major importer of soybeans (30 million metric tons per year on average, worth around USD 15 billion) and corn products (6 million metric tons per year, worth around USD 2 billion), mainly used as feed in the livestock and poultry sectors. The share of GE products in total imports is estimated at around 90 percent for soybeans and 25 percent for corn. The United States is the EU's second largest supplier of soybeans and third largest supplier of soybean meal. Imports of U.S. corn vary widely by year. With the growing adoption of biotechnology around the globe by leading agricultural producers, the EU is getting increasingly isolated internationally, and it is more and more difficult and expensive for EU companies to source non-biotech products.

The regulatory procedures for approving biotech plants in the EU takes significantly longer than in supplier countries, which has led to situations where some GE plants are produced outside the EU but cannot be commercialized in the EU. As a consequence of the zero-tolerance policy on the adventitious presence of unapproved GE crops, shipments can be stopped at EU border if they contain traces of products that have not been approved in the EU yet. European feed manufacturers have repeatedly criticized the EU policy, as it could result in price increases for feed and a loss of competitiveness for the EU livestock and poultry sectors, which would decline and be replaced by imports of meat.

Acceptance of GE crops in the EU varies greatly among countries. MS can be divided into three categories. The *Adopters* include the countries that produce GE crops and those that would do so, if the scope of plants approved for cultivation in the EU was wider. Governments and industries in this group mostly favor biotechnology. The *Conflicted* group includes countries where forces willing to adopt the technology (mainly the scientific community and professionals of the agricultural sector) are counterbalanced and usually outmatched by forces rejecting it (consumers and governments, under the influence of activists). The *Opposed* group consists of MS where most stakeholders reject the technology. In these countries, the government generally supports organic agriculture and geographical indications.

In terms of marketing, at EU level, the broad trends could be described as follows: (a) very different forms of agriculture coexist in the EU, but overall, a majority of farmers and the feed supply chain support biotechnology; (b) due to the fact that European consumers are exposed to consistent negative messaging from activists, their perceptions are mostly negative; (c) food retailers adapt their offer to consumer perceptions. However, this description is only a very rough approximation since the situation

is very heterogeneous, depending on the country.

A political agreement on a new EU regulation was reached in 2014. This regulation allows opposed MS to ban the cultivation of GE crops in their territories for non-scientific reasons. A possible effect would be that opposed MS would be less likely to vote against import files given their ability to prohibit cultivation in legally certain conditions.

As for animal biotechnology, the EU is active in research, mainly for medical and pharmaceutical purposes, but also to improve breeding and to produce insects that can be used for biological control of plant pests. No GE animal is commercialized in the EU and market acceptance is low, due to ethical and animal welfare concerns. The EU imports around USD 32 million of U.S. bovine semen every year. At the end of 2013, the European Commission published legislative proposals that would ban animal cloning for food purposes in the EU, as well as the importation of cloned animals and the marketing of food from cloned animals. It is unlikely that these legislations will be implemented before 2016 at the earliest.

Note: Country reports referred to in this document 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:

DG SANCO	Directorate General for Health and Consumers of the European Commission
EC	European Commission
EFSA	European Food Safety Authority
EGE	European Group on Ethics in Science and New Technologies
ENVI	Environment, Public Health and Food Safety Committee of the European Parliament
EU	European Union

FAO	Food and Agriculture Organization of the United Nations
FAS	Foreign Agricultural Service of the United States Department of Agriculture
GAIN	Global Agricultural Information Network of the Foreign Agricultural Service
GE	Genetically Engineered (official terminology used by the U.S government)
GMO	Genetically Modified Organism (official terminology used by the EU, and used here when quoting specific regulatory language)
JRC	Joint Research Center of the European Commission
LLP	Low Level Presence
MS	Member State of the European Union
MT	Metric Ton
NGOs	Non-Governmental Organizations
NPBTs	New Plant Breeding Techniques (terminology used in the EU)
OECD	Organization for Economic Cooperation and Development
PPP	Public-Private Partnership
RASFF	Rapid Alert System for Food and Feed
S1 - S2	First Semester - Second Semester
SCoFCAH	Standing Committee on the Food Chain and Animal Health

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SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

1) The EU is active in plant biotechnology but research is not likely to lead to the commercialization of new GE plants in the short term.

A significant number of the internationally recognized public and private researchers in plant biotechnology are European. Major European private developers include BASF, BayerCropScience, KWS, Limagrain, and Syngenta. However, the private sector's interest in developing varieties of GE

plants suitable for cultivation in the European Union (EU) has waned. Repeated vandalism of test plots by activists, together with the uncertainty and delays of the EU approval process, makes genetic engineering an unattractive investment. EU companies have thus concentrated their efforts on non-European markets, and most of their research sites in plant biotechnology are now outside Europe.

As for public institutions and universities, they conduct basic research and very limited product development. Public research is unlikely to lead to the commercialization of genetically engineered (GE) plants in the EU within the next five years, because little emphasis is placed on product development which is the end of the research pipeline, and most public institutions are unable to afford the high costs of the EU regulatory approval system.

Public-private partnerships (PPPs) are another option. In 2013, the European Commission's Joint Research Center (JRC) released a report that evaluates the potential of the plant breeding sector to fulfil the needs of the EU bioeconomy (the term bioeconomy here includes food, feed, bio-based products and bioenergy).[1] It concludes that "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 PPPs 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." The Bio-Based Industries PPP that came into force in 2014 aims to develop new biorefining technologies to transform biomass into bio-based products, materials, and fuels. It is planning to invest €3.7 billion ($4.5 billion, 25 percent of which is publicly funded) in research and innovation efforts between 2014 and 2020 with the purpose of replacing at least 30 percent of oil-based chemicals and materials with bio-based and biodegradable ones by 2030. Biotechnology is one of the fields of research covered by this PPP.

As for international research projects, European developers are involved in a variety of them, including the Wheat Initiative, an international consortium gathering public institutions and private companies to coordinate global wheat research, the International Barley Sequencing Consortium, whose objective is to physically map and sequence the barley gene space, and the Peach Genome Initiative that aims at describing the genome sequence of peach.

Between 2000 and 2010, the EU funded a variety of research projects in plant biotechnology. More than 200 million euros have been invested in these projects which focus on environmental impacts of GE plants, food safety, biomaterials and biofuels, and risk assessment and management. For an overview of the projects, please see the European Commission's publication.

2) Regulatory decisions will shape the future of new plant breeding techniques in the EU.

[1] The needs of the EU bioeconomy have been assessed in the European Commission's Bioeconomy strategy for Europe (2012)

What are new plant breeding techniques?

Since the beginning of the twentieth century, several tools have broadened the possibilities for breeding new plant varieties, including mutagenesis and hybrid seed technology. The latest wave of innovation, dating from the 1980s, came from genetic engineering. GE crops reached commercial cultivation in the mid-1990s and currently represent an area of around 175 million hectares over the globe.

During the last 20 years, additional applications of biotechnology and molecular biology have emerged, and several new plant breeding techniques (NPBTs) have been developed. NPBTs make crop improvement quicker and more precise. They can complement or substitute for genetic engineering. In addition, NBPTs have potential to address consumer concerns about GE crops by creating plants that could also have been obtained by conventional breeding.

What are the prospects for the commercial development of NPBTs?

As for commercial development of NPBTs, in its most recent report of 2011, the European Commission notes that:

a) EU institutions play a prominent role in research and development activities. Publications on NPBTs began ten years ago, with the exception of grafting on GE rootstock (20 years). The EU is leading with 45 percent of all publications, followed by North America (32 percent). Eighty one percent of the publications are produced by public institutes.
b) Companies based in the U.S. are more active than those of the EU in patenting these techniques. Eighty four patents related to NPBTs have been registered. Sixty five percent of them come from applicants based in the U.S., followed by the EU (26 percent). Seventy percent of patent applications are from private companies.
c) All techniques have been adopted by some commercial breeders in the EU and applied on one or more crop plants. In 2011, the most advanced crops were judged close to commercialization, but the pace of market introduction will depend on regulatory decisions, which are still uncertain at this stage.

Regulatory issues: what is at stake?

The potential of NPBTs to produce innovative crop varieties will be affected by the regulatory framework of the geographic region in the world where they are to be introduced.

Crops produced using most of these techniques are indistinguishable from those produced by conventional breeding techniques or by natural genetic variation. The possibilities for detecting and identifying them have been investigated by a task force of laboratory experts, and they concluded that for most NPBTs,[2] detection was not possible. However, the EU's approach to biotechnology regulation is process-based, meaning that the focus is not on the potential risks of the product, as is the case in U.S. regulation, but on the method of production. In the EU, a product is mainly characterized by the

[2] zinc finger nuclease technology 1 and 2, oligonucleotide directed mutagenesis, RNA-dependent DNA methylation, grafting on GE rootstock, reverse breeding, agro-infiltration "sensu stricto" and agro-inoculation Source: report on NPBTs by the European Commission's Joint Research Centre, 2011

techniques used in its production. As a consequence, each new technique needs to be approved.

A working group established by the European Commission in 2007 is still evaluating whether certain NPTBs constitute techniques of genetic modification and, if so, whether the resulting organisms fall within the scope of the EU legislation on genetic engineering. The report of the working group, once finalized, will be presented to the MS for further discussion and decisions. The group is discussing the following eight new techniques: zinc finger nuclease technology, oligonucleotide directed mutagenesis, cisgenesis and intragenesis, RNA-dependent DNA methylation, grafting on GE rootstock, reverse breeding, agro-infiltration, and synthetic biology.

If a technique is classified as GE, it will require additional time and financial costs to gain approval compared with nonregulated classic breeding techniques. Therefore, the legal status of the NPBTs will influence the decision on whether to use these techniques only for the introduction or modification of traits in crops with very high value or more extensively for a broad field of applications and will be of specific importance for small and medium companies. At the time of writing, we do not have an estimated timeframe for when the legal status of NPBTs will be defined.

Another challenge will be international harmonization. Should these technologies be classified differently in the EU and in other countries, it would potentially impact trade. The JRC organized a workshop on NPBTs in 2011 where approaches to these techniques by various countries were compared, including, among others, the EU, Argentina, and Canada. It turned out that the definition of a GMO differs between countries and that this determines whether or not NPBTs are classified as such.

How to conduct risk assessment of NPBTs?

In 2011, EFSA was asked to provide an opinion on whether current guidance was appropriate for the risk assessment of organisms derived through new techniques and on the possible risks of these organisms. In 2012, EFSA released two scientific opinions in response:

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

2) On the safety of plants developed using site-directed nucleases 3 (SDN-3), such as zinc finger nuclease 3, available here. This document concludes that "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 to occur they would be of the same types as those produced by conventional breeding techniques."

b) COMMERCIAL PRODUCTION

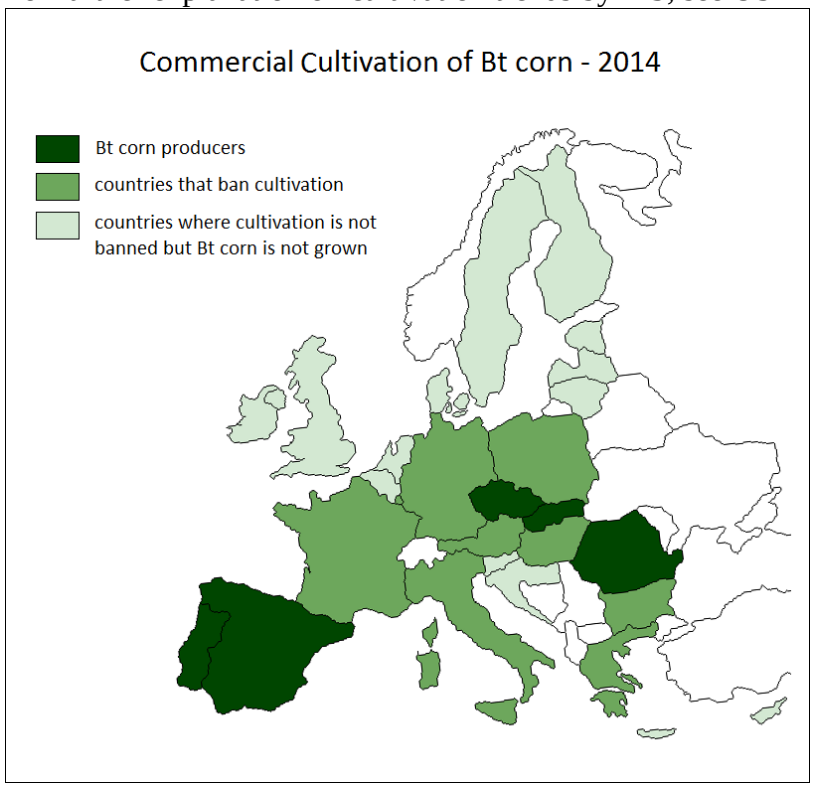
The only genetically engineered (GE) crop authorized for cultivation in the EU is MON810 corn. It is a Bacillus thuringensis (Bt) corn resistant to the European corn borer (a pest). The total cultivated area has been on an upward trend on the long run (see graph and table below). However, in 2014, the area is expected to decrease slightly to 131,477 hectares due to a drop in the total corn area cultivated in the EU (both conventional and GE).

