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## EU-28

### Agricultural Biotechnology Annual

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**Approved By:**

Jennifer Lappin  
Agricultural Attaché

**Prepared By:**

The group of FAS Biotechnology Specialists in the European Union

**Report Highlights:**

The EU's complex and lengthy policy framework for biotechnology slows down and limits research, development, production, and imports. This situation has direct consequences for EU farmers, who have limited access to agricultural tools and see their competitiveness eroding. At the same time, it creates an unattractive environment for research. The EU plant breeding sector is focusing their efforts on Innovative Biotechnologies, whose regulatory status is still to be defined. Public and private initiatives in EU Member States differentiate themselves by using voluntary genetically engineered (GE)-free labels and this increases the bloc's demand for non GE soybean meal, and discourage GE corn cultivation in the EU, which since 2017 is limited to two Member States.

## 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.

While conventional GE research is still being conducted, 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 GE plants suitable for cultivation in the EU has waned given the unattractive and uncertain investment environment. Open-field testing is permitted in eleven MS, although in 2017 only six MS carried out open field trials on a variety of biotech crops. EU Research is not likely to lead to the commercialization of new GE plants in the short term.

Most of the EU MS' plant breeding sectors are now focusing on Innovative Biotechnologies (IBs), whose regulatory status is in a grey area and its legal analysis has been put on hold until the European Court of Justice (ECJ) rules on the [four questions](#) raised by the French Supreme Court. Politically, the debate is still at an early stage. A few MS are active on this subject but in most countries, the debate has not yet emerged. In most EU countries, the general public is not aware of agricultural applications of IBs.

Commercial cultivation of GE crops in the EU is limited to just over 130,000 hectares of MON810 corn in Spain and Portugal. Regulatory constraints that prevent this area from further growth include a cultivation ban in eighteen MS, strict coexistence rules and a mandatory field register. As per agronomic reasons, the single GE crop authorized for cultivation does not fulfil the needs of the majority of the EU farmers. Additionally, the threat of protests or destruction by activists, the increased interest in non-GE products, retail requirements, and public/private initiatives such as the EU Soy Declaration, discourage the cultivation and marketing of GE crops in the EU.

The regulatory procedures for approving biotech plants in the EU takes significantly longer than in supplier countries. This 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 the EU border if they contain traces of products that have not yet been approved in the EU. This represents a challenge for commodity trading companies, as it limits their sourcing options and increases their risk. European feed manufacturers have repeatedly criticized the EU policy, as it has resulted in price increases for feed and a loss of competitiveness for the EU livestock and poultry sectors.

The EU does not export any GE products but it is a major importer of soybean, corn, and rapeseed products. These items are mainly used as feed in the livestock and poultry sectors. The share of GE products in total imports is estimated at around 85 percent for soybeans, less than 25 percent for corn, and less than 20 percent for rapeseed. Demand for GE-free soybean

meal in the EU-28 is estimated at 20 percent of consumption and is anticipated to continue to grow. While not binding, the [European Soy Declaration](#), signed by twelve EU MS, aims to boost soy production in the EU and support the further development of markets for sustainably cultivated non-GMO soybeans and soybean products.” Nevertheless, the current situation of the EU, with very little cultivation of GE plants and high imports, is not expected to change significantly in the medium term.

The EU Research Project [Consumer Choice](#), which compares consumer intentions with actual purchases, 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. While the situation may vary across countries, there are increasing examples of GE-labeled imported food products that achieve sales success. This coexists with several initiatives in EU MS to differentiate themselves at the retail level by using voluntary GE-free labels.

Acceptance of GE crops in the EU varies greatly among countries. MS can be divided into three categories. Eight MS including: Denmark, The Netherlands, Finland, Estonia, Romania, Spain, Portugal, Czech Republic and 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 MS, including France, Germany, Ireland, Sweden, Lithuania, Poland and Bulgaria 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 (retailers, consumers and governments, with activists holding significant sway over the public discourse). In the ten other MS (Austria, Slovenia, Slovakia, Italy, Greece, Croatia, Latvia and Hungary, Cyprus and Malta) most stakeholders (politicians, governmental decision makers, farmer organizations, and consumers) reject the technology.

