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Report Highlights:

In the European Union (EU), consumers, governments, industry, non-governmental organizations, and the media remain conflicted about the use of agricultural biotechnology. Acceptance varies widely across countries. The EU's complex policy framework developed under pressure from anti-biotech activists has limited research, development, and production of biotech crops. EU institutions are still working on the way innovative biotechnologies (also called new breeding techniques) should be regulated. A few Member States of the EU are active on this subject but in most countries, the debate has not emerged yet. The United Kingdom's exit from the EU is unlikely to affect EU policies or trade in the short term.

Executive Summary:

Until the 1990's, the European Union (EU) was a leader in research and development of biotech plants. Under 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 major private developers have moved their research operations to North America. The private sector's interest in developing varieties of genetically engineered (GE) plants suitable for cultivation in the EU has waned. Still, in 2016, open-field testing is being performed in eleven MSs on a variety of biotech crops.

Commercial cultivation of 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 35 percent of the corn area. An EU directive that allows opposed MSs to ban the cultivation of GE crops in their territories for non-scientific reasons was adopted in March 2015. Nineteen countries have decided to "opt out" of GE crops cultivation for all or part of their territories. This did not lead to a change on farms as none of these countries cultivated GE crops when the ban was implemented.

The EU does not export any GE products but it is a major importer of soybean, corn, and rapeseed products. They are 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, less than 25 percent for corn, and less than 20 percent for rapeseed. The United States is the EU's second largest supplier of soybeans and largest supplier of distillers' dried grains (DDGs) and corn gluten feed and meal (CGFM).

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 yet been approved in the EU. 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.

In April 2015, the European Commission (EC) released a proposal that would allow MSs to opt out of using EU-approved biotech events for non-scientific reasons (this proposal is separate from the opt-out for cultivation directive that was passed in March 2015). However, this opt-out for use proposal was widely decried as unworkable and inconsistent with the EU's single market and international obligations. The proposal is now formally put on hold with the Council. In the absence of an agreement, the EC has asserted that the unwillingness of the European Parliament (EP) and MSs to support the proposal in effect would be an acceptance of the existing rules.

Acceptance of GE crops in the EU varies greatly among countries. Member States can be divided into three categories. Nine MSs, England in the United Kingdom, and Northern Belgium produce GE crops or would do so, if more were approved for cultivation in the EU. Governments and industries in these countries mostly favor biotechnology. In seven MSs, as well as in Southern Belgium, Northern Ireland, Scotland, and Wales, forces willing to adopt the technology (mainly scientists and professionals of the

agricultural sector) are counterbalanced and usually outmatched by forces rejecting it (consumers and governments, under the influence of activists). In the ten other MSs, most stakeholders reject the technology.

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 must adapt their product offerings to meet consumer perceptions. However, this description is only a rough approximation, since the situation is very heterogeneous, depending on the country.

EU institutions are still working on the way innovative biotechnologies (also called new breeding techniques) should be regulated. Legally, it is the prerogative of the European Court of Justice to provide a binding opinion on the interpretation of EU law regarding whether or not these technologies should be regulated as genetic engineering. Politically, the debate is still at an early stage. A few MSs are active on this subject but in most countries, the debate has not yet emerged. The Netherlands, Spain and the UK are mostly favorable to using these technologies and in several other MSs, including France and Germany, there is a growing debate with conflicting views from stakeholders. In most EU countries, the general public is not aware of agricultural applications of innovative biotechnologies.

As for animal biotechnology, the EU is active in medical and pharmaceutical research, and research to improve breeding. A British company produces GE insects to control plant pest populations without using insecticides and conducts tests out of the EU. No GE animal is commercialized in the EU and market acceptance is low, due to ethical and animal welfare concerns. The EC released legislative proposals on animal cloning in December 2013, in order to ban cloning for farming purposes as long as animal welfare concerns persist. These proposals are still being discussed.

The current situation of the EU with very little cultivation of GE plants but high imports is not expected to change in the medium term. The EU livestock and poultry sectors need these imports to be competitive and decision-makers are unlikely to allow cultivation of GE crops in the countries where public opinion is opposed to it. The long-awaited decision of the EU on the regulation of innovative biotechnologies will be critical for the ability of European researchers and companies, especially small and medium ones, to keep up with the quick evolution of the techniques globally.

The United Kingdom's exit from the EU (Brexit) is unlikely to affect EU biotech policies or trade in the short term.

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
EP	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 in this report 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
NBTs	New Breeding Techniques
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
PAFF	Standing Committee on Plants, Animals, Food and Feed
UK	United Kingdom

Glossary:

“Genetic Engineering” means transgenesis.

“Innovative biotechnologies” is a synonym of New Breeding Techniques (NBTs). It excludes transgenesis.

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CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

The EU is active in plant biotechnology but research is not likely to lead to the commercialization of new genetically engineered (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. Several major private European developers have moved their research and development operations to the United States (Bayer in 2004, BASF in 2012, and KWS opened its new research center in the United States in 2015).

The biotech industry is witnessing a well-publicized consolidation. It is likely to result in an optimization of the synergies between data science, biotechnology, chemistry, and precision farming. It is not expected to change the attitude of the private sector towards the commercialization of biotech crops in the EU.

Public institutions and universities conduct basic research and limited product development. Public research is unlikely to lead to the commercialization of 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 EC'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 in targeting breeding of minor crops and in 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.

Between 2000 and 2010, the EU funded a variety of research projects in plant biotechnology that focus on environmental impacts of GE plants, food safety, biomaterials and biofuels, and risk assessment and management. More than 200 million euros have been invested in these projects. For an overview, please see the EC’s [publication](#).

As for medical applications of plant biotechnology, some laboratory research is being conducted in the EU. GE plants and plant cells are used to develop proteins of pharmaceutical interest in-lab. Proteins whose structure is simple, such as insulin and growth hormone, can be produced by GE microorganisms and some of them are commercialized. GE plants and plant cells are used to develop more complex molecules (vaccines, antibodies, enzymes).

b) COMMERCIAL PRODUCTION

• Four MS cultivate Bt corn in 2016.

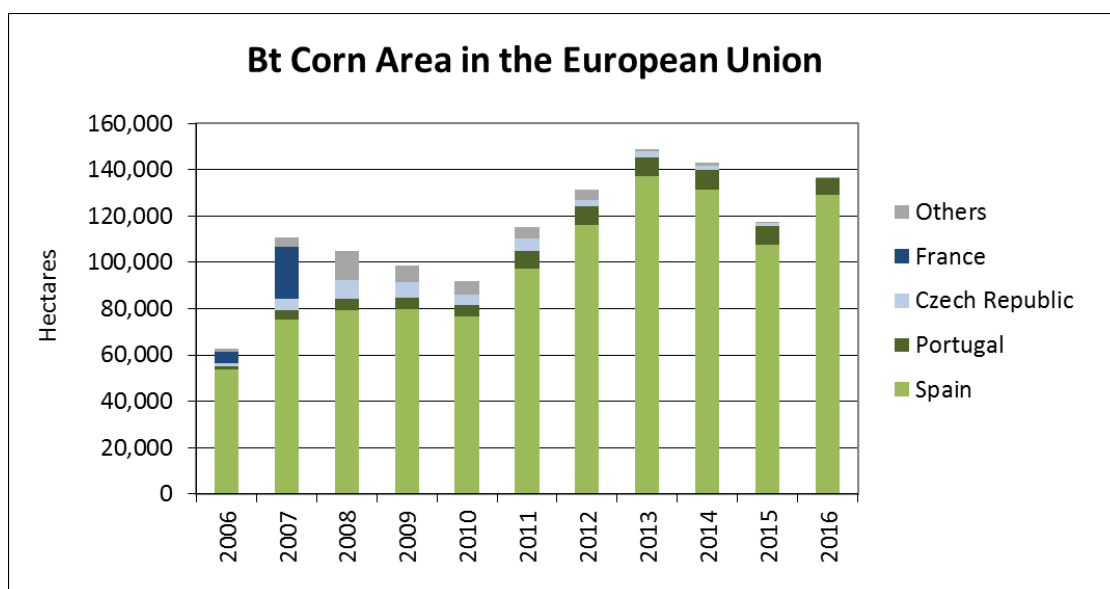
The only GE plant approved for cultivation in the EU is MON810 corn. It is a *Bacillus thuringiensis* (Bt) corn resistant to the European corn borer (a pest). Four MSs cultivate Bt corn in 2016 – Spain, Portugal, the Czech Republic, and Slovakia. Spain represents almost 95 percent of the total area in 2016. In 2016, Bt corn accounted for more than 35 percent of Spain’s total corn area.

Bt corn produced in the EU is used locally as animal feed and for biogas production. Spain-based feed grain elevators do not keep separate production lines for GE and non-GE corn as practically all marketed feed contains GE soybean as a source of protein, and consequently it is default labeled as “contains GE products.” The corn processing industry uses GE-free corn for production that is intended to enter the food chain, in many cases sourced through identity preserved programs.

The table below shows that in 2016, the area planted in Bt corn in the EU increased by 16 percent to 136,337 hectares, after an 18 percent drop between 2014 and 2015. In Spain, unusually warm conditions prevailing in summer 2015 contributed to an abnormally high pressure of the corn borer,

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

which led to higher use of the Bt corn in 2016. In the Czech Republic, the area has gradually decreased due to difficulties in marketing the corn commercially (farmers use it for biogas production and on-farm cattle feeding). Romania used to cultivate GE corn but complex traceability rules have discouraged farmers; feed manufacturers and livestock farmers prefer to avoid segregation in the warehouses and to reduce the paperwork associated with the use of GE corn. Moreover, seeds available to farmers keep evolving and MON810 corn, first approved for use in the EU in 1998, is now an old variety; in some cases, newer varieties provide better yields.



Source: USDA FAS

Bt Corn Area in the EU, by Member State

in hectares	2012	2013	2014 (updated)	2015 (updated)	2016 (estimate)
Spain	116,307	136,962	131,538	107,749	129,081
Portugal	7,700	8,202	8,542	8,017	7,069
Czech Republic	3,050	2,560	1,754	997	75
Romania	217	834	771	2.5	0
Slovakia	189	100	411	400	112
Poland	4,000	0	0	0	0
Total Bt corn area	131,463	148,658	143,016	117,166	136,337
Total corn area planted in the EU	9,720,000	9,660,000	9,564,000	9,470,000	8,800,000
Share of Bt corn in total corn area	1.35%	1.54%	1.50%	1.24%	1.55%

Source: USDA FAS

- **Nineteen MS decided to “opt out” of GE crops cultivation in 2015.**

In March 2015, [Directive \(EU\) 2015/412](#) was officially released. It allows MSs of the EU to restrict or ban the cultivation of EU-authorized GE plants in their territories for non-scientific reasons. Under the transitional measures, the MSs had until October 3, 2015 to request to be excluded from the geographical scope of the authorizations already granted or in the pipeline under “Option 1” – see below. Nineteen countries have “opted out” of GE crops cultivation for all or part of their territories.