The situation varies from country to country:

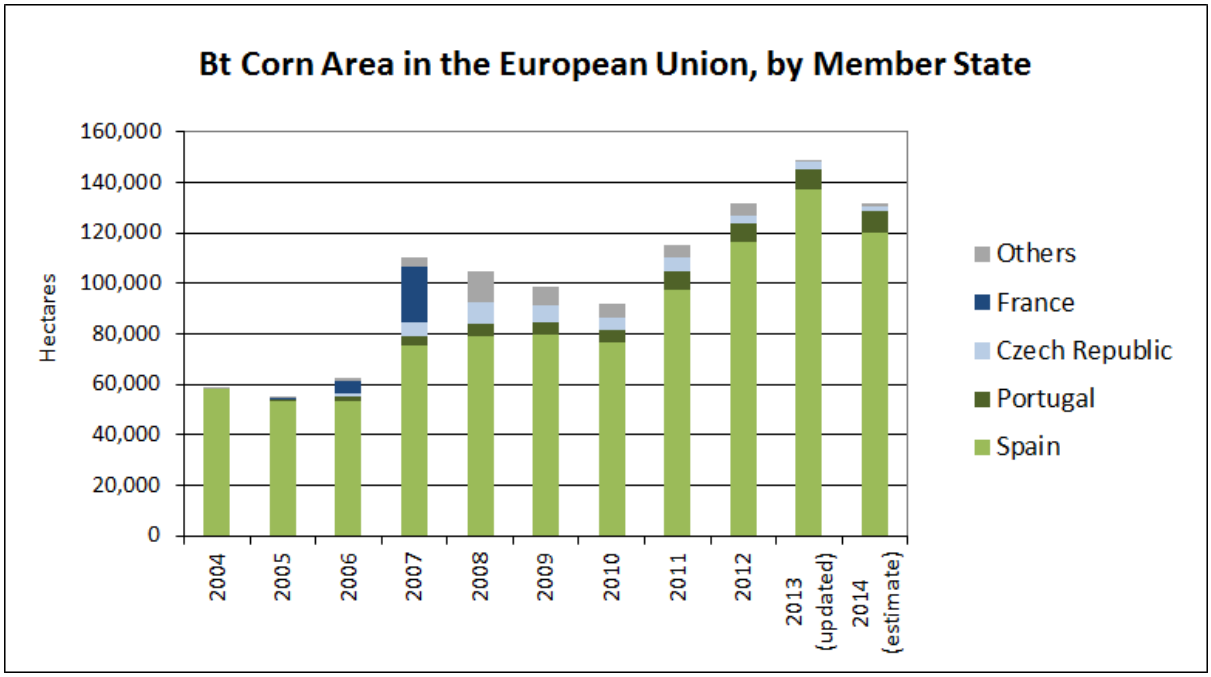
- Five MS cultivate Bt corn in 2014. Spain represents around 90 percent of the total area. Bt corn accounts for more than 30 percent of Spain's total corn production. Portugal, the Czech Republic, Romania, and Slovakia also cultivate Bt corn.
- Nine MS have implemented national bans on MON810 corn. They include Austria, Bulgaria, Greece, Hungary, Italy and Luxemburg. As for France, Germany, and Poland, they used to produce Bt corn but currently ban cultivation.
- In the other MS, cultivation is not banned but no Bt corn is currently grown for various reasons, including the fact that is not well-suited to local growing conditions (the United Kingdom would grow GE crops if there were suitable traits available to address pests and disease in key crops) and the threat of protests (public field registers detailing the location of commercially grown GE crops are compulsory in most MS).

Bt corn produced in the EU is used locally as animal feed and for biogas production.

For further explanation on cultivation trends by MS, see USDA FAS country reports, listed in Annex 2.



Source: USDA FAS



Source: USDA FAS

Bt Corn Area in the EU, by Member State (hectares)

	2006	2007	2008	2009	2010	2011	2012	2013 (updated)	2014 (estimate
Spain	53,667	75,148	79,269	79,706	76,575	97,346	116,307	136,962	120,000
Portugal	1,254	4,199	4,856	5,094	4,869	7,724	7,700	8,171	8,542
Czech Republic	1,290	5,000	8,380	6,480	4,678	5,090	3,050	2,800	1,754
Romania	0	331	7,146	3,400	822	588	217	834	771
Slovakia	30	930	1,930	875	1,281	760	189	100	411
France	5,200	22,135	0	0	0	0	0	0	0
Germany	947	2,685	3,171	0	0	0	0	0	0
Poland	100	100	300	3,000	3,500	3,900	4,000	0	0
Total Bt corn	62,488	110,528	105,052	98,555	91,725	115,408	131,463	148,867	131,478
Total corn area (1,000 ha)	8,492	8,444	8,854	8,284	7,984	9,100	9,720	9,850	9,550
Share of Bt corn in total corn	0.74%	1.31%	1.19%	1.19%	1.15%	1.27%	1.35%	1.51%	1.38%

Source: USDA FAS

c) EXPORTS

The EU does not export any GE products.

d) IMPORTS

The EU is a major importer of GE soybean and corn products, mainly used as a feed ingredient in the livestock and poultry sectors. The EU is protein deficient and does not produce enough to meet demand.

Trade data do not differentiate between conventional and GE varieties. The graphs presented in this section therefore include both categories. The table below gives the share of GE crops in total soy and corn production in major exporting countries.

Share of GE Crops in Total Production - 2014

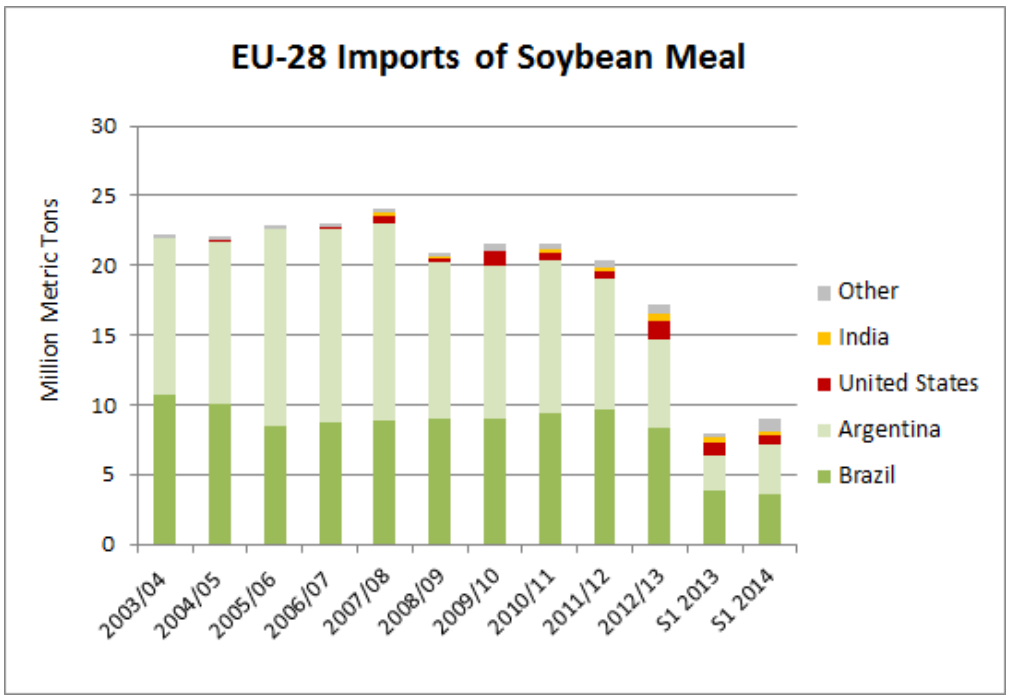
	Soy	Corn
Argentina	99 %	95 %
Brazil	91 %	82 %
Canada	62 %	81 %
United States	94 %	93 %
Paraguay	96 %	-

Source: USDA FAS

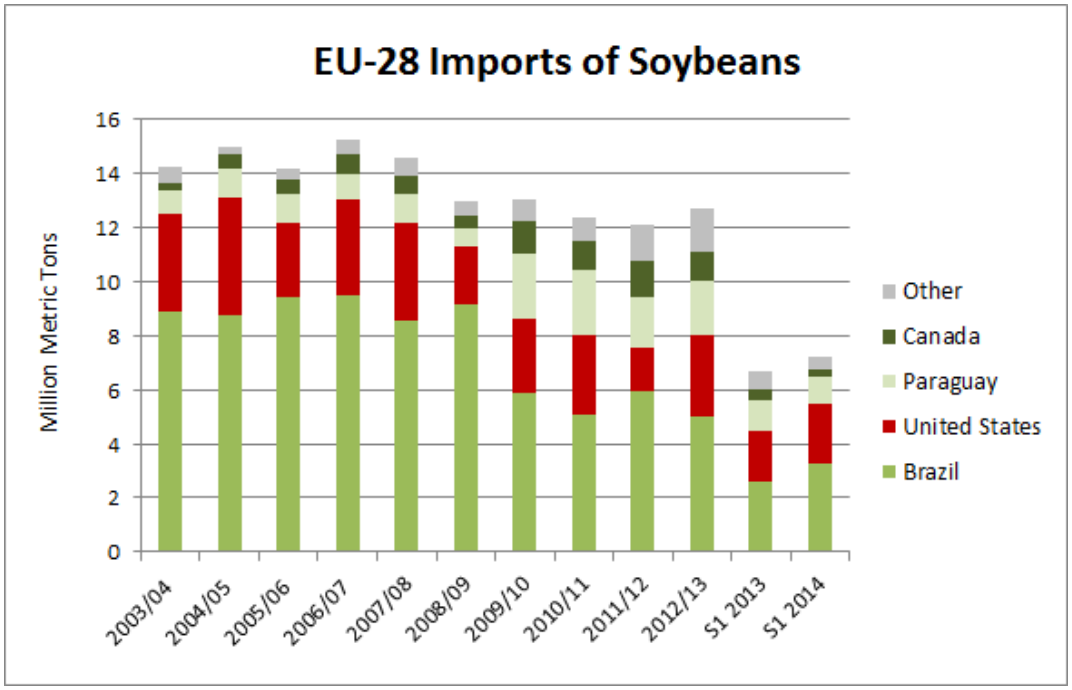
- **The EU imports more than 30 million MT of soybean products every year.**

Around 42 million metric tons (MT) of soybean products are consumed annually in the EU, mainly as animal feed, eighty percent of which is imported. The EU's leading suppliers are Brazil, Argentina and the United States. In the past ten years, soybean meal imports amounted to 21 million MT and soybean imports to 13 million MT per year on average (see graphs below).

Soybean meal is the main GE product imported in the EU. It is the primary source of proteins for livestock. The largest users of soybean meal (Spain, Germany, France, Italy, and the Benelux) are also the main producers of livestock and poultry. They represent 65 percent of total EU consumption.



S1: First Semester - Source: Global Trade Atlas



S1: First Semester - Source: Global Trade Atlas

The demand for non-biotech soybean meal in the EU is estimated at 20 percent of total meal consumption. It includes the organic sector, some of the products sold under geographical indications, and various GE-free labeling initiatives. It is mainly supplied by domestically grown soybeans and imports from Brazil and India.

As the global cultivation of GE crops expands, it is increasingly difficult for European importers to source non-biotech products. Their availability is declining and their prices are on the rise. At the beginning of 2014, the German poultry farmers association withdrew its 14-year commitment to use only non-GE soybeans in poultry feed, stating that it was impossible to meet in the current market conditions. In response, German food retailers demanded that the farmers stop using GE feed for poultry at the beginning of 2015. The debate has become an important aspect in the discussion of the future of German poultry and livestock production (alongside the national protein strategy, animal welfare, and the use of antibiotics).[3]

There has been a long-standing debate in the EU over the dependence on imports of soybeans and soybean meal. Some initiatives are promoting locally grown non-GE soybeans, like the Danube Soya Association, according to which the production potential for soybeans in the Danube region would be 4 million MT. Overall, the EU's current potential for soy and other non-GE protein crops production remains minor relative to total animal feed demand. In May 2014, the European Focus Group on protein crops published its final report.[4] The objective was to answer the following questions: What does the feed sector need in terms of protein? Why is the EU protein crops sector not competitive? How can this be remedied? Their conclusions were the following: (a) In the EU, the competitiveness of protein crops at the moment is low. Protein crops production will not rise if the yields do not increase substantially. (b) Much of the yield gap could be overcome by breeding. (c) The total innovation process would require many years, and it would be necessary to focus on a limited number of crops as financial resources would be limited.

- **The EU imports 6 million MT of corn per year on average.**

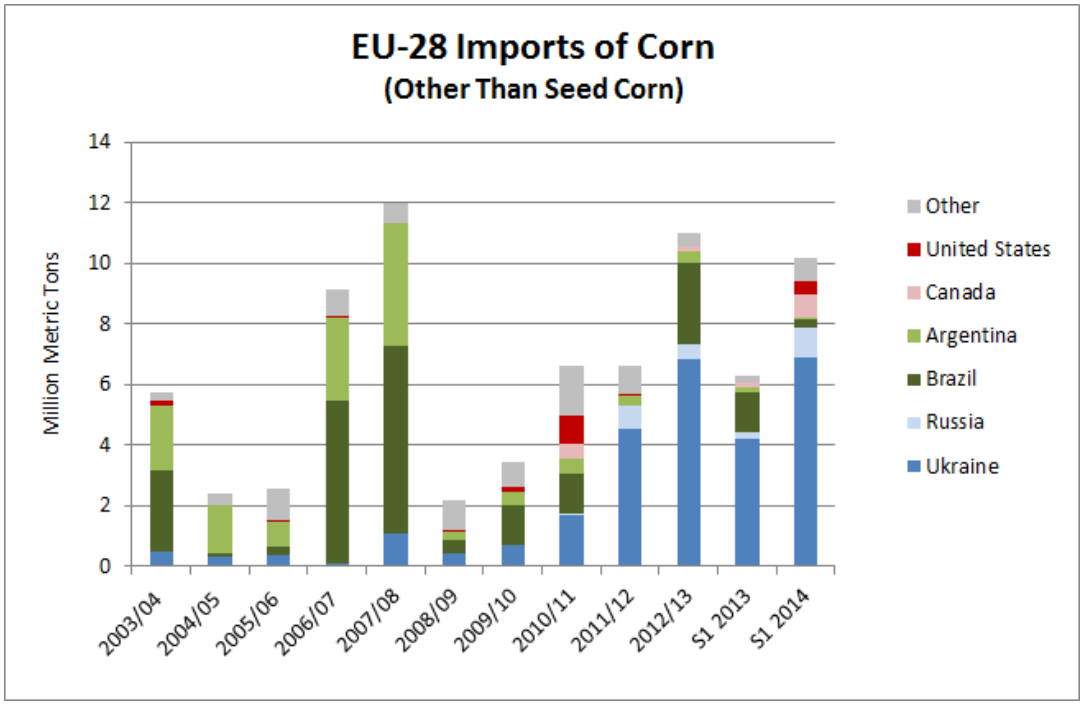
Annual EU corn consumption amounts to 62 million MT per year on average. About 10 percent of it is imported. The share of GE products out of total corn consumption is estimated to be lower than 25 percent.