As for animal biotechnology, the EU is particularly active in basic medical and pharmaceutical research. Some MS are also active in research for agricultural purposes, focusing their efforts in improving livestock breeding. No GE animal is commercialized in the EU and market acceptance is low, due to ethical and animal welfare concerns. No foods are produced from animal clones in the EU. Commercial cloning in the EU is limited to elite horses. In the absence of progress with the discussions on the legislative proposals on animal cloning in released by the European Commission in December 2013, such foods would be covered by Regulation (EU) 2015/2283 until specific regulations on animal cloning are passed.

**Acronyms used in this report are the following:**

CGF	Corn Gluten Feed
DG SANTE	Directorate General for Health and Human Safety
DDGS	Distiller's Dried Grains and Solubles
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 here when quoting specific regulatory language)
IB	Innovative biotechnologies
JRC	Joint Research Center of the European Commission
LLP	Low Level Presence
MS	Member State of the European Union
MT	Metric Ton
MMT	Million Metric Tons
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” (IBs) is a synonym of New Breeding Techniques (NBTs) and excludes transgenesis.

**This report represents a group effort of the following analysts:**

O. Bettini FAS/Rome covering Italy  
M. Boshnakova FAS/Sofia covering Bulgaria  
T. De Belder FAS/USEU/Brussels covering EU new breeding techniques policy and plant biotech in Belgium  
M. Dobrescu FAS/Bucharest covering Romania  
D. Faniadis FAS/Rome covering Greece  
M. Kobuszynska FAS/Warsaw covering Poland, Latvia, Lithuania, and Estonia  
B. Flach FAS/the Hague covering the Netherlands, Finland, Denmark and Sweden  
G. Golya FAS/Budapest covering Hungary  
M. Guerrero FAS/Madrid covering Spain and Portugal  
R. Krautgartner FAS/Vienna covering Austria and Slovenia  
L. Lefebvre FAS/Paris covering France  
J. Mikulasova FAS/Prague covering the Czech Republic and Slovakia  
A. Misir FAS/Zagreb covering Croatia  
Y. Polet FAS/USEU/Brussels covering EU and Belgium animal biotech policy  
L. Rehder FAS/Berlin covering Germany  
J. Williams FAS/USEU/Brussels covering EU plant biotech policy  
J. Wilson FAS/London covering the United Kingdom and Ireland  
FAS agricultural office responsible for the report: USEU  
Coordination and lead: FAS Madrid

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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, Monsanto in 2013 and KWS opened its new research center in the United States in 2015). Interestingly, KWS is a leading supplier of GE sugar beet seeds used by U.S. farmers. 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).<sup>1</sup> 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

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

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](#).

The **Czech Republic** is in a consortium with USDA’s Agricultural Research Service and several EU new member state research institutions (like the French INRA) that has developed a bioengineered **plum tree**, called *HoneySweet* that is resistant to the plum pox virus. While many field trials have been successfully completed already, it is expected to take several years before the EU MS gain final approval.

Additional examples of plant biotechnology research carried out by EU countries can be found in [Part B: Policy d\) Field Testing Section](#).

In **Belgium**, a consortium consisting of three different institutions (Flemish Institute of Biotechnology, the university of Ghent and the institute for agricultural and fisheries research) are developing cisgenic late blight resistant Bintje **potatoes**, which may be ready for market within a period of five years.

In The **Netherlands**, Wageningen University conducts research on cis-genic potatoes and apples.

While conventional GE research is still being conducted, the regulatory unpredictability and high costs associated with navigating the system discourage it. Consequently, most of the EU MS’ plant breeding sector has focused on IBs. Presently, public debate has not emerged yet in the large majority of MS. These technologies are currently in a regulatory gray area, and its legal analysis has been put on hold until the European Court of Justice (ECJ) rules on the four questions that were raised by the French Supreme Court.

For additional information see [Part B: Policy. e\) Innovative Biotechnologies](#).

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

- Only two MS cultivate Bt corn in 2017.

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). In 2016 four MS grew Bt corn (Spain, Portugal, the Czech Republic, and Slovakia), however, in 2017 only **Spain** and **Portugal** continue to cultivate GE corn.