Additionally, the Directive requires those MSs in which GE crop cultivation takes place to take appropriate measures aimed at avoiding possible cross-border “contamination” into neighboring MSs in which cultivation is prohibited. This effectively means that cultivating MSs bear the responsibility (and any liability) associated with cultivating GE crops.




The MSs that want to restrict or prohibit GE crops cultivation have two options:

- Option 1: During the authorization procedure, a MS may ask to amend the geographical scope of the application to exclude part of or all its territory. The manufacturer of the GE plant has 30 days to adjust or confirm the scope of the application. If the manufacturer does not answer, the scope is adjusted according to the MS’s demand. MSs are allowed to ask for their territory to be reintegrated into the geographical scope of the authorization after it has been granted.
- Option 2: After a GE variety has been authorized for cultivation in the EU, a MS may adopt national opt out measures, by invoking grounds such as environmental or agricultural policy objectives, town and country planning, land use, coexistence, socio-economic impacts, or public policy. These opt out measures may restrict or ban the cultivation of a GE variety or of a group of GE varieties defined by crop or trait.

Seventeen countries and four regions in two countries (Wallonia in Belgium; Northern Ireland, Scotland, and Wales in the United Kingdom) have implemented Option 1. All of them have banned the cultivation of MON810 and of the seven varieties of corn that were in the pipeline at that time, apart from Denmark and Luxembourg that have only banned MON810 and three from the seven varieties in the pipeline.² The map and the table below provide an overview of the situation.

Situation	Countries and regions
<div data-bbox="183 1430 272 1486" style="background-color: red; color: white; display: inline-block; width: 20px; height: 20px; text-align: center; line-height: 20px;">N</div> <p>[N = New] Eight countries and four regions where cultivation was not banned before have opted out of GE corn cultivation under the new directive. This decision will not lead to a change in the field as farmers in these countries do not cultivate GE corn for various reasons, including the fact that is not well suited to local growing conditions, the threat of protests, and administrative constraints.</p>	<p>- Eight countries: Croatia, Cyprus, Denmark, * Latvia, Lithuania, Malta, the Netherlands, ** Slovenia</p> <p>- Four regions in two countries: Wallonia in Belgium; Northern Ireland, Scotland, and Wales in the United Kingdom</p>

² The varieties that were in the pipeline were Dow Agro Sciences 1507x59122, Pioneer 1507, Pioneer 59122, Syngenta BT11, Syngenta BT11xMIR604xGA21, Syngenta GA21, and Syngenta MIR604. On October 8, 2015, Syngenta withdrew its applications for BT11xMIR604xGA21 and MIR604. The MSs demands are available online on the [European Commission’s website](#).

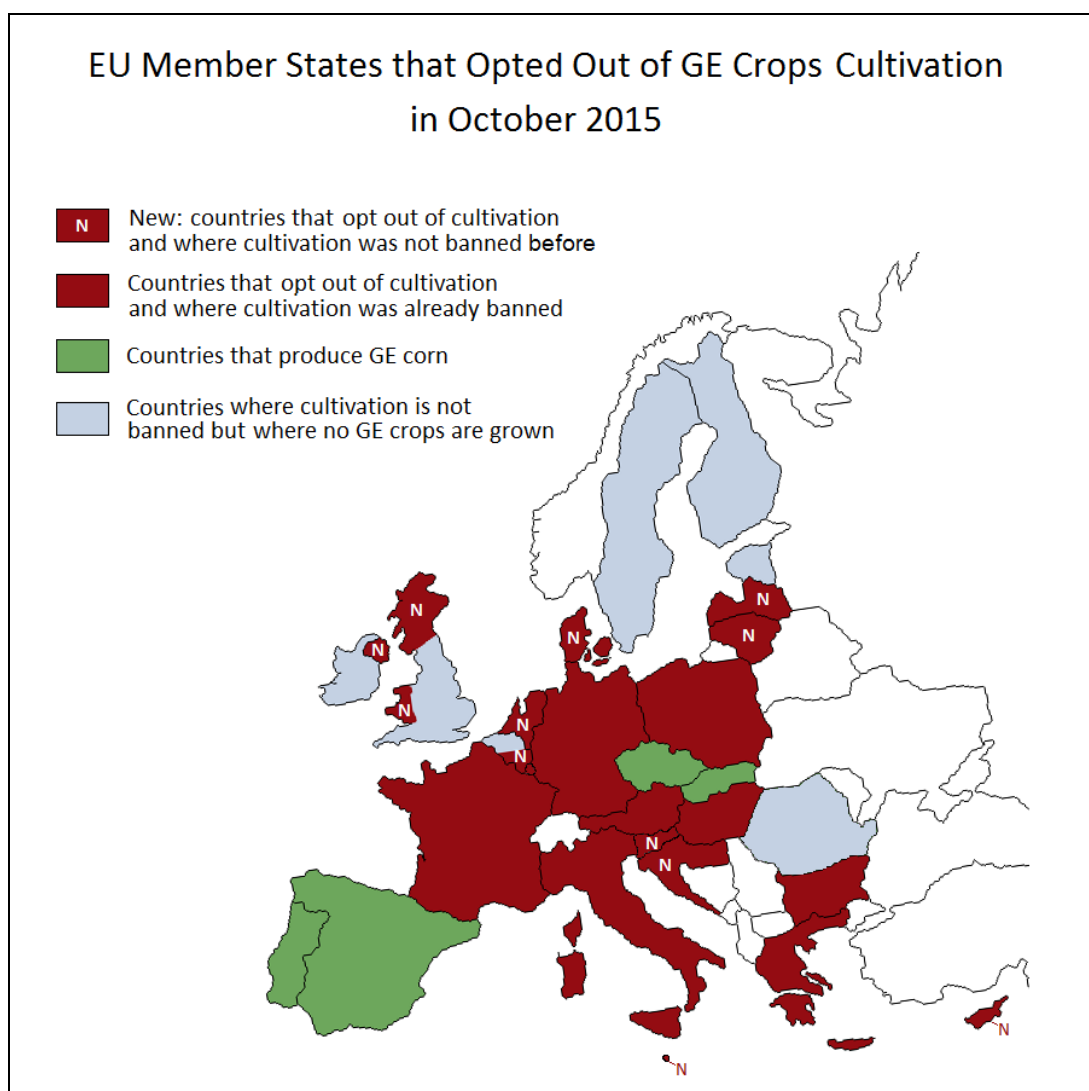
	Nine countries where cultivation was banned under various procedures have opted out of GE corn cultivation under the new directive.	Austria, Bulgaria, France, Germany, Greece, Hungary, Italy, Luxembourg,* and Poland
	Four countries grow GE corn in 2016.	Spain, Portugal, Slovakia, and the Czech Republic
	In the other countries and regions, cultivation is still allowed but no GE corn is grown for various reasons, including the fact that is not well suited to local growing conditions, the threat of protests, and administrative burden.	<ul style="list-style-type: none"> - Five countries: Ireland, Romania, Sweden, Finland, Estonia - Two regions: Flanders in Belgium, England in the United Kingdom

* Denmark and Luxembourg have only opted out of cultivation for MON810 and three from the seven varieties of corn that were in the pipeline at that time

** In the Netherlands, the government is developing its own assessment framework for GE crops cultivation. As a result of the assessment, if cultivation of a crop is allowed in the Netherlands, the government will lift any geographical restriction that may be in place.

Moreover, on November 2, 2016 the German cabinet approved a draft legislation banning the cultivation of GE crops within Germany's borders. If passed by the Parliament, the law could enter into force in spring 2017.

For further explanation on cultivation trends by MS, see USDA FAS country reports, listed in [Annex 2](#).



Source: USDA FAS

c) EXPORTS

The EU does not export any GE crops or plants. GE corn produced in the EU is used locally as animal feed and for biogas production.

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. European non-GE soybean production is expected to increase in the coming years but it remains marginal relative to imports. The EU also imports more than 2.5 million metric tons (MT) of rapeseed products every year.

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, corn,

and rapeseed production in the EU's main supplier countries.

The share of GE products in total imports is estimated at around 90 percent for soybeans, less than 25 percent for corn, and less than 20 percent for rapeseed.

Share of GE Crops in Total Production in 2015

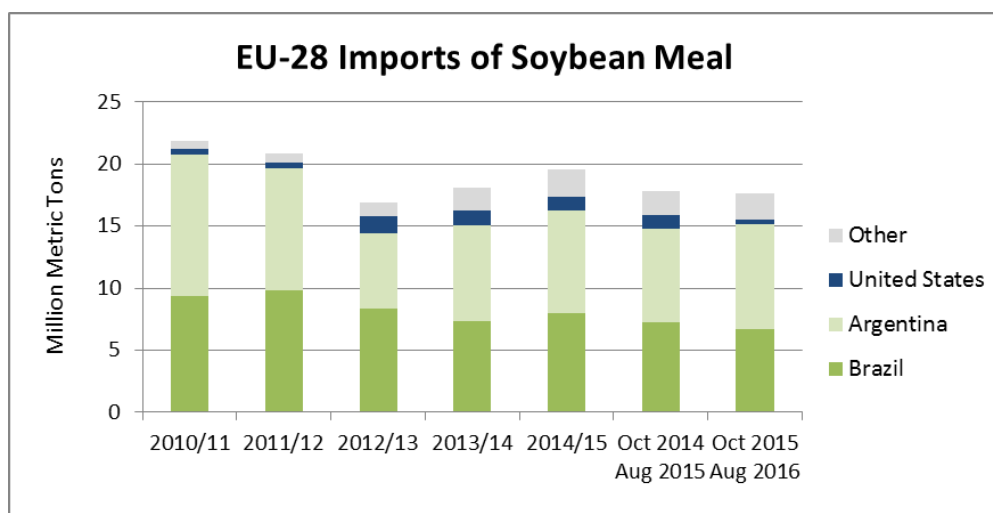
Soy	
Argentina	99 %
Brazil	93 %
Canada	62 %
Paraguay	96 %
United States	94 %
Rapeseed	
Australia	17 %
Canada	95 %
Russia	0 %
Ukraine	0 %
Corn	
Argentina	95 %
Brazil	83 %
Canada	86 %
Russia	0 %
Serbia	0 %
Ukraine	estimated at more than 30 %
United States	93 %

Source: USDA FAS GAIN reports

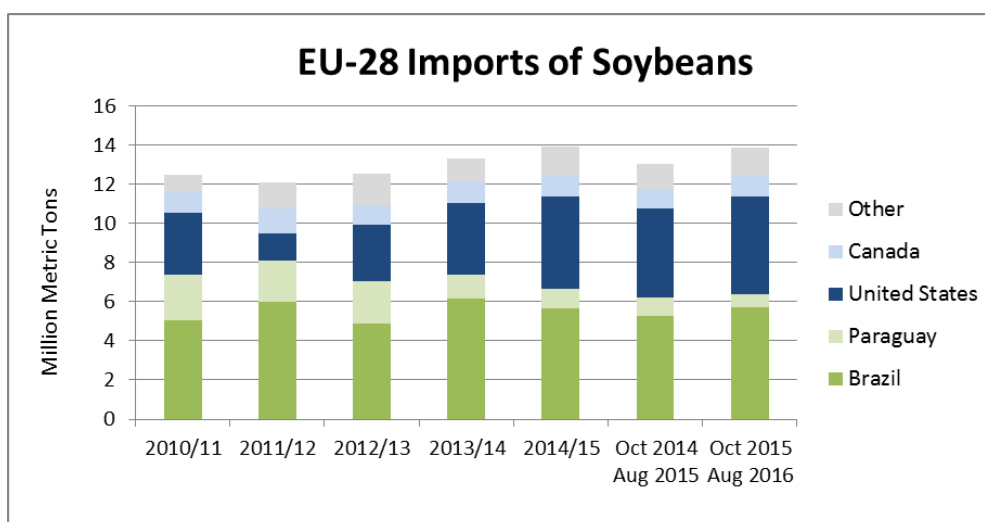
- **The EU imports more than 30 million MT of soybean products every year.**

Around 32 million MT of soybean products are consumed annually in the EU, mainly as animal feed. The EU imports around 65 percent of the soybean meal it consumes. The rest is produced by domestic crushing facilities; more than 85 percent of the soybeans crushed in these facilities are imported.