While U.S. exports of corn to the EU fluctuated between two and four million MT 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 U.S. resulted in a drastic decline in U.S. exports to the EU as a function of asynchronous approvals of GE products between the U.S. and the EU. More specifically, it takes an average of 47 months to approve a GE product in the EU as opposed to 25 months in the United States.[5] As a consequence, in 2009, shipments of approximately 180,000 MT of U.S. soy were denied entry into the EU because they contained traces of three GE corn types that had been deregulated in the United States but not yet approved in the EU.[6]

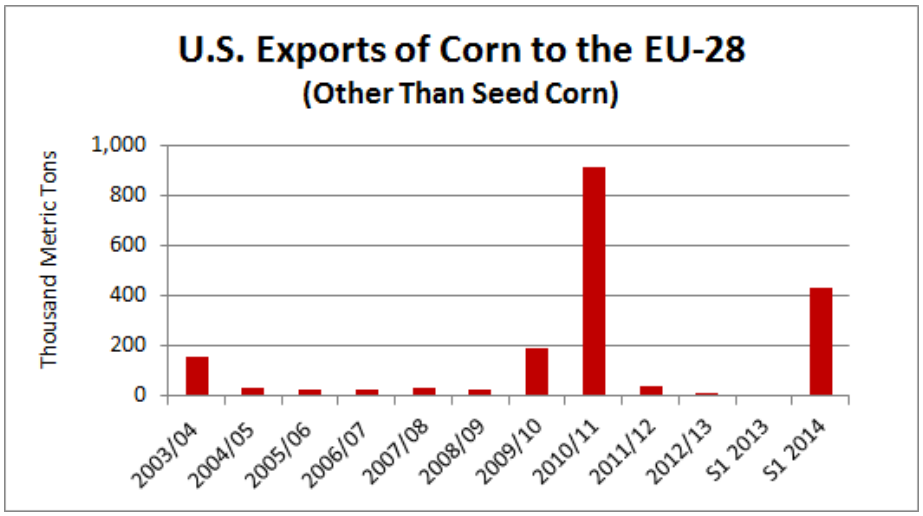
The booming of Ukraine's market share in EU imports of corn has been remarkable in the past few

[3] For more information please see the 2014 GAIN report about biotechnology in Germany
[4] This Focus Group is part of the European Innovation Partnership (EIP) "Agricultural Productivity and Sustainability," one of five EIPs which have been launched by the European Commission in a bid to step up innovation efforts. One of the objectves of a Focus Group is to propose priorities for innovative actions by suggesting potential projects.
[5] see PART B – POLICY a) Regulatory Framework iv. Distinctions Between Regulatory Treatment of the Approval for Food, Feed, Processing and Environmental Release
[6] see PART B – POLICY n) Low-level Presence Policy

years, resulting both from economic factors and from their non-biotech image. No production of GE crops has been officially allowed in the Ukraine, but rumors in the industry say that around one third of the corn grown in the country is GE.



S1: First Semester - Source: Global Trade Atlas

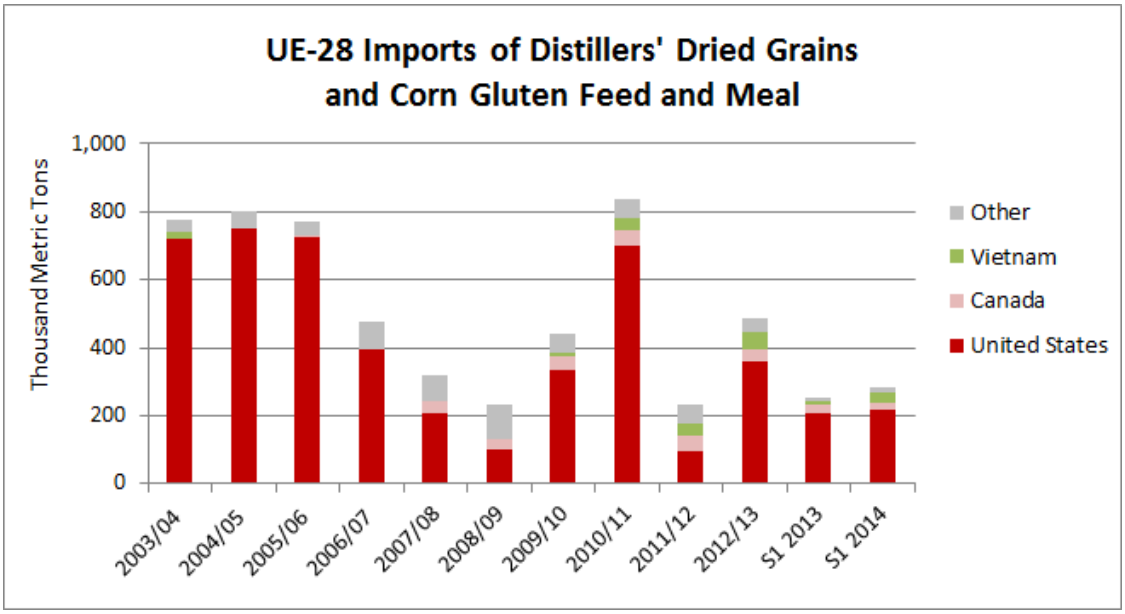


S1: First Semester - Source: Global Trade Atlas

- **The U.S. is the main supplier of distillers' dried grains and corn gluten feed and meal to the EU.**

The U.S. is the main supplier of distillers' dried grains (DDGs) and corn gluten feed and meal (CGFM) to the EU, with an average market share of 75 percent over the past ten years (see graph below). The volume of imports varies from year to year depending on prices and on the pace of EU approvals of new

GE corn varieties.



S1: First Semester - Source: Global Trade Atlas

e) FOOD AID

The EU is not a recipient of food aid.

PART B - POLICY

a) REGULATORY FRAMEWORK

The three guiding principles of EU laws on the commercial use of GE products are safety (for human and animal health and the environment), freedom of choice for consumers, farmers, and businesses (rules on coexistence, labeling and traceability), and case-by-case evaluations.

i. Responsible Government Ministries and Their Role in the Regulation of GE Plants

At the EU level, GE plants are subject to an authorization procedure whether for import, distribution, processing, or cultivation for food or feed use. The steps necessary to obtain authorization for import, distribution, or processing are set out in Regulation (EC) No 1829/2003. Directive 2001/18 EC outlines the procedure that must be followed to obtain authorization for cultivation.

In both cases, the European Food Safety Authority (EFSA) must conclude during the risk assessment phase of the authorization process 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 MS on whether or not

the product should be authorized. SANCO, the European Commission's Directorate General for Health and Food Safety,[7] administers the latter risk management phase of the procedure. SANCO submits the files as a draft Decision to MS experts at the GE Product Section of the Standing Committee on Plants, Animals, Food and Feed PAFF), or the Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms (Regulatory Committee).

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The European Commission's Joint Research Center (JRC) and DG Research and Innovation conduct research programs on life sciences and biotechnology.

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

ii. Role and Membership of the Biosafety Authority

EFSA's core task is to independently assess any possible risks of GE plants to human and animal health and the environment. EFSA does not authorize GE products: its role is limited to giving scientific advice. Main areas of activity of EFSA's panel on GE organisms are the following:

- **Risk assessment of GE food and feed applications:** EFSA's panel provides independent scientific advice on the safety of GE plants (on the basis of Directive 2001/18/EC) and derived food or feed (on the basis of Regulation (EC) No 1829/2003). Its risk assessment work is based on reviewing scientific information and data.
- **Development of guidance documents:** the guidance documents aim to clarify EFSA's approach to risk assessment, to ensure transparency in its work, and to provide the companies with guidance for the preparation and presentation of applications.
- **Scientific advice in response to ad-hoc requests from risk managers:** for instance, the Panel has provided scientific advice relating to the safety of GE plants unauthorized in the EU and to the "safeguard clauses" invoked by certain MS to temporarily prohibit the placing on their national market of specific GE plants authorized at the EU level.
- **Self-tasking activities:** on its own initiative, the Panel identifies scientific issues related to GE plants risk assessment which requires further attention. For instance, the Panel has produced a scientific report on the use of animal feeding trials in GE products risk assessment.

[7] formerly DG Health and Consumers
[8] formerly DG Health and Consumers
[9] formerly Standing Committee on the Food Chain and Animal Health (SCoFCAH)

EFSA's panel brings together 20 risk assessment experts from different European nationalities with expertise in a range of relevant fields: food and feed safety assessment (food and genetic toxicology, immunology, food allergy, etc.), environmental risk assessment (insect ecology and population dynamics, plant ecology, molecular ecology, soil science, resistance evolution in target pest organisms, impact of agriculture on biodiversity, agronomy, etc.) as well as molecular characterization and plant science (genome structure and evolution, gene regulation, genome stability, biochemistry & metabolism, etc.). Their biographies and declarations of interests are available on EFSA's website. An EFSA discussion document of 2013 acknowledges societal and institutional changes since 2012 and lays down a series of policy options which EFSA will analyze during the next few years. We understand that one of the options may be to incorporate social science in EFSA's work.

iii. Political Factors that May Influence Regulatory Decisions Related to Plant Biotechnologies

- **Public Distrust, the Establishment of the EFSA, and the Precautionary Principle**

Negative public opinion initially developed in some MS 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 non-governmental organizations (NGOs) took advantage of modern communication technologies to capitalize on public insecurity.

The European Commission attempted to counter this lack of public confidence by proposing Regulation (EC) No 178/2002 that defined the general principles and requirements of food law and established EFSA (see previous item: ii. Role and Membership of Biosafety Committee/Authority). This Regulation provides among other things for the use of the Precautionary Principle in risk analysis. More specifically, "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in (the EU) may be adopted, pending further scientific information for a more comprehensive risk assessment." The abuse of this principle by anti-biotech MS and to a lesser extent by EFSA has continuously resulted in the EU taking significantly longer than other countries to approve GE plants.

- **The Chief Scientific Adviser to the President of the European Commission**

In 2010, European Commission President Barroso created the position of Chief Scientific Adviser (CSA) to the President of the European Commission. The CSA position, which fell within the Bureau of European Policy Advisers (BEPA) structure, was directly linked to the Commission President. Barroso appointed Professor Anne Glover to the CSA post in January 2012. The mandate of the CSA was "*to provide independent expert advice on any aspect of science, technology and innovation as requested by the President*." In this role she advised the President on any aspect of science and technology, liaised with other science advisory bodies of the Commission, the MS and beyond, coordinated science and technology foresight, and promoted the European culture of science to a wide audience, conveying the relevance of science to non-scientists. She also chaired the President's Science

& Technology Advisory Council.

In 2013, Glover asserted that GE food and feed is no less safe than conventional food and feed. She noted that Sweden and the Netherlands have consistently voted for GE approvals whereas Austria and Luxembourg have consistently voted against them while all four MS have been presented with the same scientific evidence. As such, Glover expressed her wish that politicians who vote against GE food and feed admit that they do so for reasons other than science.

Professor Glover argued that the incoming Juncker Commission must find better ways of separating evidence-gathering processes from the "*political imperative*." She also called for the creation of an "*evidence service*" within the Commission, able to work with the CSA to assess policy proposals in light of the best available sciences. During the summer of 2014, scientists put pressure on then Commission President elect Juncker to maintain the CSA position; there was similar pressure in the other direction exerted by anti-biotech NGOs. In November 2014, it was announced that Glover's tenure as CSA expired with the end of Barosso's Commission's mandate on November 1, 2014, and that the post of CSA would be eliminated. Glover will leave the Commission at the end of her contractual engagement at the end of February 2015. At the same time, Commission President Juncker announced that BEPA would be dissolved and replaced by the European Center of Strategic Policy (ECSP) in January 2015. A Commission spokesperson asserted that "*President Juncker believes in independent scientific advice. He has not yet decided how to institutionalize this independent scientific advice."*

Another worrying item in Juncker's agenda is his intention to review the legislation applicable to the authorization of GE products because "*it is simply not right that under the current rules, the Commission is legally forced to authorize new organisms for import and processing even though a clear majority of Member States is against it. The Commission should be in a position to give the majority views of democratically elected governments at least the same weight as scientific advice, notably when it comes to the safety of the food we eat and the environment in which we live.*"

It is unclear whether or not Juncker's assertion was political posturing or a substantive undertaking. Current EU legislation (post-Lisbon) already gives the Commission the choice (as opposed to the obligation) to adopt its proposals after the Appeal Committee has not given an opinion for or against them. As such, it would not be necessary for EU legislation to be reviewed in order for the College of the Commission to delay or not allow agricultural biotech approvals. However, Juncker's stated political attitude towards agricultural biotechnology remains of great concern.

iv. Distinctions Between Regulatory Treatment of the Approval for Food, Feed, Processing and Environmental Release

EU regulations provide a detailed approval process for GE products. Requirements differ depending on whether the GE products are intended for import, distribution, processing, or cultivation for food or feed use in the EU.

- Regulation (EC) No 1829/2003 provides the steps necessary to obtain authorization for import, distribution, or processing.
- Directive 2001/18/EC outlines the procedure that must be followed to obtain authorization for cultivation.

- In order to simplify the process for the applicants, the European Commission defined a unique application procedure under Regulation (EC) No 1829/2003 which allows a company to file a single application for a product and all its uses. Under this simplified procedure, a single risk assessment is performed and a single authorization is granted for cultivation, importation and processing into food, feed or industrial products. However, the criteria established by Directive 2001/18/EC still have to be met in order to obtain the authorization for the cultivation of the GE crop concerned.

- **Authorization for placing biotech events on the market for food or feed use**[10]

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

- An application[11] 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.

- EFSA is obliged to respect a limit of six months from the time it receives a valid application to when it gives 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 of publication.

- Within three months from receiving the opinion from EFSA, the European Commission presents the Plants, Animals, Food and Feed Meetings (SCoPAFF) with a draft decision reflecting EFSA's opinion. SCoPAFF votes on the draft decision.

- Draft decisions that have been put to the SCoPAFF after March 1, 2011, are subject to the procedural rules outlined in the Lisbon Treaty. Under these rules, in the case of no qualified

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

[11] 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.

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 MS). 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 and at the latest one year before the expiration 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 expiration date, the period of authorization is automatically extended until a decision is taken.

The full list of approved products is available on the European Commission's website.

The list of biotech products pending renewal authorization under Regulation (EC) 1829/2003 is available on EFSA's website.

- **Authorization for cultivation of biotech events**[12]

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[13] to the appropriate national competent authority of 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.

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

[13] 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.

- 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.