In the past five years, soybean meal imports amounted to 19 million MT and soybean imports to 13 million MT per year on average (see graphs below). The EU's leading suppliers are Brazil, Argentina and the United States. The largest users of soybean meal (Germany, Spain, France, the Benelux, and Italy) are also the main producers of livestock and poultry. They represent 65 percent of total EU consumption.



Source of data: Global Trade Atlas



Source of data: Global Trade Atlas

- **It is increasingly difficult for the EU to source non-biotech soybeans.**

As the global cultivation of GE crops expands, it is increasingly difficult for European importers to source non-biotech soybean products. Their availability is declining and prices are on the rise. 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.

- **Several initiatives aim at reducing the EU's dependence on imported soybeans.**

There has been a long-standing debate in the EU over the dependence on imports of soybeans and soybean meal. Overall, the EU's current potential for soy and other non-GE protein crops production remains minor relative to total animal feed demand. EU soybean production is expected to increase

from around 1.8 million MT in 2014/15 to around 2.2 million MT in 2016/17, to be compared to the 32 million MT of soybean products imported every year. The minor impact on imports is expected to be partly offset by a rising demand for feed.

Several countries are taking initiatives to produce non-biotech protein feed locally:

- The [Danube Soya Association](#), a non-governmental association supported by the Austrian government, promotes the production of non-biotech soybeans in the Danube region (Austria, Bosnia Herzegovina, Bulgaria, Croatia, Germany, Hungary, Romania, Serbia, Slovakia, Slovenia and Switzerland). According to the association, the production potential for soybeans in the Danube region would be 4 million MT (13 percent of total EU consumption of soybean products).
- France and Germany have national strategies for protein crops, which aim to reduce their dependence on imports.
- Under the 2014-2020 Common Agricultural Policy, several countries have chosen to give farmers coupled supports for soybeans.

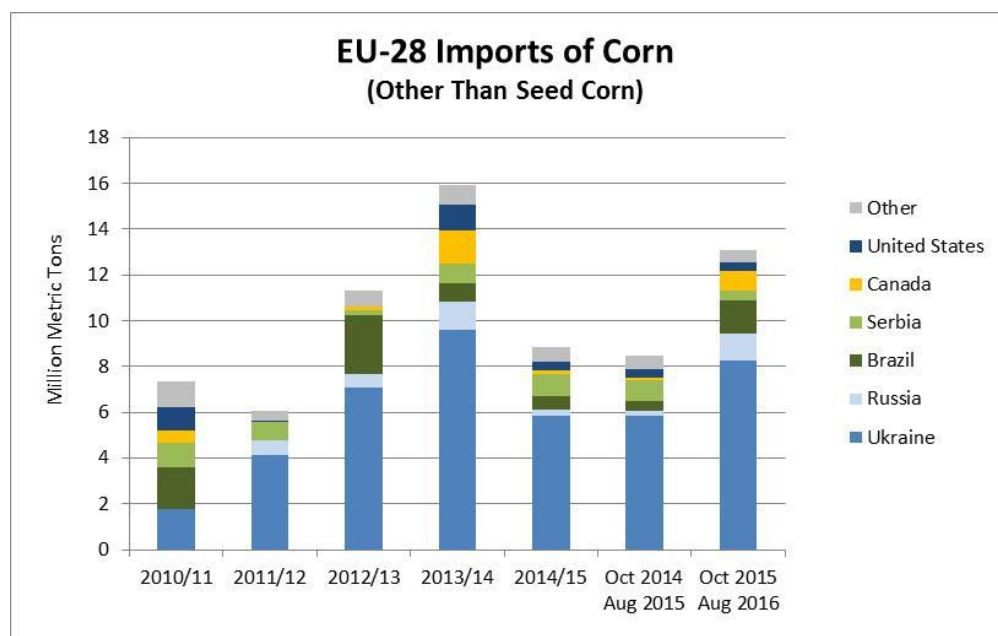
In 2014, the European [Focus Group](#) on protein crops published its [final report](#).³ The objective was to answer the following questions: what does the feed sector need in terms of protein? Why is the EU protein crops sector not competitive? How can this be remedied? Their conclusions were the following: (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 7 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 imports is estimated to be lower than 25 percent.

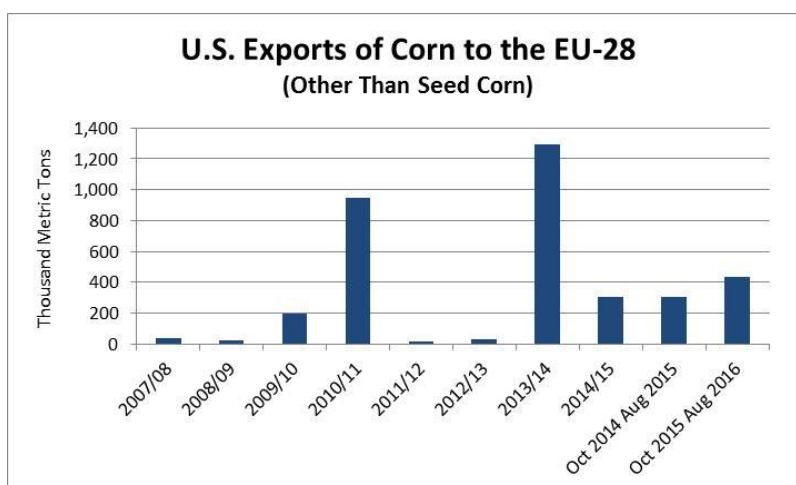
The booming of Ukraine's market share in EU imports of corn has been remarkable in the past few years. In 2014/15, Ukraine accounted for more than 65 percent of the EU's imports of corn. No production of GE crops has been officially allowed in Ukraine, but there have been reports that around one third of the corn grown in the country is GE.

³ 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 EC in a bid to step up innovation efforts. One of the objectives of a Focus Group is to propose priorities for innovative actions by suggesting potential projects.



Source of data: Global Trade Atlas

While U.S. exports of corn to the EU fluctuated between two and four million MT per year until 1997, they have been limited since then (see graph below) – with only two peaks in 2010/11 at 946,000 MT and in 2013/14 at 1.3 million MT. The beginning of GE corn plantings in the United States resulted in a drastic decline in U.S. exports to the EU. This is due to the lag of the EU's approvals of GE traits compared to those of the United States ([asynchronous approval](#)), and to the EU's [low-level presence policy](#). Imported U.S. corn is mainly used as animal feed and to produce bioethanol.

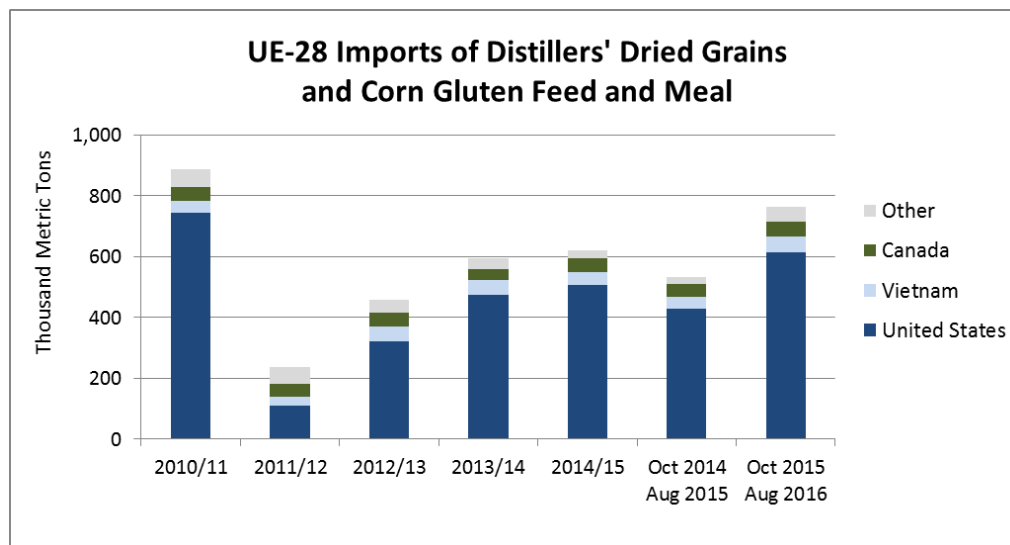


Source of data: Global Trade Atlas

- **The United States is the main supplier of DDGs and CGFM to the EU.**

The EU imports between 200 and 900 thousand metric tons of DDGs and CGFM per year. The share of GE products out of total imports is estimated to be around 80 percent. The United States is the main supplier of DDGs and CGFM to the EU, with an average market share of 72 percent over the past five

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.



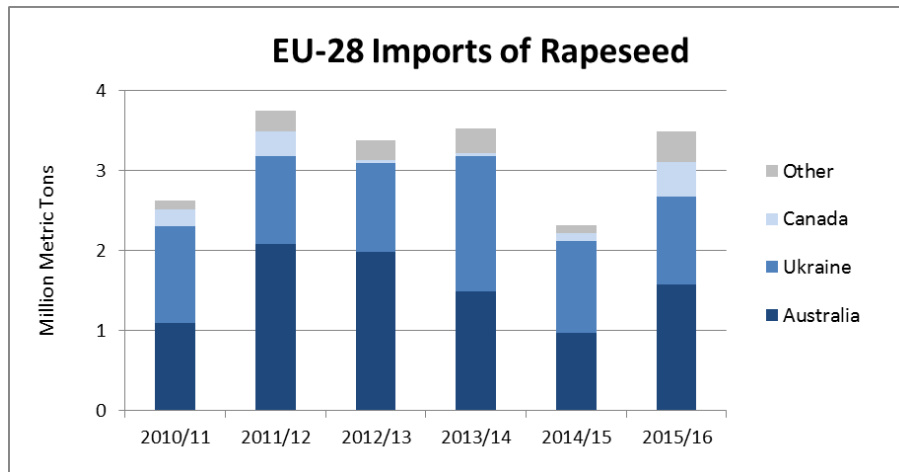
Source of data: Global Trade Atlas

- **The EU imports more than 2.5 million MT of rapeseed products every year.**

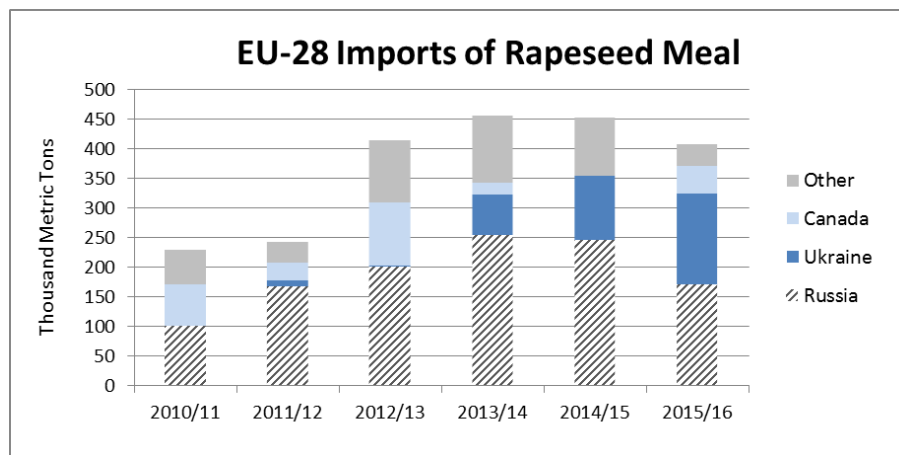
In the last six years, the EU imported between 2.3 and 3.8 million MT of rapeseed and between 230,000 and 460,000 MT of rapeseed meal per year (see graphs below). In 2015/16, 12 percent of the EU's imports of rapeseed and 11 percent of its imports of meal came from Canada, where 95 percent of rapeseed is GE; and 45 percent of rapeseed came from Australia, where 17 percent of rapeseed is GE.

Although the EU is the world's largest producer of rapeseed, Europe's demand exceeds its domestic supply and large quantities of rapeseed are imported for crushing. Meal is used for feed in the livestock sector. Biodiesel industry is the main driver for the demand of rapeseed oil but food and industrial use are also influencing demand.

Imports from Canada resumed when the country started using the International Sustainability and Carbon Certification (ISCC) system, which meets Europe's criteria in the Renewable Energy Directive.



Source of data: Global Trade Atlas



Source of data: Global Trade Atlas

e) FOOD AID

The EU provides food aid in the form of food products, money, vouchers, equipment, seeds, or veterinary services. The EC's Humanitarian Aid and Civil Protection department (ECHO) is in charge of food aid. In 2014, it provided 349 million euros for humanitarian food assistance projects implemented by partner organizations in 54 countries. The aid does not include GE products.

More information is available on the [European Commission's website](#).

The EU is not a recipient of food aid.

f) TRADE BARRIERS

• Asynchronous Approvals

New GE crops are entering the global market place at an increasingly rapid rate. The EU regulatory procedures for approving biotech plants take 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. 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](#).

- **Cultivation Bans**

Nineteen MSs have banned GE crop cultivation on all or part of their territories for reasons other than risks to health or to the environment under [Directive \(EU\) 2015/412](#). For more information, see [Chapter 1 Part A b\) Commercial Production](#).

- **Proposal to allow Member States to “opt out” of use of EU approved biotech crops**

Upon taking office in November 2014, EC President Juncker tasked the Commissioner for Health and Food Safety, Vytenis Andriukaitis, with reviewing the EU’s authorization process for GE food and feed. Juncker’s instructions followed on from his announcement to the EP before its vote on his nomination as EC President in July 2014 that “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.” This statement is not based on fact. A clear majority of MSs have never voted against GE import and processing proposals.

Andriukaitis has been a defender of a scientific-based decision process, but has been under constant criticism from all quarters including the EP, the European Council, as well as many civil society groups. In April 2015, Andriukaitis announced his review of the EU authorization process, which would allow MSs to “opt out” of using EU-authorized GE crops. In October 2015, the EP rejected the “opt out” for use proposal. Members of the European Parliament both for and against increased use of biotechnology decried the proposal as unworkable and inconsistent with the EU’s single market and WTO obligations. Proponents of the technology were concerned that the proposal would lead to import bans, and Greenpeace considered that it did not go far enough. As a result, the EP requested the EC to withdraw the proposal, which the EC declined to do. After rejection by the EP, the proposal is now formally tabled with the Council, although it seems highly unlikely that MSs will vote on the proposal. Essentially, in the absence of an agreed proposal, the EC has asserted that the unwillingness of the EP and MSs to support the proposal in effect is an acceptance of the existing rules. In response, the EP has adopted various non-binding resolutions against GE events. These resolutions have no legal impact and are more an act of political posturing by the EP.

- **Towards a needlessly more burdensome environmental risk assessment**

In October 2016, the EC notified the WTO Committee on Technical Barriers to Trade of a draft Regulation amending [Directive 2001/18/EC](#) as regards the environmental risk assessment of GE

organisms. The draft integrates key elements of the 2010 European Food Safety Authority (EFSA) Environmental Risk Assessment Guidance into the Annex of the Directive. Its adoption would likely lead to a needlessly more burdensome GE approval process.

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, 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. The EC's Directorate General for Health and Food Safety (DG SANTE) administers the latter risk management phase of the procedure. During this phase, files of a draft decision are submitted 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).

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

ii. Role and membership of the biosafety authority

The core task of EFSA is to assess independently any possible risks of GE plants to human and animal health and the environment. The role of EFSA is limited to giving scientific advice; it does not authorize GE products. The 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, EFSA's panel has provided scientific advice relating to the safety of GE plants unauthorized in the EU.

- **Self-tasking activities:** on its own initiative, the panel identifies scientific issues related to GE plants risk assessment that require further attention. For instance, the panel has produced a scientific report on the use of animal feeding trials in GE products risk assessment.

The EFSA panel brings together 20 risk assessment experts from different European nationalities. The member's relevant fields of expertise range from the following: food and feed safety assessment (food and genetic toxicology, immunology, food allergy); 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); and molecular characterization and plant science (genome structure and evolution, gene regulation, genome stability, biochemistry & metabolism). Their biographies and declarations of interests are available on [EFSA's website](#).

iii. Political factors that may influence regulatory decisions related to plant biotechnologies

The EU has had a conflicted relationship with agricultural biotechnology since it was introduced over 30 years ago. The EC continues to pursue inconsistent and unpredictable approaches regulating the technology. Due to the strong emotional and ideological stance taken by EU consumers and non-governmental organizations (NGOs) on biotechnology, born in many ways out of the misleading information provided by anti-biotechnology groups, legislation adopted by the EC as well as the process surrounding the approval for cultivation and use of GE crop varieties has suffered. At the same time, the EU's agriculture industry relies on significant imports of GE feed for its large livestock sector. Argentina, Brazil, Canada, and the United States help to fill this need, and do so primarily with GE soybean and corn varieties. The events of the past year reflect the continued difficulties and uncertainties in utilizing GE products.

For more information on anti-biotech groups in the EU and on their influence on regulatory decisions, see [Part C a\) Public/Private Opinions](#).

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. [Directive \(EU\) 2015/412](#) allows MSs to restrict or ban the cultivation of EU-authorized GE plants in their territories for non-scientific reasons.
- In order to simplify the process for the applicants, the EC 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 use⁴**

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

- An application⁵ 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 MSs and the EC 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 EC, the MS, 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 EC presents the PAFF with a draft decision reflecting EFSA's opinion. PAFF votes on the draft decision.
- Draft decisions that have been put to the PAFF 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 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 EC. 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 EC 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

⁴ Regulation (EC) No 1829/2003 of the European Parliament and of the Council

⁵ 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.

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.

For the list of approved products, see [Part B b\) Approvals](#).

- **Authorization for cultivation of biotech events⁶**

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 to the appropriate national competent authority of the MS within whose territory the release is to take place.⁷
- Using the information exchange system that has been set up by the EC, 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 MSs within 30 days following their receipt.
- Those MSs may present observations through the Commission or directly within 30 days.
- The national competent authority has 45 days to evaluate the other MSs 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 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 MSs). 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 EC. Post-Lisbon procedural rules give more discretion to the Commission. Previously, the Commission was

⁶ Directive 2001/18/EC of the European Parliament and of the Council

⁷ 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.

obliged to adopt the draft decision. Under the new rules, the Commission has the option to adopt or not.

For the list of approved products, see [Part B b\) Approvals](#).

Moreover, [Directive \(EU\) 2015/412](#) allows MSs to restrict or ban the cultivation of EU-authorized GE plants in their territories for non-scientific reasons. More information about this Directive is available in [Part A b\) Commercial Production](#).

v. Legislations and regulations with the potential to affect U.S. exports

See [Chapter 1 Part A f\) Trade Barriers](#)

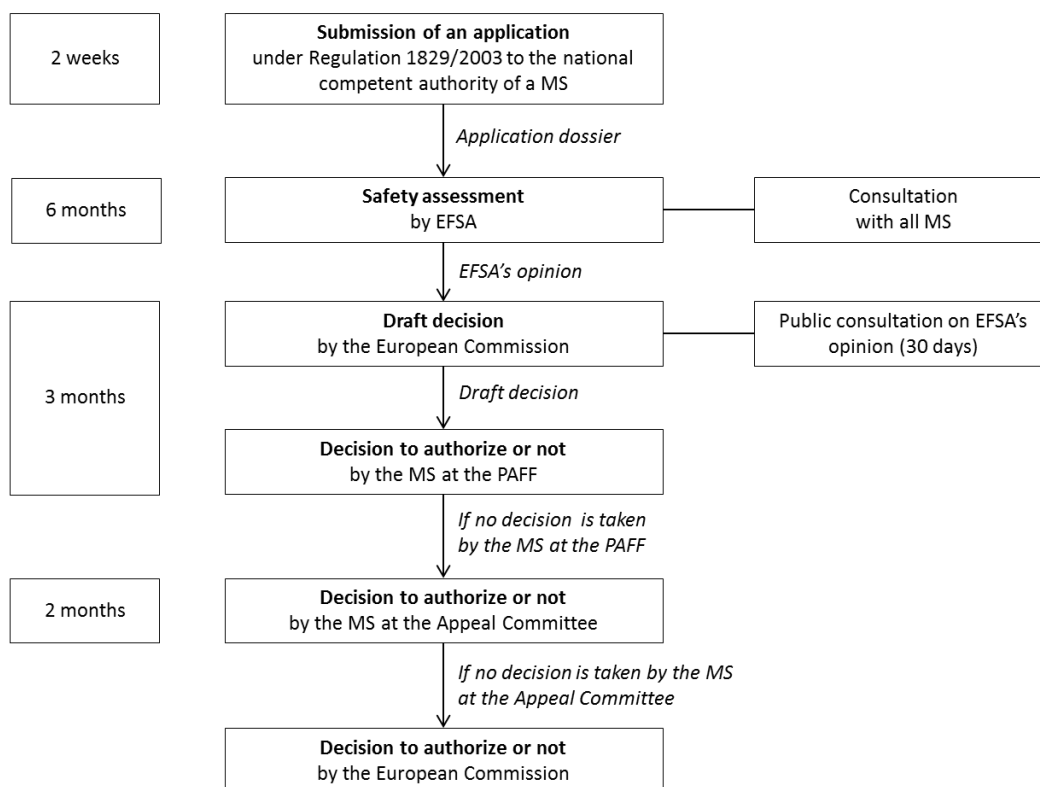
vi. Timeline followed for approvals

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 EC puts into a draft decision for vote by the MSs. The Commission waits ten months on average as opposed to the prescribed three months before requesting MSs to vote. In contrast, the average approval process takes about 25 months in Brazil and the United States and 35 months in Korea.