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

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

Currently, the "safeguard clause" in the EU legislation (Article 23 in Directive 2001/18/EC) governing plant biotechnology allows MS to ban the cultivation of biotech crops in their territories, if new scientific evidence suggests that such cultivation could be harmful to the environment, or human or animal health. Austria, Bulgaria, France, Germany, Greece, Hungary, Italy, and Luxembourg have invoked the safeguard clause to impose national cultivation bans on MON810 corn. However, EFSA has determined that these bans are not justified by scientific evidence, which is a precondition of using the safeguard clause. The Commission has allowed the bans to continue despite the EFSA determinations. As such, the Commission has not been fulfilling its role as "Guardian of the Treaties" by allowing MS to abuse EU law and has sought a means by which MS could legally "opt out" of cultivating approved GE crops without using spurious science to invoke the safeguard clause.

The Environment Council of December 2008 under the French Presidency of the EU Council of Ministers requested the European Commission to report to the European Parliament and Council on socioeconomic implications of biotech plant cultivation on the basis of MS contributions. In response to a request from 13 MS made in June 2009, the Commission presented a package of proposals in July 2010 that would expand the reasons that a MS could use to justify bans on cultivating EU approved GE crops in its territory on grounds other than health and environmental considerations (the "Opt Out" proposal). The proposal has been examined during several Presidencies. In July 2011, the European

Parliament adopted a set of amendments to the Commission proposal. The Environment Council of March 2012 was unable to reach a political agreement, as a blocking minority of delegations still had concerns regarding certain aspects of the proposal. In March 2014, the Environment Council confirmed the willingness of MS to re-open discussions on the legislative proposal on the basis of a Presidency compromise text. Since then, the Greek Presidency convened several meetings of the ad hoc Working Party, which demonstrated that a new revised proposal could gather broad support.

On June 12, 2014, the Environment Council reached a political agreement with almost unanimous support on a draft Directive that is subject to agreement by both the Council and the Parliament. The draft includes the following elements:

- the link between the first (EU level application of EU authorization) and the second phase (national application in every MS where cultivation is planned);
- the MS' request for adjustment of the geographical scope will be channeled exclusively via the Commission and no timely response is considered to be a tacit agreement;
- a non-exhaustive list of possible grounds that can be used by MS to restrict or prohibit the authorizations, including environmental reasons, socio-economic reasons, land use and town planning, agricultural policy objectives and public policy issues;
- amendments to establish the set of deadlines and responsibilities governing the decisions relating to the adjustment of the geographical scope of the authorization, including an additional opting out option based on new objective circumstances;
- a number of transitional measures that can be adopted after the entry into force of the legal act, in particular, until up to 6 months after the entry into force of the Directive, a MS may request, via the Commission, to adjust the geographical scope of a notification/application granted before the date of entry into force of this Directive;
- four years after the entry into force of the Directive, the Commission will present a report to the European Parliament and to the Council on the use of this Directive and its effectiveness, including on environmental risk assessments.

The political agreement was formally adopted by the Council at First Reading. At a trilogue meeting convened on Wednesday, December 3, a common position was reached by the MS and the EP. The most significant aspect to this position is that the link between the first phase (where a MS which does not want to cultivate an approved biotech crop can request the provider, via the Commission, to exclude it from the cultivation application) and second phase (where a MS can inform the Commission that it will not permit cultivation of an approved biotech crop on its territory for reasons other than scientific reasons, e.g., policy reasons) has disappeared. Whereas the Council position agreed to in June 2014 required those MS which did not want to cultivate GE crops to use the first phase initially and, in the unlikely event that agreement could not be reached during that stage, subsequently use the second phase. The trilogue position broke this sequential link. As such, anti-GE MS may either invoke the first or second phase at any time. The text will be discussed in the MS' capitals in December 2014 with a view to the EP voting the measure at plenary probably in January 2015. The measure would then be applicable from the spring 2015.

Those MS which are in favor of GE technology and support the cultivation "Opt Out" proposal do so because they feel that its adoption would allow anti-GE MS to prohibit cultivation of biotech crops on all or part of their respective territories without reverting to the use of spurious science to invoke the "safeguard clause." By extension, it is asserted that a possible "knock on effect" would be that those

anti-GE MS would be less likely to vote against GE import files given their facility to prohibit cultivation in legally certain conditions.

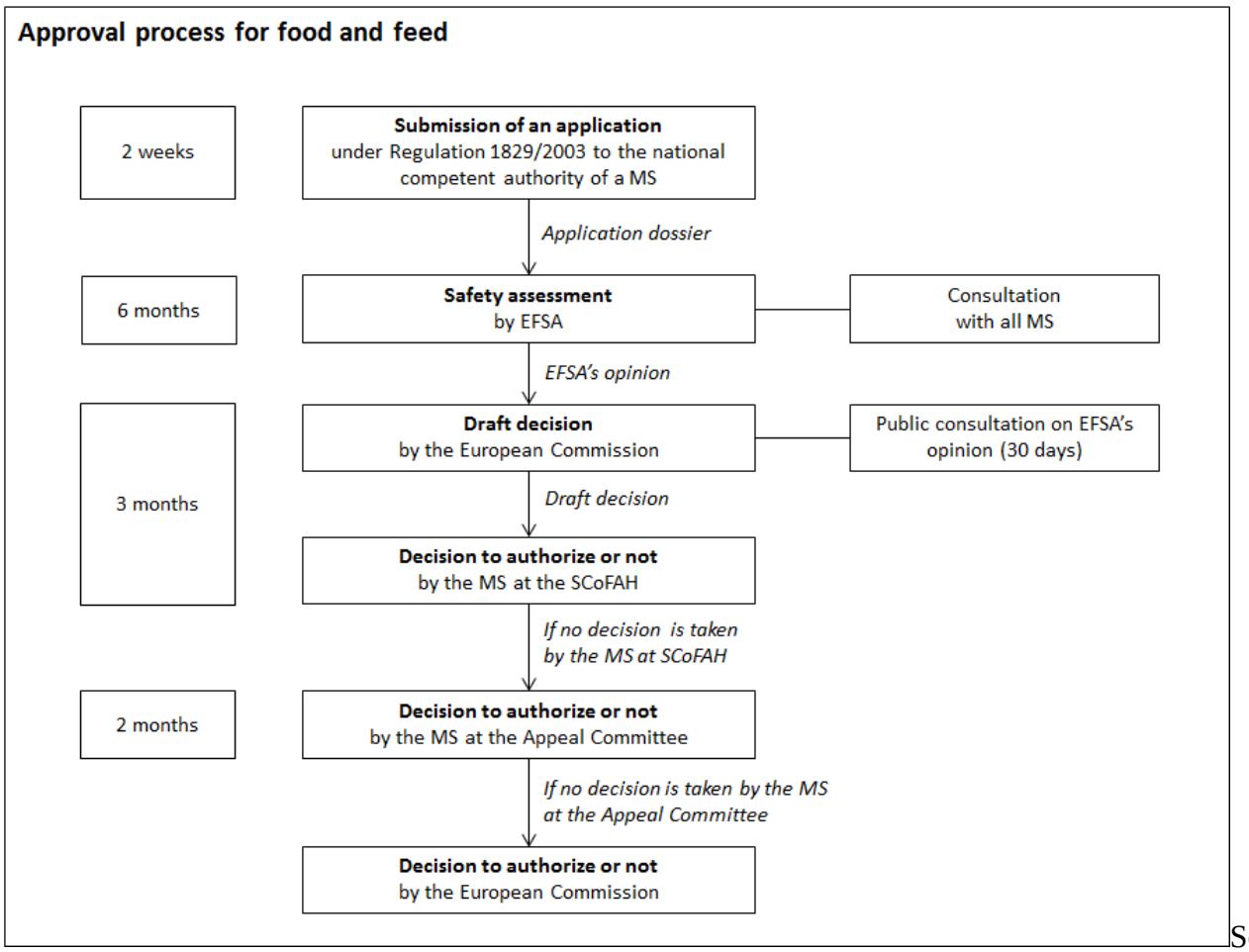
vi. Timeline Followed for Approvals

The timelines that should be followed for approvals according to the EU regulations are given in the charts below. Although the legally prescribed approval process should take around 12 months, it takes an average of 47 months for a GE 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 MS. The Commission waits ten months on average as opposed to the prescribed three months before requesting MS to vote. In contrast, Brazil and the U.S. average about 25 months and Korea 35 months.

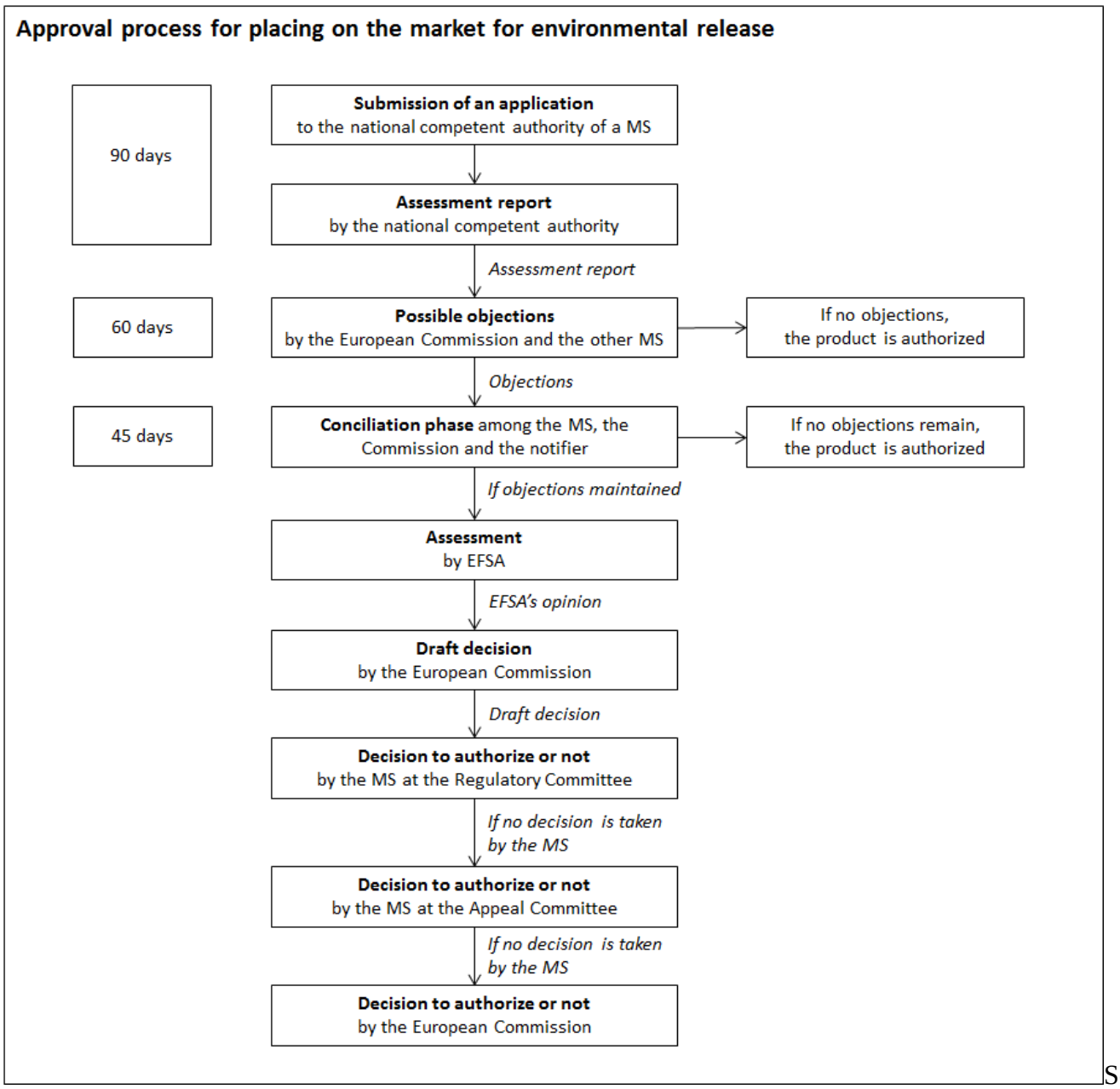
Each year, more biotech applications have been submitted than authorization decisions made, creating a growing backlog both in EFSA and at the Commission. In December 2014, 58 events were awaiting approval and the number of applications continues to exceed the number of approvals. The EU livestock industry relies on imports of GE feed with soy products being the largest agriculture import into the EU, and the delay in approvals creates risks for the trade.

It is likely that Commission Implementing Regulation (EU) No 503/2013, published in June 2013, establishing requirements for applications for GE approvals, will lead to additional delays in GE approvals and additional burdens for exporters. The provisions of the Regulation go beyond or conflict with the approach to safety assessment as outlined in the Codex Plant Guideline.

The EU-wide authorization procedure for food and feed is described in the chart below.



Source: USDA FAS



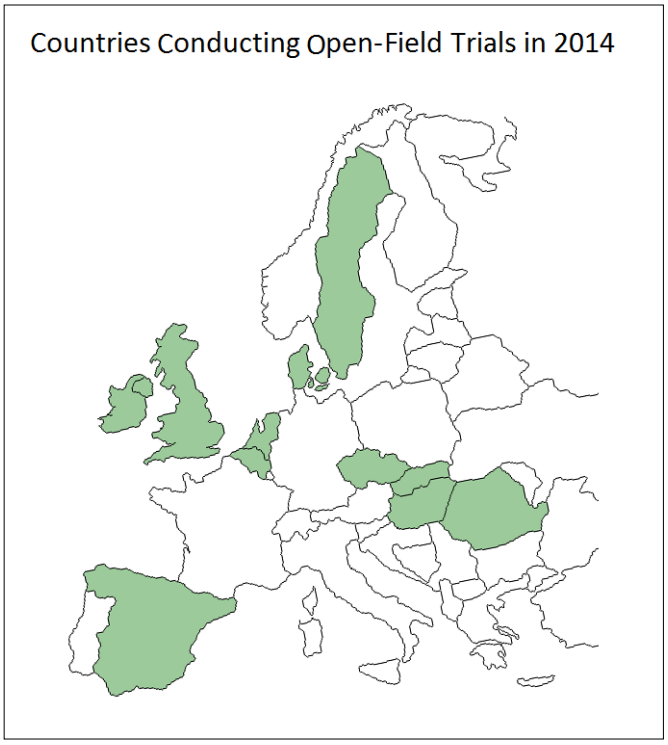
Source: USDA FAS

b) APPROVALS

The full list of approved GE products, as well as products for which an authorization procedure is pending, is available on the European Commission's website. The list of GE products for which an authorization procedure is pending is also available on the EFSA's website.

At the time of this report, GE products authorized for food or feed use in the EU include 37 varieties of corn, 8 of cotton, 7 of soybean, 5 of rapeseed, one of sugar beet and two microorganisms.