Each year, more biotech applications have been submitted than authorization decisions made, creating a growing backlog both in EFSA and at the Commission. Industry groups were very active during the past year, putting pressure on the EC and MSs to adhere to the legally prescribed approval process. Three EU industry groups (COCERAL, FEFAC, and EuropaBio) filed a case with the EU Ombudsman in September 2014 concerning the significant delays in authorizations. The EU Ombudsman is an entity that investigates complaints about maladministration in the institutions and bodies of the EU. In January 2016, the Ombudsman ruled that maladministration on behalf of the EC had occurred and the delay in the authorizations was unjustifiable.

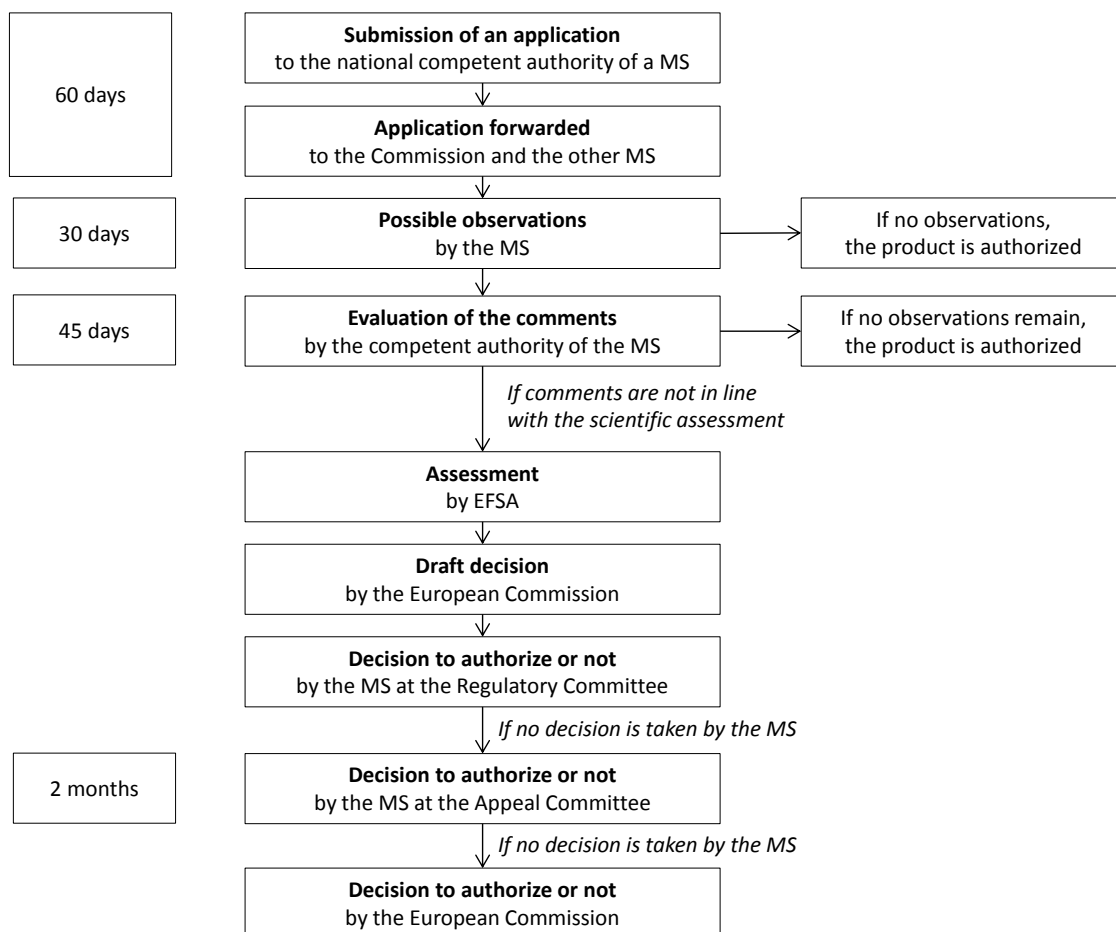
The EU-wide authorization procedure for food and feed is described in the chart below.

Approval process for food and feed



Source: USDA FAS

Approval process for cultivation



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 EFSA's [website](#).

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

At the time of this report, GE products authorized for food or feed use in the EU include a number of varieties of corn, cotton, soybean, rapeseed, sugar beet and microorganisms.

In 2016, the EC adopted 14 new authorizations for GE crops for food or feed use:

- On September 16, 2016, the EC authorized [eleven corn varieties](#),⁸ all of which are stacks from previously approved singles.
- On July 22, 2016, the EC authorized three glyphosate resistant soybean varieties.⁹ They were expected to be approved in December 2015. However, NGOs had made a well-publicized link between these traits and the reauthorization of glyphosate, which, according to a March 2015 report from the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) based in Lyon, France, was classified as "probably carcinogenic." The risk assessment undertaken by EFSA and published in November 2015 found, however, that glyphosate "is unlikely to pose a carcinogenic threat to humans." A joint report from the United Nations Food and Agriculture Organization (FAO) and the WHO's meeting on pesticide residues published in May 2016 distanced itself from the IARC's earlier report by concluding that glyphosate is "unlikely to pose a carcinogenic risk to humans from exposure through diet." On June 29, 2016, after much debate and public exposure, the EC agreed to temporarily extend the authorization for glyphosate for 18 months pending a review by the European Chemicals Agency (ECHA). The EP proposed a seven-year extension while the Council supported a shorter extension period. With the glyphosate issue at least temporarily resolved the EC authorized the three GE soybean varieties.

Moreover, on November 23, 2016, the EC authorized placing a GE cut flower (carnation line SHD-27531-4) on the market. The decision excludes cultivation. The genetic modification is for a specific flower color.

All the GE events approved in 2016 have undergone the full authorization procedure, including a favorable scientific assessment by EFSA. They received "no opinion" from the MSs in both the Standing and Appeal Committees, and the Commission decided to adopt the pending decision. The authorization decision is valid for 10 years, and any products produced from these GE events will be subject to the EU's strict labelling and traceability rules.

c) 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.

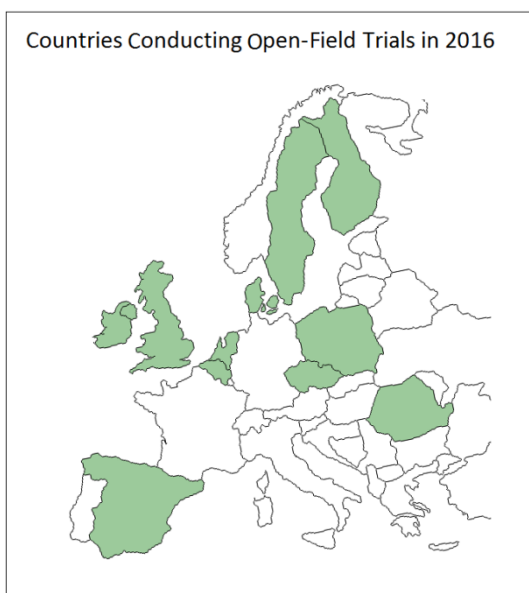
d) FIELD TESTING

Eleven MSs conducted open-field testing in 2016: Belgium, the Czech Republic, Denmark, Finland,

⁸ GE corn Bt11 x MIR162 x MIR604 x GA21; four related GE corn varieties combining three different single GE events (Bt11 x MIR162 x MIR604, Bt11 x MIR162 x GA21, Bt11 x MIR604 x GA21, MIR162 x MIR604 x GA21); six related GE corn varieties combining two different single GE events (Bt11 x MIR162, Bt11 x MIR604, Bt11 x GA21, MIR162 x MIR604, MIR162 x GA21 and MIR604 x GA21)

⁹ MON87705xMON89788, MON87708xMON89788, and Bayer FG72

Ireland, the Netherlands, Poland, Romania, Spain, Sweden, and the United Kingdom. Tested plants include apples, barley, corn, cotton, flax, peas, the plum pox virus resistant plum tree, poplar trees, potatoes, sugar beets, tobacco, tomatoes, and wheat.



Source: FAS Posts

In Spain, in 2016, all notifications for deliberate release have been withdrawn by the requester. Hence, for the first time since 2003 no new field trials are being carried out in Spain. Open-field testing is also allowed in Portugal but there has been no notification since 2010. Previously there were many field trials in France and in Germany, but their numbers had fallen to zero by 2014 due to repeated destruction of test plots by activists. Some public institutions that conduct laboratory research go into partnership with private companies, in order to carry out field trials in other countries, such as the United States.

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.

For more information on field testing in each country, please see USDA FAS country reports listed in [Annex 2](#).

e) INNOVATIVE BIOTECHNOLOGIES¹⁰

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 180 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 (NBTs), also called “innovative biotechnologies” have been developed. Innovative biotechnologies make crop improvement quicker and more precise. They can complement or substitute for genetic engineering.

European Union scientists, plant breeders, biotech industry, and MSs urged the EC to clarify the legal status of innovative biotechnologies since [Directive 2001/18/EC](#) does not reflect the progress made in the development of new techniques. The overall concern is that an expensive and lengthy authorization procedure would be required for these techniques and its products, even in a case that no foreign DNA is contained in the resulting product, or a case where these products are completely indistinguishable from conventionally bred crops.

¹⁰ “Genetic Engineering” means transgenesis.

“Innovative biotechnologies” is a synonym of New Breeding Techniques (NBTs). It excludes transgenesis.

Publishing of the EC legal opinion on whether or not innovative biotechnologies fall under the scope of Directive 2001/18/EC was expected during the first half of 2016 after multiple delays.¹¹ This legal opinion was expected to facilitate the harmonization of MS approaches to regulate or not regulate innovative biotechnologies. However, it is the sole prerogative of the European Court of Justice to provide a final and binding opinion on the interpretation of EU law. In July 2016, DG SANTE Commissioner Andriukaitis indicated that the EC will not present its legal opinion as it would not provide legal clarity it had aimed for and would not be legally binding. Furthermore, he emphasized that the EC will only issue its legal opinion if it would be supported by a majority of MSs. The EC is currently still reflecting on how to proceed with this legal opinion.¹²

On October 3, 2016, the French Supreme Court (Conseil d'Etat) referred four interlocutory questions about innovative biotechnologies and mutagenesis to the European Court of Justice. In these questions, the term “mutagenesis” includes oligonucleotide-directed mutagenesis (ODM) and site-directed nucleases (SDN):

- Are the organisms produced through mutagenesis GMOs under Directive 2001/18/EC? Which of these organisms are regulated as GMOs under Directive 2001/18/EC?
- Are the organisms produced through mutagenesis GMOs under Directive 2002/53/CE?
- If organisms produced through mutagenesis are not regulated as GMOs under Directive 2001/18/EC, does it mean that the MSs are not allowed to set their own regulations for these organisms?