MON810 Bt corn is the only GE plant authorized for cultivation.



c) FIELD TESTING

Source: FAS Posts

Eleven MS conducted open-field testing in 2014: Belgium, the Czech Republic, Denmark, Hungary, Ireland, the Netherlands, Romania, Slovakia, Spain, Sweden, and the United Kingdom (see map below). Tested plants include apples, barley, corn, cotton, flax, peas, the plum pox virus resistant plum tree, poplar trees, sugar beets, potatoes, tobacco, tomatoes, and wheat.

Open-field testing is also allowed in Portugal but there has been no notification since 2010. There used to be many field trials in France and in Germany but their number has fallen to zero in 2014 due to repeated destruction of test plots by activists during the past few years. Some public institutions that conduct laboratory research go into partnership with private companies, in order to carry out field trials in countries where they are not likely to be destroyed by activists, such as the United States.

For more information on field testing in each country, please see USDA FAS country reports listed in Annex 2.

The steps to obtain authorization to release GE plants into the environment for experimental purposes are detailed in Part B - Policy, a - Regulatory Framework, iv. Distinctions between regulatory treatment of the approval for food, feed, processing and environmental release.

The list of the notifications for deliberate release of GE plants into the environment is available on the JRC website. The number of projects actually conducted may be lower than the number of notifications.

d) STACKED EVENT APPROVALS

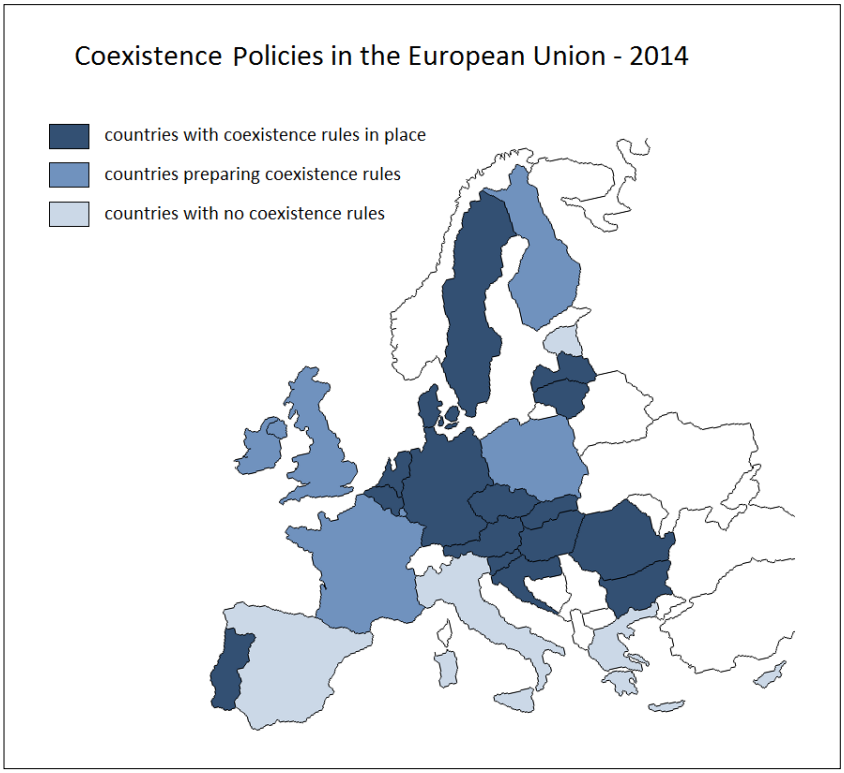
The approval process of stacked events is the same as in the case of single events.

The risk assessment follows the provisions of Regulation (EU) No 503/2013, Annex II. The applicant shall provide a risk assessment of each single event or refer to already submitted applications. The risk assessment of stacked events shall also include an evaluation of (a) stability of the events, (b) expression of the events, and (c) potential interactions between the events.

e) ADDITIONAL REQUIREMENTS

In almost all MS, with the notable exception of Spain, farmers that produce GE crops must register their fields with the government. In some countries, this obligation tends to discourage farmers from growing GE crops, since it can be used by activists to locate fields.

f) COEXISTENCE



Coexistence rules of GE plants with conventional and organic crops are not set by EU authorities but by MS national authorities. At EU level, the European Coexistence Bureau organizes the exchange of technical and scientific information on best agricultural management practices for coexistence. On this basis, it develops crop-specific guidelines for coexistence measures.

The map below shows that most MS have adopted or are preparing coexistence rules.

Countries that produce GE crops have enacted specific legislation on coexistence, except Spain where coexistence is managed by following the good agricultural practices defined by the National Association of Seed Breeders.

In some parts of the EU such as Southern Belgium and Hungary, coexistence rules are very restrictive and strongly limit the cultivation of GE crops.

Some countries are preparing coexistence rules. In Poland, the draft legislation is expected to enter into force not earlier than in 2016. In the United Kingdom, rules will be implemented "when GE crops are grown." In France, several regulations are in place but the rules governing distances between GE crops and other fields have not been defined yet.

For more information on coexistence rules in each country, please see USDA FAS country reports listed in Annex 2.

Source: FAS Posts

g) LABELING

- **European Regulation: Mandatory Labeling of GE Products and Exemptions**

In order to ensure consumer rights to information, EU regulations (EC) No 1829/2003 and (EC) No 1830/2003 require food and feed produced from or containing GMOs to be labeled as such. These regulations apply to products originating in the EU and imported from third countries. Bulk shipments and raw materials must be labeled, as well as packaged food and feed.

Some products exempt from labeling obligations are:
- Animal products originating from animals fed with GE feed (meat, dairy products, eggs);
- Products that contain traces of authorized GE ingredients in a proportion no higher than 0.9 percent, provided that this presence is adventitious or technically unavoidable;
- Products that are not legally defined as ingredients according to Article 6.4 of Directive 2000/13/EC, such as processing aids (like food enzymes produced from GE microorganisms).

In practice, consumers rarely find GE labels on food, because many producers have changed the composition of their products to avoid losses in sales. Indeed, although products undergo a safety assessment and labels are simply there to inform consumers, they are often interpreted as warnings, and producers expect labeled products to fail in the market.

- **Voluntary "GMO-free" Labeling Systems**

In France, Germany, and Austria, the government has implemented a national voluntary "GMO-free" labeling system. For more information, please refer to USDA FAS country reports listed in Annex 2.

Besides, some food manufacturers and retailers voluntarily label their products as "GMO-free." However, they represent a small share of the food products commercialized in the EU. Such labels are mainly found on animal products (meat, dairy products, and eggs), canned sweet corn and soybean products.

h) TRADE BARRIERS

- **Asynchronous Approvals**

The EU regulatory procedures for approving biotech plants take a significantly longer than those in supplier countries. Differences in the speed of authorizations lead to situations where products are approved for commercial use outside the EU but not within the EU. Shipments of agricultural commodities destined for the EU have been rejected when traces of such events have been detected at the point of entry.

While new GE crops are entering the global market place at an increasingly rapid rate, only five application files were approved for import into the EU in 2013 and none have been approved since then. In fact, twelve files for food and feed import and one for cultivation, all having received positive safety assessments from EFSA, remain pending with the College of Commissioners as of December 2014. European feed manufacturers and cereals and feedstuffs traders have repeatedly criticized the length of the EU authorization process, as the delays could result in trade disruptions and price increases for protein-rich products which the EU needs for its animal feed sector.

The effect of these asynchronous approvals is reinforced by the EU low-level presence policy.[14]

- **National Bans**

Several MS have banned the cultivation, import, or processing of GE plants on the basis of the safeguard clause[15] or of the emergency measures[16] (see table below). However, EFSA has determined that several of these bans are not justified by scientific evidence, which is necessary to implement them. In some countries, the bans have been lifted and immediately reintroduced several times, with the governments giving a new reason each time for banning the GE plant concerned. In order to overcome this issue, an "opt-out" proposal is currently being discussed at EU level.[17]

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 Amflora potato	Cultivation	2010
Bulgaria	Monsanto MON810 corn	Cultivation	2010
France	Bayer Rapeseed Topas 19/2	Import/Processing	1998
	Bayer MS1XRf1 rapeseed	Import/Processing	1998
	Monsanto MON 810 corn	Cultivation	2008, 2012, 2014
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
	BASF Amflora potato	Cultivation/Feeding	2010
Italy	Monsanto MON810 corn	Cultivation	2013
Luxemburg	Syngenta Bt176 corn	Cultivation	1997
	Monsanto MON 810 corn	Cultivation	2009
Poland	Monsanto MON810 corn	Cultivation	2013

Source: FAS Posts

i) INTELLECTUAL PROPERTY RIGHTS

[14] see specific section on this issue below: n) LOW-LEVEL PRESENCE POLICY
[15] set out in Article 23 of Directive 2001/18/EC
[16] referred to in Article 34 of Regulation (EC) No 1829/2003
[17] see Part B - POLICY, a. REGULATORY FRAMEWORK, v. Legislations and regulations with the potential to affect U.S. exports

- **Comparison Between Plant Variety Rights and Patents**

Several intellectual property systems apply to inventions relating to plants in the EU. The table below compares plant variety rights (also referred to as plant breeders' rights) and patents.

	Plant variety rights	Patents
What does the property right cover?	Plant breeders' rights cover **a plant variety**, defined by its whole genome or by a gene complex.	Patents cover **a technical invention**. Elements that are patentable include: - plants, if the plant grouping is not a variety, if the invention can be used to make more than a particular plant variety, and as long as no individual plant varieties are mentioned in the claim; - biological material (e.g., a gene sequence) isolated from its natural environment or technically produced, even if it previously occurred in nature; - microbiological processes and their products; - technical processes. Plant varieties and essentially biological processes for the production of plants and animals are not patentable.
Conditions to be met	Plant varieties can be granted variety rights provided that they are clearly distinguishable from any other variety, sufficiently uniform in their relevant characteristics, and stable.	Patents can only be granted for inventions that are new, involve an inventive step, and are susceptible of industrial application.[18]
Scope of the protection	One single variety and the varieties essentially derived from it are protected within the EU.	All plants with the patented invention are protected within the EU.
Exemptions	- Breeders' exemption allows free use of a protected variety for further breeding and free commercialization of new varieties (except for essentially derived ones). - There is an option for producers to use farm-saved seed under certain conditions.	At EU level, according to the European Patent Office, the plant is protected for all its uses.[19]
Duration	The variety is protected for 25 years from the date of issue (30 years for some plants: trees, vines, potatoes, legumes, etc.).	The invention is protected for 20 years from the application date.

[18] According to the European Patent Office, a specific legal definition of novelty has developed over the years, with "new" meaning "made available to the public." This means, for example, that a gene, which existed before but was hidden from the public in the sense of having no recognized existence, can be patented when it is isolated from its environment or when it is produced by means of a technical process.

[19] This point has been controversial in some EU countries.

Responsible office	The Community Plant Variety Office (CPVO) is responsible for the management of the plant variety rights system.	The European Patent Office (EPO) examines European patent applications.
Number of applications	In 2013, the CPVO received around 3,300 applications. 198 of them (6 percent) were submitted by companies from the United States. The CVPO does not give any figures for the share of biotech varieties. More than 80 percent of the applications are successful.	- The EPO receives between 500 and 800 applications relating to plant biotechnology each year. - 95 percent of plant patents granted by the EPO are related to biotechnology. Inventions include improved plants (nutrition, drought resistance, high yield, pest and herbicide resistance), plants as a biofactory (vaccines, antibodies), and methods for making new plants. Thirty nine percent of all plant patents come from the U.S., 42 percent of them come from Europe (mainly Germany, The United Kingdom, Belgium and France). - On average, just under one third of applications relating to biotechnology[20] are granted. About five percent of the patents granted by the EPO are opposed, mostly by competitors of the patent holder, but in some cases also by individuals, NGOs or special interest groups.
Legal basis	All the legislations in place are available on the CPVO website. They include Regulation (EC) No 2100/94 on plant variety rights. The UPOV website gives the text of the UPOV Convention (International Convention for the Protection of New Varieties of Plants) and the legislation of MS that has been notified in accordance with it.	The legal basis for patenting biotechnological inventions in the EU include: - the European Patent Convention (EPC), an international treaty ratified by all MS that provides the legal framework for the granting of patents by the EPO; - the case law of the EPO boards of appeal, that rules on how to interpret the law; - Directive 98/44/EC on the legal protection of biotechnological inventions, that has been implemented into the EPC since 1999 and shall be used as a supplementary means of interpretation; - national laws that implement EPC and Directive 98/44/EC (in place in all MS since 2007, see USDA FAS country reports).

- **Position of International Organizations on Plant Variety Rights and Patents**

The position of the International Seed Federation (ISF) is that the most effective intellectual property

[20] all biotechnology applications (not only plant biotechnology ones)

system should balance protection as an incentive for innovation and access to enable other players to further improve plant varieties. ISF favors plant variety rights.

The European Seed Association (ESA), that represents the European seed sector, supports the co-existence of patents and plant variety rights. ESA also supports the exclusion of plant varieties and essentially biological processes from patentability. Besides, ESA thinks that free access to all plant genetic material for further breeding has to be safeguarded, as is the case in the French and German patent laws via an extended research exemption.

j) CARTAGENA PROTOCOL RATIFICATION

The Convention on Biological Diversity (CBD) is a multilateral treaty that was opened for signature in 1992 at the Rio Earth Summit. It has three main objectives: the conservation of biological diversity, the sustainable use of the components of biological diversity, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

Two supplementary agreements to the CBD have been adopted since then: The Cartagena Protocol on Biosafety (2000) and the Nagoya Protocol on Access to Genetic Resources (2010).

- ### Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety (CPB) aims to ensure the safe handling, transport, and use of living modified organisms. The European Union signed it in 2000 and ratified it in 2002. Regulations implementing the CBP are in place (see the CBP website for a complete list of them).

The competent authorities are the European Commission's Joint Research Centre (JRC), EFSA GMO Panel, the European Commission Directorate General for the Environment, and DG SANCO.

Regulation EC 1946/2003 regulates trans-boundary movements of GMOs and transposes the Cartagena Protocol on Biosafety into EU law. Procedures for the trans-boundary movement of GMOs include: notification to importing parties; information to the Biosafety Clearing House; requirements on identification and accompanying documentation.

For more information, see the European Union's profile on the CBP website.