Is the exclusion of mutagenesis from Directive 2001/18/EC consistent with the precautionary principle?

It takes on average between one year and a half and two years for the Court of Justice to answer Member States' questions. Depending on the answers, the EC may have to reopen Directive 2001/18/EC.

To know more about the situation in each country, see [Part C b\) Market Acceptance](#).

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.

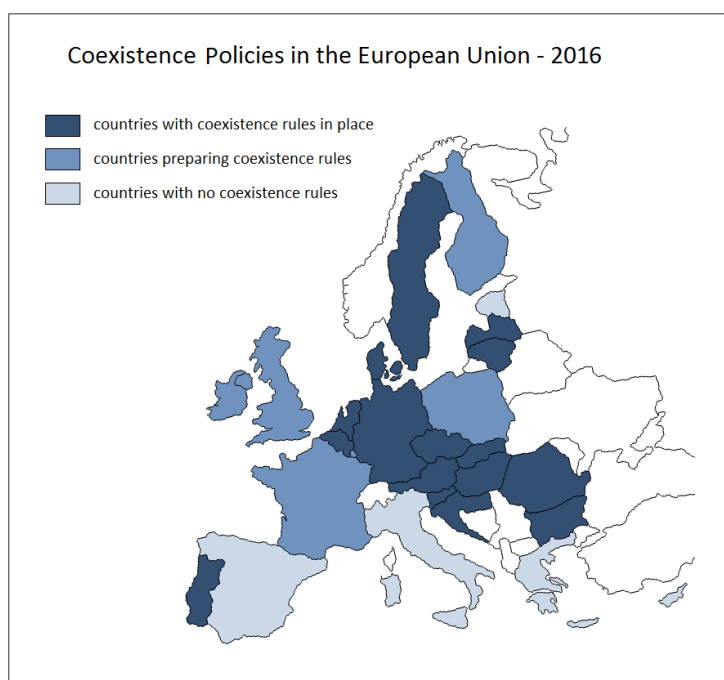
The map below shows that most MSs have adopted or are preparing coexistence rules.

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.

¹¹ For more information, see [GAIN report E16013](#).

¹² There is a [page on innovative biotechnologies](#) on the EC's website.



Source: FAS Posts

For more information on coexistence rules in each country, please see USDA FAS country reports listed in [Annex 2](#).

g) LABELING

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

EU regulations [\(EC\) No 1829/2003](#) and [\(EC\) No 1830/2003](#) require food and feed produced from or containing GE ingredients 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.

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.

The 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).

Labeling regulations **for food products** are presented in [Regulation \(EC\) No 1829/2003](#), articles 12-13:

- Where the food consists of more than one ingredient, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must follow in brackets immediately after the ingredient concerned. A compound ingredient with a GE component should be labeled “contains [name of ingredient] produced from genetically modified [name of organism].” For example, a biscuit containing soy oil derived from GE-soy must be labeled “contains soy oil from genetically modified soy.”
- Where the ingredient is designated by the name of a category (e.g., vegetable oil), the words “contains genetically modified [name of organism]” or “contains [name of ingredient] produced from genetically modified [name of organism]” must be used. For example, for vegetable oils containing rapeseed oil produced from GE rapeseed, the reference “contains rapeseed oil from genetically modified rapeseed” must appear in the list of ingredients.
- The designations may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients.

- Where there is no list of ingredients, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must appear clearly in the labeling. For example, “genetically modified sweet corn;” or “containing caramel produced from genetically modified corn” for a product with no list of ingredients.
- In the case of products without packaging the labels must be clearly displayed in close proximity to the product (e.g. a note on the supermarket shelf).

Labeling regulations **for feed** are presented in [Regulation \(EC\) No 1829/2003](#), articles 24-25:

- For feed containing or consisting of GE ingredients, the words “genetically modified” or “produced from genetically modified [name of the organism]” must follow in brackets immediately after the name of the feed.
- For feed produced from genetic engineering, the words “produced from genetically modified [name of organism]” must follow in brackets immediately after the name of the feed.
- Alternatively, these words may appear in a footnote to the list of feed. They shall be printed in a font of at least the same size as the list of feed.

Moreover, the **traceability rules** defined in Regulation 1829/2003 require all business operators involved to transmit and retain information on GE products in order to identify both the supplier and the buyer of the product. Operators must provide their customers with the following information, in writing:

- an indication that the product – or certain ingredients – contains, consists of, or is obtained from “GMOs;”
- information on the unique identifier(s) for these “GMOs;”
- in the case of products consisting of or containing mixtures of “GMOs” to be used only as food or feed or for processing, this information may be replaced by a declaration of use by the operator. It has to be accompanied by a list of the unique identifiers for all those “GMOs” that have been used to constitute the mixture

For a period of five years after every transaction within the supply chain, every operator must keep a record of this information and be able to identify the operator from whom they bought the products and the one to whom they supplied them.

• Voluntary “GMO-free” Labeling Systems

There is no EU-harmonized legislation on GE-free labeling. GE-free labels are allowed on a voluntary basis and provided they do not mislead the consumer. Such labels are mainly found on animal products (meat, dairy products, and eggs), canned sweet corn and soybean products. In 2015, the EC published a [study](#) assessing the potential for a harmonized EU-wide approach. The study looks at GE-free labeling and certification schemes in seven MSs and a number of third countries including the United States.

Austria, France, Germany, Hungary (since 2016), and the Netherlands have legislation and/or guidelines in place to facilitate GE-free labeling. Sweden has adopted legislation that explicitly prohibits such labeling. The UK has no formal government position on this issue but there are a large number of private-operator led schemes. Italy has a number of private-operator led schemes.

For more information, please refer to the EC’s [study](#) and to USDA FAS country reports listed in [Annex 2](#).

h) MONITORING AND TESTING

- **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 “GMO”¹³ on the market is the submission of an application. This application must include a monitoring plan for environmental effects.¹⁴ 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.¹⁵
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 EC 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.¹⁶
4. The results of the monitoring must be made publicly available.¹⁷
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.¹⁸

- **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 EC, 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.

Details of the notifications are available on [RASFF's portal](#).

¹³ “Organism” means “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.

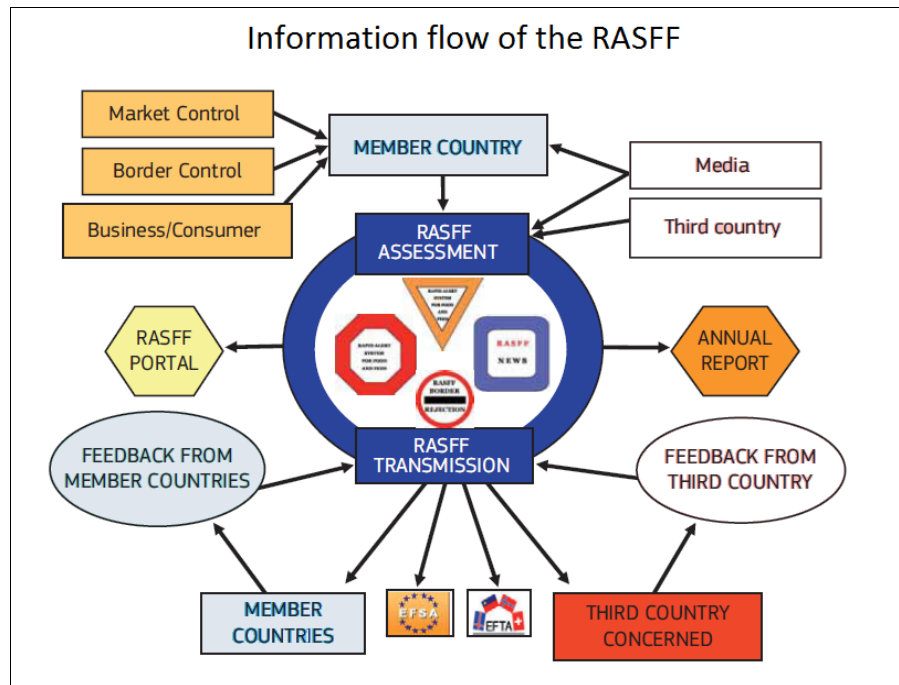
¹⁴ Directive 2001/18/EC: Article 5 and Annex III for experimental releases, Article 13 and Annex VII for placing on the market

¹⁵ Regulation (EC) No 1829/2003 Articles 5 and 17

¹⁶ Directive 2001/18/EC Article 20

¹⁷ Directive 2001/18/EC Article 20 - Regulation (EC) No 1829/2003 Article 9

¹⁸ Directive 2001/18/EC Article 17 - Regulation (EC) No 1829/2003 Articles 11 and 23



Source: RASFF 2013 annual report

i) LOW LEVEL PRESENCE POLICY

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 where importing countries block shipments, and destroy or return them to the country of origin.

Two types of incidents can happen:

- 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 of these incidents are associated with 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).

In 2009, the EU denied the entry of 180,000 metric tons of U.S. soy because the shipment contained traces of three biotech corn types that the EU had not approved for food, feed, or import, although these products were allowed for use in the United States. Consequently, in 2011 the EC published a regulation allowing a 0.1 percent limit for yet unapproved biotech events in feed shipments (technical solution that defines zero), as long as the application was submitted to EFSA. At that time, the EC committed to evaluate the need for the introduction of similar limits for shipments of food.

In July 2016, the EC's Standing Committee on Plants, Animals, Food, and Feed (PAFF) failed to establish a technical solution (a threshold that defines zero) for a LLP allowance of biotech events in food. Thus, an absolute zero tolerance for unapproved biotech events found in shipments of food to the EU continues. This decision makes it difficult to export many food products to the EU market, since it

is nearly impossible to guarantee that these products will not contain minute traces of biotech events. Many food manufactures have subsequently adjusted their ingredients to avoid this situation.

j) ADDITIONAL REGULATORY REQUIREMENTS

In almost all MSs, 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.

k) INTELLECTUAL PROPERTY RIGHTS

• 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. ¹⁹
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	At EU level, according to the European Patent Office, a plant is protected for all its uses. ²⁰

¹⁹ 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.

	<p>further breeding and free commercialization of new varieties (except for essentially derived ones).</p> <p>- There is an option for producers to use farm-saved seed under certain conditions.</p>	
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.
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 CPVO does not give any figures for the share of biotech varieties. More than 80 percent of the applications are successful.	<p>- The EPO receives between 500 and 800 applications relating to plant biotechnology each year.</p> <p>- 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. 39 percent of all plant patents come from the United States, 42 percent of them come from Europe (mainly Germany, The United Kingdom, Belgium and France).</p> <p>- On average, just under one third of applications relating to biotechnology²¹ 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.</p>
Legal basis	<p>All the legislations in place are available on the CPVO website. They include Regulation (EC) No 2100/94 on plant variety rights.</p> <p>The UPOV website gives the text of the UPOV Convention (International Convention for the Protection of New Varieties of Plants) and the legislation of MSs that has been notified in accordance with it.</p>	<p>The legal basis for patenting biotechnological inventions in the EU include:</p> <ul style="list-style-type: none"> - the European Patent Convention (EPC), an international treaty ratified by all MSs 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;

²⁰ This point has been controversial in some EU countries.

²¹ all biotechnology applications (not only plant biotechnology ones)

		- national laws that implement EPC and Directive 98/44/EC (in place in all MSs since 2007, see USDA FAS country reports).
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• 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 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](#)), representing 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.

In March 2015, the Enlarged Board of Appeal of the European Patent Office ruled that plants or seeds obtained through conventional breeding methods were patentable.²² ESA deplores this decision. In a [press release](#), ESA:

- advocated that patents should only be allowed for biotechnological inventions.
- underlined that this decision contradicts the breeder's exemption, which allows free use of a protected variety for further breeding under the plant certificate system.
- supported a more restrictive interpretation of patentability in order to safeguard access to biological material for further research and breeding.

ESA stated: "We want an effective breeders' exemption and that means an effective exclusion from patentability of not only plant varieties and essentially biological processes but also of plants obtained by such processes."

On November 3, 2016, the EC adopted a [clarifying notice](#) on certain articles of Directive 98/44. It made clear that plants obtained by "essentially biological processes" (selecting and crossing of plants) should not be patentable under EU law. In a [press release](#), ESA called upon the EPO to follow the Commission's interpretation in its granting practices with regard to pending as well as newly incoming patent applications concerning products obtained by "essentially biological processes."

I) 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).

²² European Patent Office's [decision](#)

- **Cartagena Protocol on Biosafety**

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

The competent authorities are the EC's JRC, EFSA's "GMO" Panel, the EC Directorate General for the Environment, and DG SANCO.

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

For more information, see the EU'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 EU 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 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."²³

m) INTERNATIONAL TREATIES/FORA

Individual MSs generally express similar position on biotechnology in international fora.

The EU is a member of the Codex Alimentarius alongside its 28 MSs. The EC represents the EU in the Codex; DG SANCO is the contact point.

All MSs have signed the International Plant Protection Convention (IPPC), an international treaty that 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.

²³ See ESA's [press release](#)

n) RELATED ISSUES

The EC has funded a three-year, 7.76 million euro project titled “GMO” Risk Assessment and Communication of Evidence (GRACE). The project aimed to provide comprehensive reviews of the evidence on the health, environmental and socio-economic impacts of GE plants; considering both risks and possible benefits. It also tested various types of animal feeding trials and alternative in vitro methods in order to determine how suitable they are and what useful scientific information they provide for health risk assessments of GE food and feed.

GRACE published its [final conclusions and recommendations](#) at the end of 2015. The key results are the following:

- There is no indication that the performance of 90-day feeding studies (following OECD or EFSA guidelines and current practice) with whole food or feed would provide additional information on the safety of maize MON810.
- Alternative in vitro methods are very promising but cannot yet replace animal feeding trials.

The project also established new methods for systematically collecting and assessing existing scientific evidence on environmental, health and socio-economic effects (risks and benefits) of GE plants: systematic reviews and evidence maps.

More information is available on [GRACE website](#) and on the [European Commission’s website](#).

PART C – MARKETING

a) 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. They are generally opposed to economic growth and globalization. They see more risks than opportunities in technical progress and campaign for a broad application of the precautionary principle. Some of them defend an ideal science that would focus solely on understanding phenomena, and not on developing useful and profitable applications; others reject or strongly criticize science and progress, in line with philosophers such as Hans Jonas and Bruno Latour. They are skeptical of new technologies, in general, and for biotechnology specifically they feel it is dangerous, of little public benefit, and developed by companies that seek private profit at the expense of the common good. As part of their political strategy, their actions include lobbying public authorities, acts of sabotage (destruction of research trials and cultivated fields), and communication campaigns to heighten public fears.

These groups are a minority. However, they are passionate about their cause and very active in the media. The extent to which they are accepted varies across countries, but they have highly developed communication skills. The effectiveness of their campaigns, amplified by the media, has had a strong effect on public opinion. The fact that most of the GE plants cultivated in the world today are insect- or herbicide-resistant plants that bring direct benefits to farmers rather than consumers has made it easier for anti-biotech groups propaganda to be well-received by the public. These groups have played an important part in the adoption of regulations that have restricted the adoption of biotechnology in the EU, directly through lobbying and indirectly through their impact on public opinion. Their actions have

made biotechnology a sensitive political issue, and it is now difficult for an elected official to remain neutral on biotechnology, forcing them to take a public position for or against and suffer the political consequences.

Stakeholders that defend the use of GE plants at EU level are scientists and professionals in 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, 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.

b) MARKET ACCEPTANCE/STUDIES

- **Acceptance varies greatly across EU countries.**

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

- The “Adopters” include producers of Bt corn (**Spain, Portugal, Slovakia, the Czech Republic**) and MSs that would possibly produce GE crops if more were approved for cultivation in the EU (**Denmark, Estonia, Finland, Flanders in Northern Belgium, the Netherlands, Romania, and England in 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” MSs, most scientists, farmers, and the feed industry are willing to adopt the technology, but consumers and governments, influenced by anti-biotech groups, reject it. **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. **Sweden** used to be an adopter, but it has been in the conflicted group since 2015. As for **Northern Ireland, Scotland, and Wales**, they have been in the conflicted group since 2016 following their decision to opt out of GE crops cultivation. Within this group, Germany has become increasingly vocal against agricultural biotechnology.

- In the “Opposed” MSS, 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 and Luxembourg** are also Opposed MSs. In these countries, the government generally supports organic agriculture and geographical indications and a minority of farmers is supportive of growing biotech crops.

Source: FAS Agricultural Offices

- **General Trends**

An appropriate way to discuss acceptance of GE plants is through the three groups with strong interest in this technology: 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) that there is only one GE crop authorized for cultivation in the EU, and nineteen MSs have implemented a 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 MSs.

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.

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 that 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 that provide environmental benefits. The 2010 [survey](#) by the EC 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 EC’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 must adapt their product offerings to meet consumer perceptions

The EU has approved over 50 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.

- **A debate on innovative biotechnologies is emerging in some EU countries**

Member States can be arranged into three categories depending on their situation regarding innovative biotechnologies – also called New Breeding Techniques (NBTs):

- **Spain** and the **United Kingdom** favor biotechnology and are open to innovative techniques. In the **Netherlands**, the government sees innovative biotechnologies as an important propagation tool for the domestic plant breeding sector. However, there is some opposition from anti-biotech groups in these countries.
- Several MSs can be seen as conflicted in that their position is not clear yet but pro and con forces are active in the country. **The Czech Republic, France, Germany, and Italy** are in this situation. In France and Germany, the main farm organizations are in favor of innovative biotechnologies; public awareness is low; the government has no official position or is conflicted. The government faces opposition from anti-biotech groups that want all plants produced through innovative biotechnologies to be regulated as “GMOs” under Directive 2001/18/EC. The Czech Republic can be seen as conflicted insofar as the country is favorable to agricultural biotechnology but the advisory body to the Ministry of the Environment has adopted a position on oligonucleotide-directed mutagenesis stating that this technique produces “GMOs.” In February 2016, the Italian Minister of Agriculture advocated for innovation involving cisgenesis and genome editing, but not transgenesis.
- In most EU countries, the general public is not aware of agricultural applications of innovative biotechnologies. No debate has emerged on this subject. The government has no official position and is waiting for the conclusion of EU institutions. It is the case in **Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Romania, Slovenia, Slovakia, and Sweden.**

- **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

CHAPTER 2 – ANIMAL BIOTECHNOLOGY

PART D – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

The MSs 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:

- to study diseases. Animal models of human diseases are produced by biotechnologies, such as genome editing and genetic engineering.
- to produce tissues or organs from GE pigs (xenotransplantation).
- to produce proteins of pharmaceutical interest (blood factors, antibodies, vaccines) in the milk of mammals or in egg white produced by hens. Proteins can also be produced by animal cells in-lab.

Some of these countries also use animal biotechnology to improve animal breeding (high yielding sheep, dairy cows and swine genomics, resistance to avian flu).

In the United Kingdom, the [company Oxitec](#) is developing GE insects to address human health issues and agricultural issues (e.g., GE olive flies developed as a biological control to protect olive trees from insect infestation, GE mosquitoes to reduce the populations of mosquitoes that are vectors for diseases like dengue and Zika, [GE diamondback moths](#)).

Researchers at the [Roslin Institute](#) in Edinburgh (United Kingdom), where Dolly the cloned sheep was developed in 1996, have produced piglets designed to be resistant to the African swine fever virus. Researchers have used genome editing techniques, which can mimic a natural genetic mutation so closely that the piglets are indistinguishable from animals produced by conventional means with natural genetic variation. Genome editing also does not involve the use of antibiotic-resistance genes. Scientists hope it could make genetic engineering more acceptable to the public. Professor Whitelaw, head of developmental biology at the Roslin Institute, believes that disease resistant animals could be commercially available within five to 10 years.

The Roslin Institute also focuses on using genome editing to enhance resistance to infectious disease in livestock and on producing a chicken that cannot transmit avian flu.

b) COMMERCIAL PRODUCTION

No GE animal for food use is commercialized in the EU and to date no application has been submitted

to EFSA for the release into the environment or placing on the market of GE animals.

A French company clones sport horses, together with Italian industry. These animal clones are elite breeding horses.

c) EXPORTS

The EU does not export any animals directly produced through biotechnology for food purposes. France exports sport horse clones.

d) TRADE BARRIERS

The main barriers to using animal biotechnology to improve animal breeding are the public and political opposition to it, due to ethical and animal welfare concerns.

PART E – POLICY

a) REGULATORY FRAMEWORK

i. Responsible Government Ministries

The three European entities regulating animal biotechnology are the following:

- The EC's Directorate General for Health and Food Safety ([DGSANTE](#))
- 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](#))

The EU regulatory framework for GE animals is the same as for GE plants (see [Chapter 1 Part B iv](#)).

[EFSA](#) published a guidance on the risk assessment of GE animals in 2013 and a guidance on the risk assessment of food and feed from GE animals and on animal health and welfare aspects in 2012.

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

A new EU regulation on novel foods ([Regulation \(EU\) 2015/2283](#)) was adopted in November 2015 and published in December 2015. Most of its provisions will apply from January 1, 2018. It repeals Regulations (EC) 258/97 and (EC) 1852/2001. While no foods are produced from animal clones in the EU currently, theoretically such foods would be covered by Regulation (EU) 2015/2283 until specific regulations on animal cloning are passed.

The European Parliament tried for years to use the novel foods legislation to leverage an EU ban on animal cloning, as well as on the marketing of all products from animal clones and their offspring. Ultimately, the novel foods regulation was adopted with the inclusion of a statement that products from animal cloning remain subject to the novel foods regulation until specific regulations on animal cloning have been passed.