- ### Nagoya Protocol on Access to Genetic Resources

The Nagoya Protocol on Access to Genetic Resources aims at sharing the benefits arising from the utilization of genetic resources in a fair way, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies. The European Union signed it in 2011.

Regulation (EU) No 511/2014 implementing the mandatory elements of the Protocol entered into force in October 2014. According to this regulation, users must ascertain that their access to and use of genetic resources is compliant, which requires seeking, keeping and transferring information on the genetic resources accessed.

The European Seed Association, that represents the European seed sector, considers that given the very high number of genetic resources used in the creation of a plant variety, "it will create an enormous administrative burden," and "small companies which form the vast majority of Europe's seed sector will find this impossible to comply with."[21]

k) INTERNATIONAL TREATIES/FORA

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

The EU is member of the Codex Alimentarius alongside its 28 MS. The European Commission represents the EU in the Codex; DG SANCO is the contact point. The EU and its MS draw up EU position papers on the issues discussed in the Codex. The latest position pertaining to biotechnology is the 2011 comment on GE food labeling. It states that EU policy was designed to address the needs expressed by the European consumers, but that the EU has no intention to impose GE labeling to the rest of the world

All MS have signed the International Plant Protection Convention (IPPC), an international treaty which works to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. DG SANCO is the IPPC official contact point in the EU. The EU has not taken any position related to plant biotechnology in the IPPC recently.

In 2011, France chaired the G20 and introduced agriculture among the top issues discussed at the ministerial level. A meeting of the ministers of agriculture of the G20 countries took place in Paris. The declaration they adopted unanimously called for "improved agricultural technologies" and "innovation in plant breeding" to "increase the agricultural production and productivity." Plant biotechnology is part of these tools. The action plan of the G20 created the Wheat Initiative, an international consortium gathering public institutions and private companies to coordinate global wheat research. A vision document was issued in 2013.

l) RELATED ISSUES

The European Commission has funded a three-year, 6 million euro (US$7.5 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.

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

m) MONITORING AND TESTING

[21] See ESA's press release

- **Mandatory Monitoring Plans for Environmental Effects and for Use as Food or Feed**

Directive 2001/18/EC and Regulation (EC) No 1829/2003 state that:

1. The first step to obtain authorization to place a GMO22 on the market is the submission of an application. This application must include a monitoring plan for environmental effects.[23] The duration of the monitoring plan may be different from the proposed period for the consent.
2. Where appropriate, the application must include a proposal for post-market monitoring regarding use as food or feed.[24]
3. Following the placing on the market, the notifier shall ensure that monitoring and reporting are carried out according to the conditions specified in the written consent given by the competent authority. The reports of this monitoring shall be submitted to the European Commission and the competent authorities of the MS. On the basis of these reports, in accordance with the consent and within the framework for the monitoring plan specified in the consent, the competent authority which received the original notification may adapt the monitoring plan after the first monitoring period.[25]
4. The results of the monitoring must be made publicly available.[26]
5. Authorizations are renewable for ten year periods. Applications for renewal of an authorization must include, among other items, a report on the results of the monitoring.[27]

- **Rapid Alert System for Food and Feed**

The Rapid Alert System for Food and Feed (RASFF) is used to report food safety issues. The general functioning of the RASFF is illustrated in the graph below.

Whenever a member of the RASFF network (the European Commission, EFSA, a MS, Norway, Liechtenstein, or Iceland) has any information relating to the existence of a risk to human health deriving from food or feed, this information is immediately transmitted to the other members of the network. The MS shall immediately notify of any measure aimed at restricting the placing on the market of feed or food, and of any rejection at a border post related to a risk to human health.

Most notifications concern controls at the outer borders in points of entry or border inspection points when consignments are not accepted for import.

Detail of the notifications is available on RASFF's portal. Between January and October 2014, there were 11 border rejections due to the presence of unauthorized GE products, mainly cotton seeds from Ivory Coast and rice products from China (Decision 2011/884/EU requires systematic screening for genetic modifications of rice products from China).

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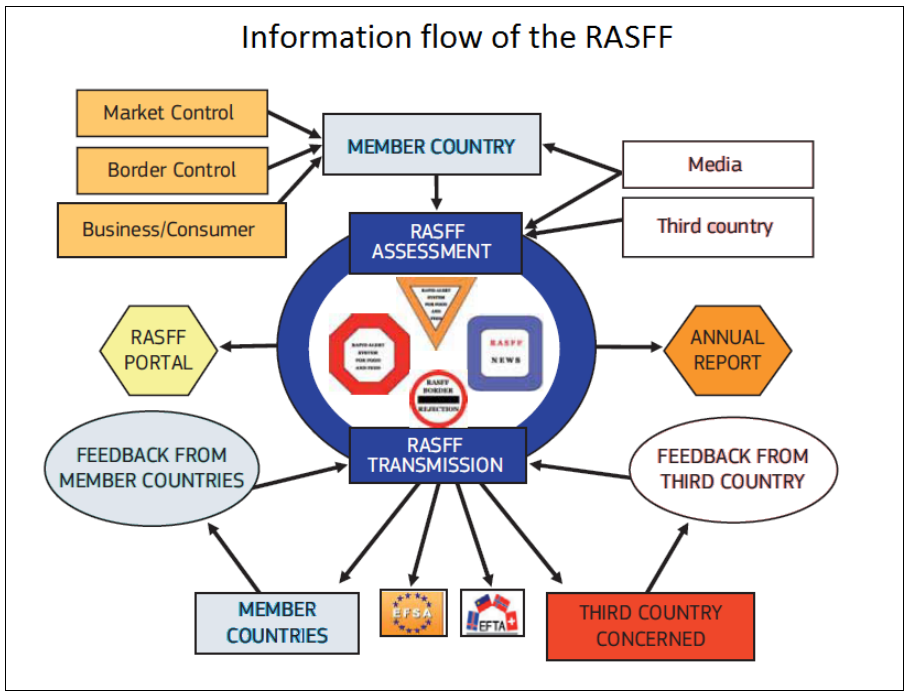
[22] "Organism" meaning "any biological entity capable of replication." No monitoring plan for environmental effects needs to be included for food and feed that do not contain any entity capable of replication.
[23] Directive 2001/18/EC: Article 5 and Annex III for experimental releases, Article 13 and Annex VII for placing on the market
[24] Regulation (EC) No 1829/2003 Articles 5 and 17
[25] Directive 2001/18/EC Article 20
[26] Directive 2001/18/EC Article 20 - Regulation (EC) No 1829/2003 Article 9
[27] Directive 2001/18/EC Article 17 - Regulation (EC) No 1829/2003 Articles 11 and 23



Source: RASFF 2013 annual report

n) LOW LEVEL PRESENCE POLICY

- **FAO Consultation on Adventitious Presence of GE Crops in International Shipments**

The steady growth of the land area under cultivation with GE crops around the globe over the last two decades has led to a higher number of traces of such crops being adventitiously present in traded food and feed. This has resulted in trade disruptions with shipments being blocked by importing countries and destroyed or returned to the country of origin.

In March 2014, the FAO held a technical consultation on low levels of GE crops in international food and feed trade. Two types of incidents have been considered:

- Low Level Presence (LLP), defined as the detection of low levels of GE crops that have been approved in at least one country, but not in the importing country. Most incidents are linked to asynchronous approval systems.
- Adventitious Presence (AP), defined as the unintentional presence of GE crops that have not been approved in any country (in such case, the mixed crops come either from field trials or from illegal plantings).

The results of the FAO survey show that the number of incidents is low relative to the millions of tons of food and feed traded every day. Seventy five countries have answered the survey. They have reported 198 LLP or AP incidents in the past ten years (2003 - 2013). The shipments concerned originate mainly from the United States (27 percent), Canada (27 percent), and China (23 percent). The most impacted commodities are rice and rice products (70 detections), linseed (52 detections), and corn (29 detections). Soybean and soybean products represent 10 detections in 10 years. Sixty one percent of the respondents have not defined a threshold level for LLP, 39 percent have. Specifically regarding

shipments originating from the U.S. and imported in the EU, 44 incidents were reported in ten years; they involved shipments of rice, corn, soybean products and pet food.

- **EU Policy on LLP**

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 GE corn types that had not been approved for food, feed or import by the EU but had been allowed in the United States.

This situation prompted the European Commission to propose a 0.1 percent threshold for as yet EU unapproved biotech events in feed to be allowed, known as the "technical solution." However, the 0.1 percent presence permitted by the "technical solution" is too low to be commercially viable.

Despite the European Commission's commitment in 2011 to evaluate the impact of this decision on the food and feed chain, which could result in the development of policy options relating to expanding the scope to food and seeds, there has been little movement towards this until recently. It is understood that the Commission is currently engaged in the process of tendering for a consultant to undertake the evaluation with a view to proposing appropriate policy options. The Commission has claimed that it would take a "step-by-step" approach on LLP. Since a technical solution for feed has already been introduced, the next step would be for the EU to consider the same kind of solution for food, then for seeds.

In September 2012, 13 countries endorsed an International Statement on LLP as part of a joint effort to address risks to trade. The signatories are Australia, Argentina, Brazil, Canada, Chile, Costa Rica, Mexico, Paraguay, Philippines, Russia, the U.S., Uruguay, and Vietnam. They made a commitment to continue to work collaboratively to address the overarching problem of asynchronous approvals of biotech products, while trying to mitigate the impact of LLP situations in food and feed. The EU is absent from the countries that have endorsed the Statement.

The slow pace of authorizations coupled with the absence of a commercially viable LLP policy create problems for U.S. exporters of conventional and biotech products to the EU. They have little confidence to trade because shipments could contain trace amounts of a biotech product which has been allowed in another country 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.

PART C – MARKETING

a) MARKET ACCEPTANCE

Acceptance of GE crops in the EU varies greatly from MS to MS. The map below shows that there are three major categories of countries. Some broad trends are highlighted in order to give an overall picture of the EU, which is necessarily an approximation since the situation is very heterogeneous.

- **Acceptance Varies Greatly Across EU Countries**

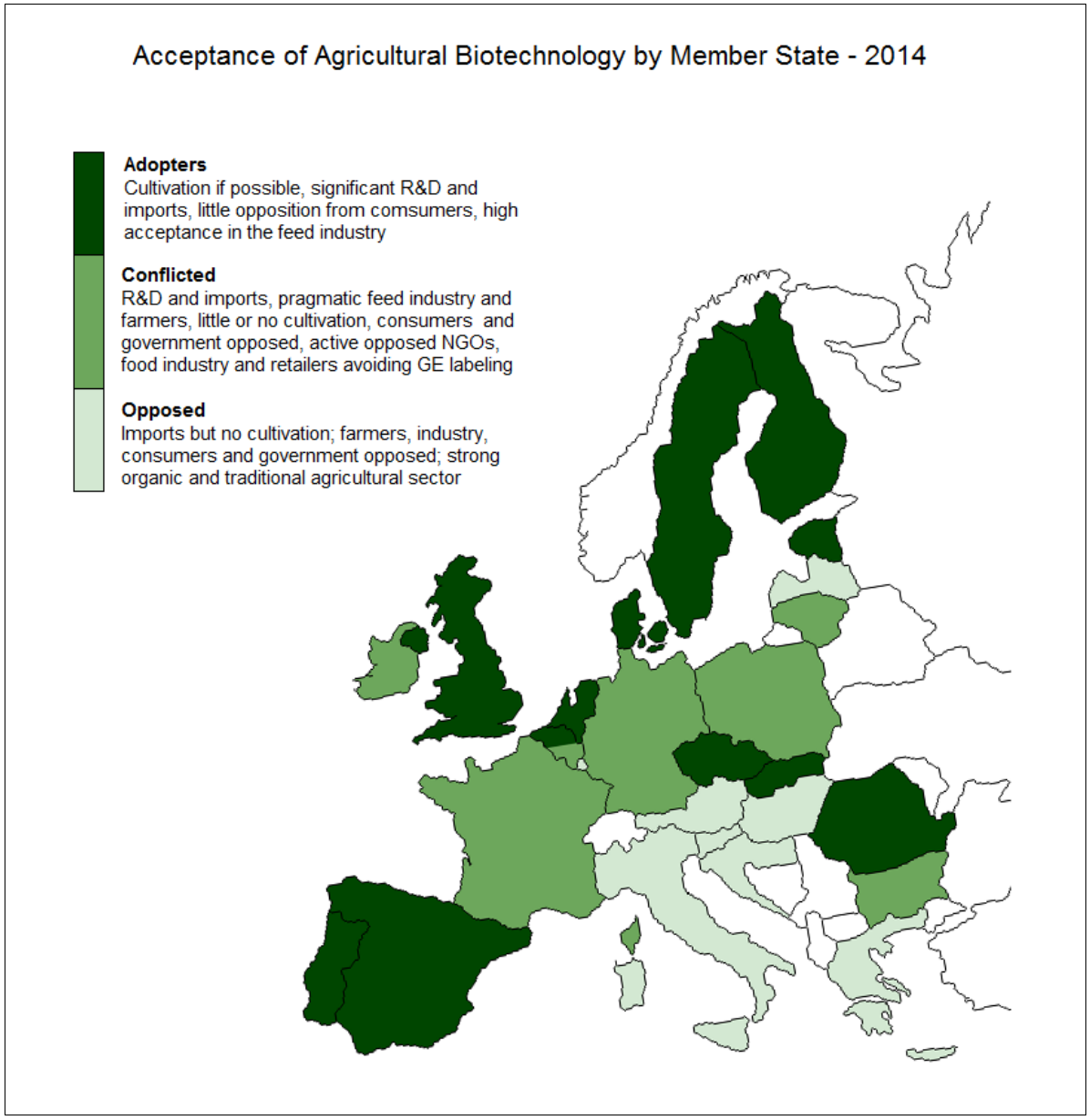
There are three major categories of MS depending on their acceptance of plant biotechnology, as

illustrated in the map below.

- The "Adopters" include producers of Bt corn (**Spain, Portugal, Czech Republic, Slovakia, and Romania**) and MS that would produce GE plants if the scope of approved products for cultivation in the EU was wider (**Denmark, Estonia, Finland, Flanders in Northern Belgium, the Netherlands, Sweden, and the United Kingdom**). The Adopters have pragmatic governments and industry generally open to the technology. For example, the government of the United Kingdom has openly taken a position in favor of adopting agricultural biotechnology since 2012.