The EC released legislative proposals on animal cloning in December 2013, in order to ban cloning for farming purposes as long as animal welfare concerns persist. In June 2015, the European Parliament's Agriculture (AGRI) and Environment, Public Health and Food Safety (ENVI) Committees adopted their [joint report](#) on the EC's proposals. The report called for an amendment of the original proposal to include a total ban on animal cloning, imports of animal clones, germinal products, and the marketing and imports of food derived from animal clones and offspring. The joint report also calls for the two proposed Commission cloning directives to be combined into a single proposal for a regulation to be adopted under the co-decision procedure.

Following its approval at the plenary session in September 2015, the joint AGRI/ENVI report went to the Council for its first reading. In the first reading phase of the co-decision procedure, there are no deadlines or timetables for the Council's action. The Council may either accept the EP's amendments or, if they do not accept the EP's position, adopt a common position. However, discussion of the proposals in the Council has not yet gone beyond the technical level. Given the political sensitivity of the issue, the Council is reportedly unwilling to take up full discussions of the proposals.

b) INNOVATIVE BIOTECHNOLOGIES²⁴

There have been no developments or legislative activities on animal produced through innovative biotechnologies (also called “new breeding techniques”) in the EU recently.

c) LABELING AND TRACEABILITY

EU regulations [\(EC\) No 1829/2003](#) and [\(EC\) No 1831/2003](#) require food and feed produced from GE animals to be labeled as such (see [Chapter 1 Part B g\) Labeling](#)).

As for animal clones, Article 9 of [Regulation \(EU\) 2015/2283](#) on novel foods states that “the entry for a novel food in the Union list (...) shall include the specification of the novel food and, where appropriate (...) specific labelling requirements to inform the final consumer of any specific characteristic or food property, such as the composition, nutritional value or nutritional effects and intended use of the food, which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population.”

d) INTELLECTUAL PROPERTY RIGHTS

The legislative framework on patents for animals produced through biotechnology is the same as for GE plants (see [Chapter 1 Part B k. Intellectual Property](#)).

²⁴ “Innovative biotechnologies” is a synonym of New Breeding Techniques (NBTs). It excludes transgenesis.

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 processes²⁵

e) INTERNATIONAL TREATIES/FORA

The EU is member of the Codex Alimentarius alongside its 28 MSs. 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 MSs draw up EU position papers on the issues discussed in the Codex.

The World Organization for Animal Health (OIE) has no specific guidelines on GE animals, but it has some on the use of animal clones. The EC is actively involved in the work of the OIE and organizes the input from the MSs.

Twenty-one out of the 28 MSs of the EU are members of the [OECD](#), which has working groups and develops guidelines on biotechnology policies.

The EU is a party to the [Cartagena Protocol on Biosafety](#), which aims to ensure the safe handling, transport, and use of living modified organisms (see [Chapter 1 Part B I\) Cartagena Protocol](#)).

PART F – MARKETING

a) PUBLIC/PRIVATE OPINIONS

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 may increase the acceptance of the technologies. However, a share of the population would likely still reject it as being “unnatural.” Opinions vary with the intended use. Food use is widely rejected (see next paragraph); medical applications are the most accepted. Public awareness of biotech insects is low.

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

b) MARKET ACCEPTANCE/STUDIES

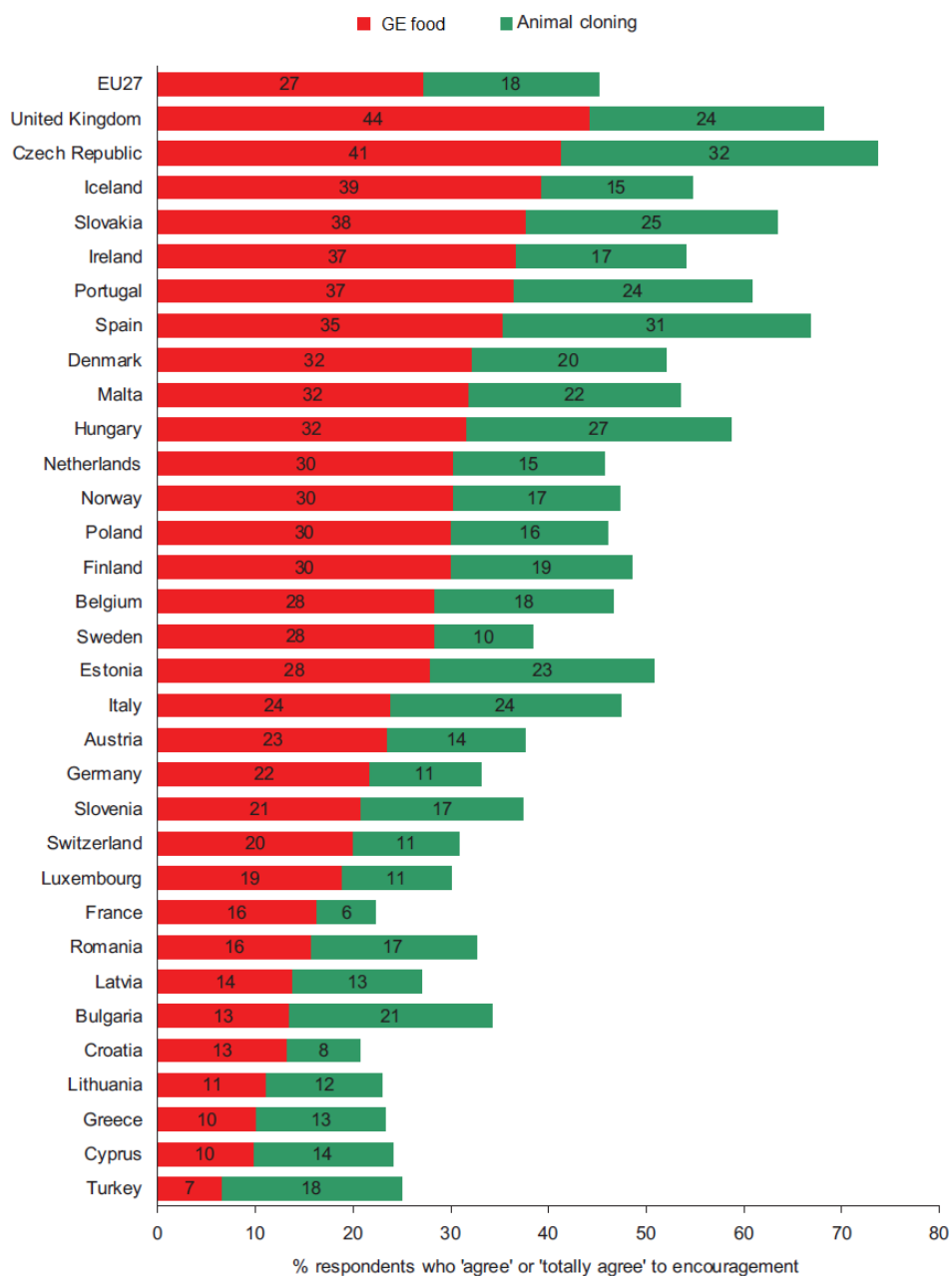
There is little public awareness of animal biotechnology in the EU, but overall, market acceptance is low among policy makers, industry, and consumers, due to ethical and animal welfare concerns. Animal biotechnology is a controversial issue that is not widely discussed.

²⁵ Source: [European Patent Office](#)

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

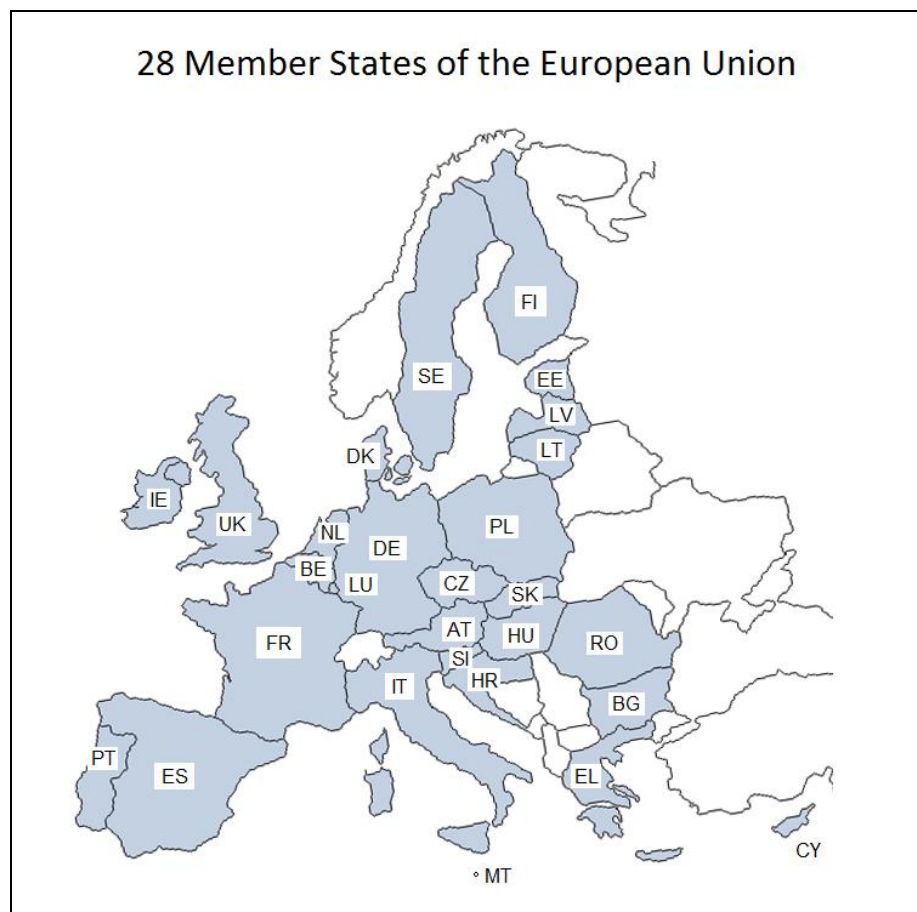
According to the EC's 2010 [survey](#) on biotechnology, “the idea of the ‘natural superiority of the natural’ captures many of the trends in European food production, such as enthusiasm for organic food, local food, and worries about food-miles. Moreover, if ‘unnaturalness’ is one of the problems associated 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.

Encouragement for GE food and animal cloning for food products



Source: European Commission 2010 [survey](#) on biotechnology

ANNEX 1 – 28 MEMBER STATES OF THE EUROPEAN UNION



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

ANNEX 2 – RELATED REPORTS

USDA Foreign Agricultural Service writes comprehensive reports about individual EU Member States. The latest versions of the Agricultural Biotechnology Annual report are available for those countries listed below:

[Austria](#)
[Belgium](#)
[Bulgaria](#)
[Croatia](#)
[Czech Republic](#)
[France](#)
[Germany](#)
[Greece](#)
[Hungary](#)
[Italy](#)
[Netherlands](#)
[Poland](#)
[Portugal](#)
[Romania](#)
[Spain](#)
[United Kingdom](#)

USDA Foreign Agricultural Service also writes a variety of reports about recent developments in biotechnology. These are available at the [GAIN database](#) and on the [Foreign Agricultural Service website](#).