- In the "Conflicted" MS, the scientific community, farmers, and the feed industry are willing to adopt the technology, but consumers and governments, influenced by activist Green parties and NGOs, reject it. In this group, **France, Germany, and Poland** cultivated Bt corn in the past, but have since implemented national bans. **Southern Belgium (Wallonia), Bulgaria, Ireland and Lithuania** are under the influence of the other countries of this group, especially France and Poland. Within this group, Germany has become increasingly vocal against agricultural biotechnology. As for France, it used to abstain when voting on import files (see table below) but it has voted against them since mid-2013.

- In the "Opposed" MS, most stakeholders and policy makers reject the technology. Most of these countries are located in Central and South Europe (**Austria, Croatia, Cyprus, Greece, Hungary, Italy, Malta, and Slovenia**). **Latvia** is also an Opposed MS. Organic food and products sold under geographical indications represent a significant part of the farm and food production in these MS. A minority of farmers is supportive of growing biotech crops in these countries.



Source: FAS Posts

- **General Trends**

Acceptance of GE plants must be looked at from the point of view of farmers, consumers, and retailers. At EU level, the general trends, which are only rough approximations, include the following:

1. Most EU farmers and the feed supply chain support agricultural biotechnology

The EU is a major importer of GE products, mainly used as feed in the livestock and poultry sectors. Market acceptance of GE products is high in the animal production sectors and their feed supply chains, including animal feed compounders, as well as livestock and poultry farmers who depend on imported products to make balanced animal feeds. European importers and feed manufacturers have repeatedly

criticized the EU policy (length of the authorization process, absence of commercially viable LLP policy), arguing that it could result in shortages, price increases for feed, and a loss of competitiveness for the breeding sector, which would decline and be replaced by imports of meat from animals raised according to lower production standards.

A majority of the EU farmers support the use of GE varieties due to the proven yield gains and lower input use, and many of them would grow GE crops if they were allowed to. The main factors that prevent them from doing so currently are: (a) the fact that in 2014, there is only one GE crop authorized for cultivation in the EU, and nine MS have implemented a national ban on it; (b) the threat of protests or destruction by activists, given that public field registers detailing the location of commercially grown GE crops are compulsory in most MS.

2. Consumer perceptions are mostly negative

For nearly two decades, European consumers have been exposed to consistent negative messaging from NGOs purporting that GE crops are harmful. As a result, consumer attitudes towards GE products are mostly negative, with concerns about the potential risks of cultivating and consuming them, and their use in food has become a highly contentious and politicized issue. In European countries that grow GE crops, such as Spain, consumer perception is better. The benefit they value the most is the reduction of insecticide use that Bt corn allows.

Several developments have changed the dynamic of the debate to some extent and have the potential to begin to change consumer perceptions. They are: GE crops which provide nutritional or other benefits to consumers; new plant breeding techniques, such as cisgenesis that are perceived as more 'natural' than transgenesis; and GE crops which provide environmental benefits. The 2010 survey by the European Commission indicates that objections to GE food are related to concerns about safety seen in the context of a lack of perceived benefit, and that these are objections which may wane if new varieties offer clear benefits.

The portrait of European citizens painted in the European Commission's 2010 report, in comparison to earlier surveys, shows that the crisis of confidence in technology that characterized the 1990s is no longer dominant. Today, there is a greater focus on each technology, in order to understand if it is safe and useful, but there is no rejection of the impetus towards innovations.

3. Food retailers adapt their offer to consumer perceptions

The EU has approved over 40 GE plants for food use. However, as a consequence of consumer negative perceptions, most food retailers, especially major supermarkets, market themselves as carrying only non-GE products. They also fear actions by activist organizations that would likely target any retailer offering GE-labeled products, which means an unacceptable brand risk that hinders the introduction of GE-labeled food. As always, the situation varies across countries, and in the United Kingdom there are increasing examples of GE-labeled products that achieve sales success.

The EU Research Project Consumer Choice, which aims at comparing individual purchasing intentions with actual behavior, shows that responses given by consumers when prompted by questionnaires about GE foods are not a reliable guide to what they do when shopping in grocery stores. In reality, most

shoppers do not avoid GE labeled products when they are available.

b) PUBLIC/PRIVATE OPINIONS

In the EU, different types of civil society organizations have militated against agricultural biotechnology since it was first introduced in the 1990s. Their actions include lobbying public authorities, vandalism (destruction of research trials and cultivated fields), and communication campaigns to heighten public fears in the service of their political strategy. The extent to which they are accepted and the effectiveness of their attempts to convince the public vary across countries, but there is no denial that they have played an important role in the adoption of regulations that have restricted the adoption of biotechnology in the EU.

Stakeholders that defend the use of GE plants at EU level are scientists and professionals of the agricultural sector, including farmers, seed companies, and representatives of the feed supply chain including importers. Their visibility to the general public is lower than that of biotech opponents. Professionals of the agricultural sector are concerned about the negative economic impact of restrictive policies, including a loss of competitiveness for the European seed and livestock and poultry sectors. Scientists underline that the action of biotechnology opponents has resulted in a loss of scientific knowledge in the EU, including for public research and in the field of risk assessment.

Public opinion generally expresses distrust of private international biotech companies. Public research exists but is less visible, even though it is considered more credible and neutral than NGOs and private companies.

The perception of the public varies: (a) with the intended trait, and GE crops which provide consumer and environmental benefits have changed the dynamic of the debate to some extent; (b) with the intended use, fiber and energy uses being less controversial than food use. Medical use of GE plants is not controversial.

c) MARKET STUDIES

The table below references relevant studies on the perception of GE plants and plant products in the EU.

Report	Comment
Eurobarometer Survey on Biotechnology	The most recent Eurobarometer survey about biotechnology by the European Commission (2010)
Europeans and Biotechnology in 2010, Winds of Change?	A report to the European Commission's Directorate General for Research
Eurobarometer Survey on Food-Related Risks	The most recent Eurobarometer survey about consumers' perceptions of food-related risks by the European Commission (2010)

Comparing Perceptions of Biotechnology in Fresh versus Processed Foods	A 2013 cross-cultural study carried out by the Food and Resource Economics Department from the University of Florida

PART D - CAPACITY BUIILDING AND OUTREACH

a) ACTIVITIES

In the EU, USDA's Offices of Agricultural Affairs work to facilitate knowledge availability and understanding between the United States and the MS of the EU by maintaining a close dialogue with public authorities, farmers, industry groups, and scientists. The meetings, visits, and seminars with European officials and U.S. visitors (government, industry, farmer groups, and research scientists) facilitate bilateral information flow.

In 2014, country-specific biotech outreach activities were conducted in several MS. For more details, see separate GAIN reports of the various MS listed in Annex 2.

b) STRATEGIES AND NEEDS OF THE EUROPEAN UNION

The Bioeconomy strategy for Europe released by the European Commission in 2012 refers to biotechnology as a way to achieve some of its goals. Bioeconomy is defined as the production of renewable resources and the conversion of these resources and waste streams into value-added products, such as food, feed, bio-based products and bioenergy. The challenges identified include:

- Ensuring food security, which requires an increase in primary production
- Managing natural resources sustainably, which requires "to produce more with less"
- Reducing dependence on fossil resources as carbon and energy sources, which requires "producing industrial crops at a competitive price without compromising food security" and includes "driving research into renewable resources, such as microalgae"
- Mitigating and adapting to climate change, which requires reducing greenhouse gases emissions

A 2013 report of the European Commission's Joint Research Centre evaluates the potential of the plant breeding sector to fulfil the needs of the EU bioeconomy strategy by 2020. The breeding approaches considered in the report include modern biotechnologies (genetic engineering and NPBTs). Plant biotechnology is considered to be one the best approaches to phytoremediation (the use of plants to clean up contaminated soils, water, or air) and to increase the percentage of biomass used for the synthesis of biochemicals and biomaterials.

CHAPTER 2 – ANIMAL BIOTECHNOLOGY

PART E – PRODUCTION AND TRADE

a) BIOTECHNOLOGY PRODUCT DEVELOPMENT

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 and pharmaceutical research purposes (including xenotransplantation, and production of proteins, enzymes and other substances in the pharmaceutical industry). Some of them also use animal biotechnology to improve animal breeding (high yielding sheep, dairy cows and swine genomics, resistance to avian flu).

In the United Kingdom, a company is developing GE insects to address human health issues and agricultural issues (e.g., olive flies developed as a biological control to protect olive trees from insect infestation). In 2014, it opened a production unit of GE mosquitoes in Brazil to fight against dengue and applied to USDA/APHIS for field studies of GE diamond back moths in the United States.

Researchers at the Roslin Institute in Edinburgh (United Kingdom), where Dolly the cloned sheep was developed in 1996, announced in 2013 that they had created Pig 26, a GE piglet resistant to the African swine fever virus. It was produced thanks to the gene-editing technique, which mimics a natural genetic mutation so closely that Pig 26 is indistinguishable from an animal produced by natural genetic variation. Besides, gene-editing does not involve the use of antibiotic-resistance genes. Scientists hope it could make genetic engineering more acceptable to the public. The Roslin Institute is now focusing on using gene-editing to enhance resistance to infectious disease in livestock and on producing a chicken that cannot transmit avian flu.

b) COMMERCIAL PRODUCTION

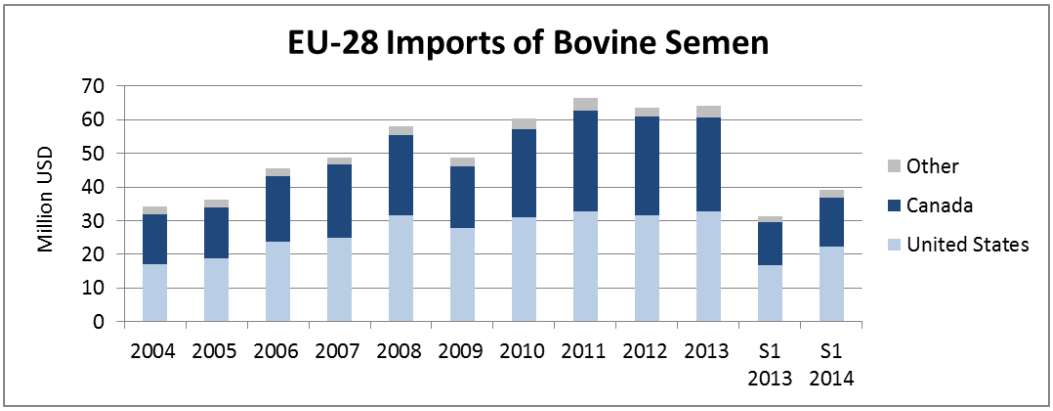
There is no GE animal commercialized in the EU. A French company clones sport horses, together with Italian industry. Cloned animals are elite breeding horses.

c) BIOTECHNOLOGY EXPORTS

The EU does not export any animals produced through biotechnology.

d) BIOTECHNOLOGY IMPORTS

The U.S. is the EU's leading supplier of bovine semen, sharing the bulk of the market in almost equal proportions with Canada.



S1: First Semester - Source: Global Trade Atlas

PART F – POLICY

a) REGULATION

i. Responsible Government Ministries

The three European entities regulating animal biotechnology are the following:

- The European Commission's Directorate General for Health and Consumers (DGSANCO)
- The Council of the EU
- The European Parliament, especially the following committees: Environment, Public Health and Food Safety (ENVI), Agriculture and Rural Development (AGRI), International Trade (INTA)

ii. Political Factors Influencing Regulatory Decisions

The stakeholders that influence regulatory decisions on animal biotechnology include animal welfare NGOs, local food groups, biodiversity activists and consumer associations.

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 (see CHAPTER 1 PLANT BIOTECHNOLOGY, PART B POLICY, a. REGULATORY FRAMEWORK, iv. Distinctions between regulatory treatment of the approval for food, feed, processing and environmental release).

To date, no application has been submitted to EFSA for the release into the environment or placing on the market of GE animals. The publication of EFSA's guidance documents on risk assessment and on GE animals' health and welfare has opened up the way for potential applications:

a) In 2013, EFSA published its guidance on the risk assessment of GE animals. It provides guidance for assessing potential effects of GE fish, insects, mammals and birds on animal and human health and the environment. The potential risks that applicants have to consider are the following:

persistence and invasiveness of the GE animal, including vertical gene transfer; horizontal gene transfer; interactions of the GE animal with target and non-target organisms; environmental impacts of the specific techniques used for the management of the GE animal; impacts of the GE animal on biogeochemical processes; and impacts of the GE animal on human and animal health.

b) In 2012, EFSA published its guidance on the risk assessment of food and feed from GE animals and on animal health and welfare aspects.

EFSA's webpage on GE animals provides EFSA's news and publications.

- **Animal Cloning**

No foods are produced from cloned animals currently. However, from a theoretical perspective, foods that would be produced from cloned animals would be covered by the novel foods regulation in the EU. The European Commission released new legislative proposals on animal cloning and novel foods in December 2013, in order to ban cloning for farming purposes as long as animal welfare concerns persist. They are still under discussion, and it is unlikely that they will be implemented before 2016 at the earliest.

The European Commission published legislative proposals on animal cloning in 2013

Currently, food derived from cloned animals (not from their offspring) is covered by Regulation (EC) No 258/97 on novel foods. After a proposal to revise this regulation failed to be approved in 2011,[28] the European Commission started work to launch a new legislative proposal.

In preparation of the new proposal, the European Commission took the following actions:
- published a roadmap outlining five policy options in February 2012
- asked EFSA for an update on its scientific opinion on animal health and welfare, environmental impacts and food safety. EFSA published it in July 2012
- ran a public consultation from May until September 2012

On December 18, 2013, the Commission announced three legislative proposals:[29]
1) a proposal that would ban animal cloning for food purposes in the EU and the import of cloned animals or embryos (bovine, porcine, ovine, caprine and equine species). The ban on cloning would be in place for five years, after which the scientific progress of the cloning technique would be assessed.
2) a proposal that would ban the marketing of food, both meat and dairy, from cloned animals
3) a new proposed regulation for novel foods

The objective of these proposals is to ban cloning for farming purposes, as long as animal welfare concerns persist. Cloning would be allowed for purposes such as research, conservation of rare breeds and endangered species or for use in the production of pharmaceuticals and medical devices, where it

[28] See GAIN report EU Novel Foods Proposal failed to win Approval
[29] See GAIN report EU Publishes Proposals on Animal Cloning

can be justified. The impact assessment on which these proposals are based was published simultaneously, as well as a FAQ document.

Neither of the proposed cloning directives would cover offspring from cloned animals nor products derived from their offspring. In a press release, DG SANCO Commissioner Tonio Borg explained that labeling for meat from offspring of cloned animals could be required at a later date, pending a feasibility study report from DG AGRI on the consequences of labeling for both the EU domestic meat market and meat imports. For more information, see DG SANCO's webpage on animal cloning and novel foods.

The European elections in May 2014 resulted in the new European Commission taking office from November 1, 2014, with Mr. Juncker as its Commission President, as well as a widely reshuffled European Parliament. As a result of the delay in the procedure because of this change and because of the expected length of time necessary for the legislative approval procedure, it is unlikely that these legislations will be implemented before 2016 at the earliest.

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.

The European Commission's proposals are consistent with the risk assessments.

European institutions published several risk assessments on animal cloning:

1) The first risk assessment (2008) by EFSA concludes that there are no indications that food products derived from healthy clones or their offspring are different from those of healthy conventionally bred animals, and that there are no indications that clones or their progeny would pose any new or additional environmental risks compared with conventionally bred animals.
2) The 2008 report by the European Group on Ethics in Science and New Technologies (EGE) to the European Commission highlights concerns about animal welfare of cloned animals.
3) A further statement published in 2010 by EFSA supplements the previous report. It focuses on the health and welfare of animal clones.
4) A 2012 update by EFSA reiterates safety of derived food products but underscores animal health and welfare issues.

The European Economic and Social Committee has issued an opinion on the proposals.

The European Economic and Social Committee (EESC) issued an opinion on the European Commission's proposals in April 2014:

"The EESC believes it is necessary and appropriate to regulate cloning of animals in the EU with the aim of ensuring uniform conditions of production for farmers, while protecting the health and welfare of animals.
The EESC believes that the temporary ban should be reviewed after a reasonable period of time, taking into account the experience that MS gain in implementing the legislation, scientific and technical progress and the development of the international environment.

The EESC reiterates that the legislation applicable in the EU must also apply to imported animals so that EU farmers are not placed at a disadvantage compared to farmers in third countries.
The EESC stresses that, given that animal cloning is permitted in certain non-EU countries, the MS must adopt all appropriate measures to prevent foods obtained in third countries from animal clones being imported into the EU.
The EESC is concerned at the lack of adequate systems for detecting the existence of meat and milk from cloned animals in food imported from third countries; in this connection it demands that the full traceability requirement be extended to imports, as this is the only reliable guarantee of an animal's origin and an indispensable tool for managing health risks."

Novel Foods Trilogues to Continue in 2015

Member of European Parliament (MEP) James Nicholson drafted a report on the Commission's novel foods proposal. Other MEPs had until October 17, 2014 to propose amendments to this draft report. They proposed 486 amendments in total, some of which relate to animal cloning. A number of MEPs wants to introduce a ban on food from cloned animals and offspring in the novel foods regulation until specific legislation on cloning is adopted. Other MEPs, including James Nicholson, consider the animal cloning issue too controversial to be included in the novel foods debate and want cloning to remain in separate legislation. European Commission representative Eric Poudelet said that the Commission has tabled parallel cloning and novel food proposals because of the difficult debate surrounding the issue, and that until these specific proposals are adopted, the "*status quo*" should be maintained in which food from cloned animals but not offspring would be covered by the novel foods regulation. Informal negotiations (trilogues) are taking place between the European Commission, the Council and the EP with a view to reach a "first reading agreement" in 2015.

b) LABELING AND TRACEABILITY

EU regulations (EC) No 1829/2003 and (EC) No 1830/2003 require food and feed produced from GE animals to be labeled as such (see CHAPTER 1 PLANT BIOTECHNOLOGY, PART B POLICY, g. LABELING).

As for cloned animals, according to Regulation (EC) No 258/97 on novel foods, it depends whether the food is considered different than food from conventional animals. According to Article 8 of this regulation, "labeling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of any characteristic or food property (…) which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient. A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this Article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient."

c) TRADE BARRIERS

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

d) INTELLECTUAL PROPERTY RIGHTS

The legislative framework on patents for animals produced through biotechnology is the same as for GE plants (see CHAPTER 1 PLANT BIOTECHNOLOGY, PART B POLICY, i. INTELLECTUAL PROPERTY RIGHTS).

No European patent can be granted for any of the following:

- animal varieties
- methods for treatment of the animal body by surgery or therapy, and diagnostic methods practiced on the animal body
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and animals resulting from such processes [30]

e) INTERNATIONAL TREATIES/FORA

The EU is member of the Codex Alimentarius alongside its 28 MS. The Codex has working groups and develops guidelines on biotech animals. For example, it has developed guidelines for the conduct of food safety assessment of foods derived from GE animals. The EU and its MS draw up EU position papers on the issues discussed in the Codex. The latest position pertaining to biotechnology is the 2011 comment on GE food labeling. The Secretariat of the Codex Alimentarius Commission is located at FAO headquarters (Italy).

The World Organization for Animal Health (OIE) has no specific guidelines on GE animals, but it has some on the use of cloned animals. The European Commission is actively involved in the work of the OIE and organizes the input from EU Member States.

Twenty one out of the 28 MS of the EU are members of the OECD, which has working groups and develops guidelines on biotechnology policies. France hosts both OECD and the OIE.

The European Union is a party to the Cartagena Protocol on Biosafety, that aims to ensure the safe handling, transport, and use of living modified organisms (see CHAPTER 1 PLANT BIOTECHNOLOGY, PART B POLICY, j. CARTAGENA PROTOCOL RATIFICATION).

PART G – MARKETING

a) MARKET ACCEPTANCE

There is little awareness of animal biotechnology among the public in the EU, but overall, market acceptance is low among policy makers, industry, and consumers, due to ethical and animal welfare concerns. Animal biotechnology is a controversial issue that is not widely discussed.

The EU livestock industry does not favor the commercialization of cloned or GE animals but is interested in animal genomics and marker-assisted selection for animal breeding.

[30] Source: European Patent Office

b) PUBLIC/PRIVATE OPINIONS

In the EU, a number of scientific institutions are active in public, with a positive engagement on animal biotechnologies.

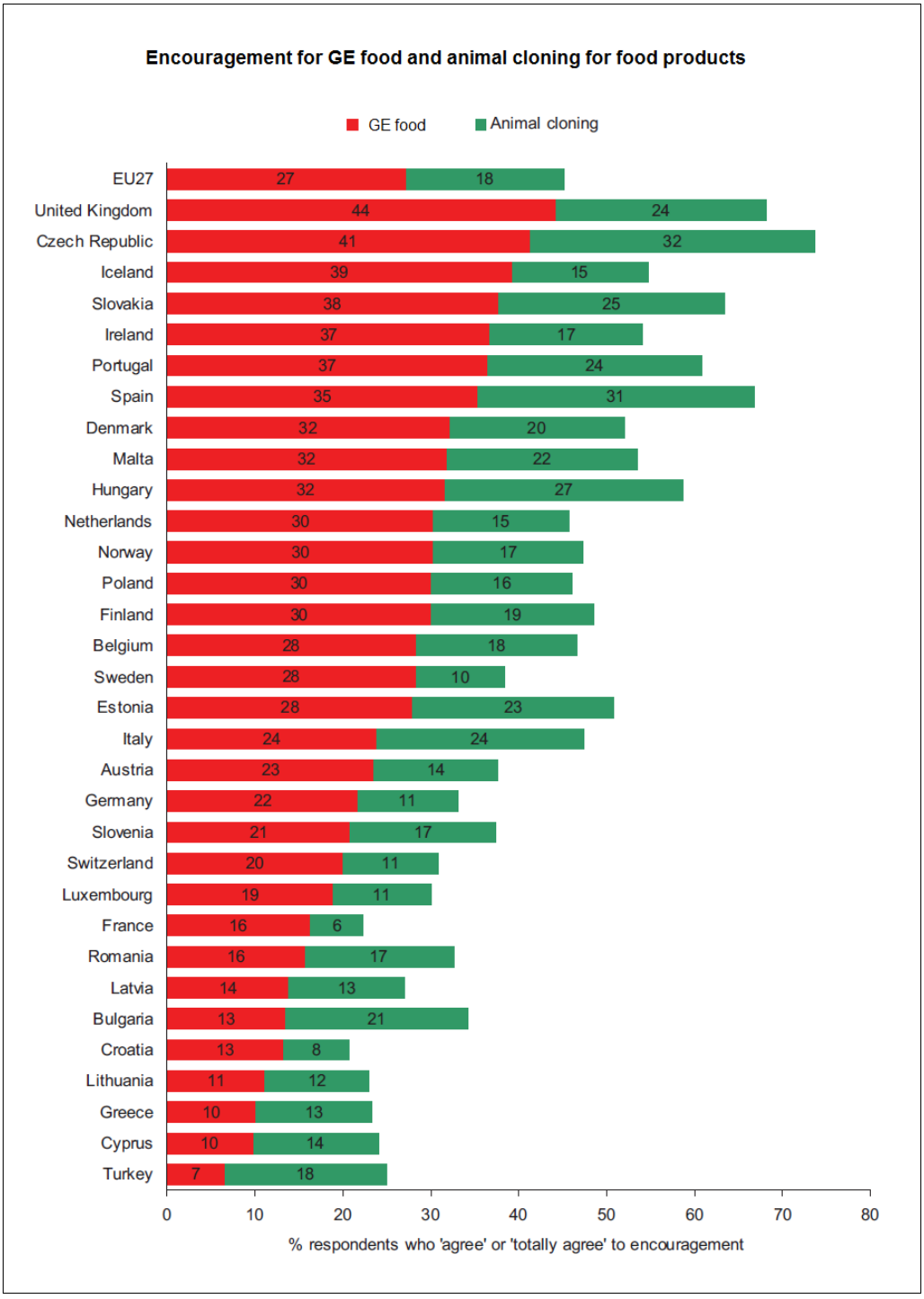
There are also a number of organizations actively campaigning against the technologies, including animal welfare NGOs, local food groups, and biodiversity activists.

There is limited knowledge about animal biotechnology among the public although, if asked, people are generally more hostile to it than to plant biotechnology, due to ethical concerns. If the awareness level on positive animal welfare traits (such as breeding cattle without horns so that they do not have to be de-horned) were higher, it should be expected that this would increase the acceptance of the technologies. Opinions vary with the intended use; medical applications are the most accepted.

c) MARKET STUDIES

According to the European Commission's 2010 survey on biotechnology, "the idea of the 'natural superiority of the natural' captures many of the trends in European food production, such as enthusiasm for organic food, local food, and worries about food-miles. Moreover, if 'unnaturalness' is one of the problems associated with GE food, it appears to be an even greater concern in the case of animal cloning and food products." The graph below reflects the combination of consumer acceptance of food derived from GE plants and animal cloning in each MS.

Besides, the Dutch advisory body, the Commission on Genetic Modification (COGEM), investigated if the legislative framework and procedures in the Netherlands and Europe were equipped to deal with the market introduction of GE animals. The report was published in 2012: Genetically Modified Animals: a Wanted and Unwanted Reality.



Source: European Commission 2010 survey on biotechnology

PART H – CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES

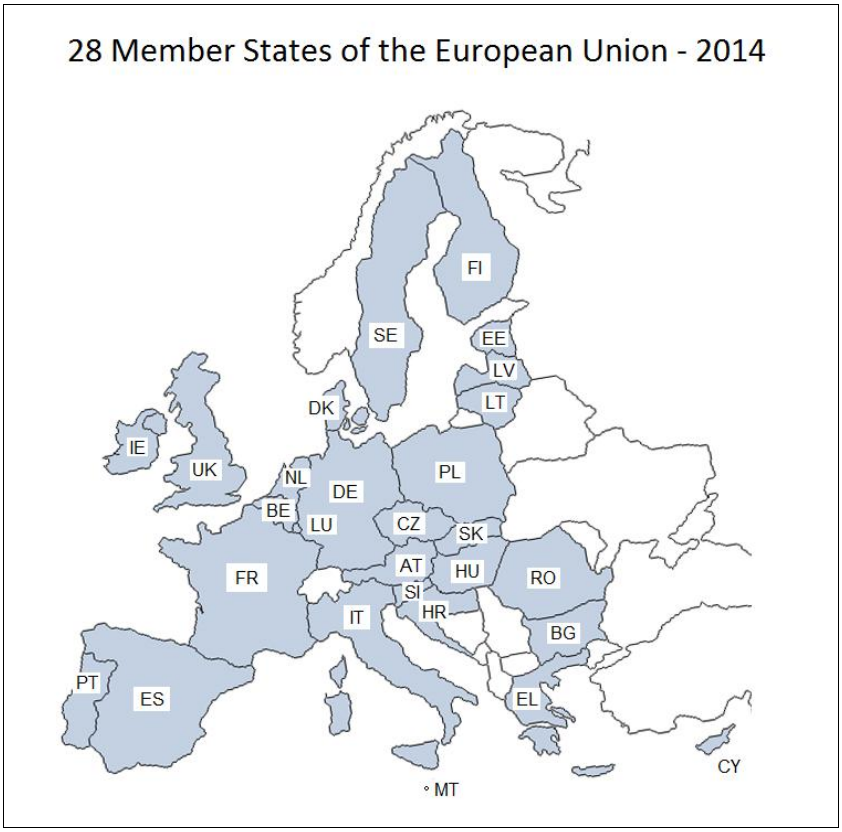
Activities across the EU include sharing information with European and Member States authorities

relative to commercial and regulatory practices in the U.S. on animal biotechnology, in the form of seminars, visits and meetings. For more detailed information, see separate GAIN reports of the various MS listed in Annex 2.

b) STRATEGIES AND NEEDS OF THE EUROPEAN UNION

Overall, many stakeholders in the EU would welcome more information on regulation and use of animal biotechnology in the U.S. and other countries.

ANNEX 1 – 28 MEMBER STATES OF THE EUROPEAN UNION



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

HR HU	Croatia Hungary	UK	Slovakia United Kingdom

ANNEX 2 – RELATED REPORTS

In 2013 and 2014, USDA Offices of Agricultural Affairs in the European Union prepared comprehensive reports about agricultural biotechnology in the following 15 EU Member States:

Austria
Belgium
Bulgaria
Croatia
Czech Republic
France
Germany
Greece
Hungary
Italy
Netherlands
Poland
Romania
Spain
United Kingdom

USDA Offices of Agricultural Affairs also prepared a variety of voluntary reports about recent developments in biotechnology, which are available in the public GAIN database.