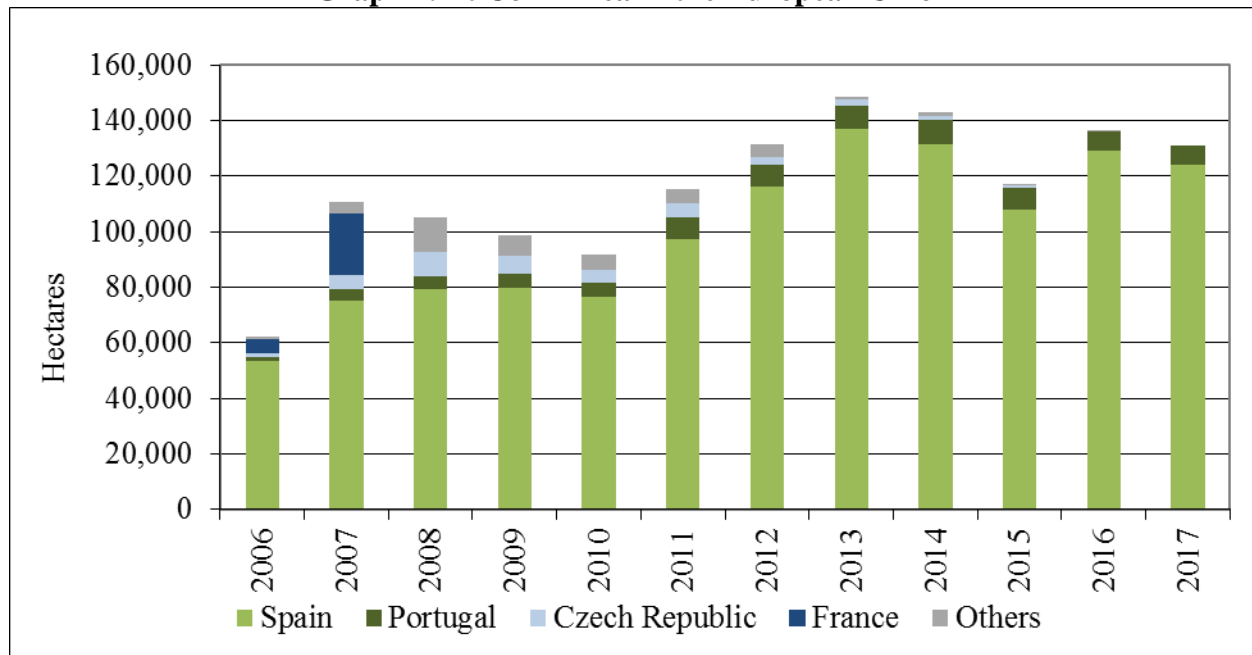
MON810 is only grown by farmers in areas where the corn borer represents a problem. Approvals of new traits for cultivation could raise the interest for GE crops in other MS. For instance, in Northeastern Europe, the interest on GE corn varieties is low as the importance of this crop is rather limited; however, countries in this region could benefit from using some of the traits that are available for rapeseeds in other EU trade partners.

Bt corn produced in the EU is used locally as animal feed and for biogas production. Spain and Portugal's 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. Better prices paid by the food corn processing industry may have also been a strong contributing factor for some farmers to opt for increased plantings of conventional corn varieties.

**Graph 1** and **Table 1** below show how in **2017**, the area planted in Bt corn in the EU decreased by 4 percent to 131,263 hectares. **Spain** represents 95 percent of the total area in 2017 and **Portugal** the remaining 5 percent. For the first time in more than a decade (since 2005 and 2006 respectively), Bt corn cultivation has been discontinued in the **Czech Republic** and **Slovakia**.

The area planted to GE corn has remained fairly stable in **Portugal**, while **Spain's** GE corn area has registered a marginal decline slightly over the total production corn area. Although the **Czech** government decided upon a science-based approach to biotechnology, farmers have opted not to grow GE corn due to the difficult marketing. The use of domestic production of GE corn in the **Czech Republic** was limited to biogas production and on-farm cattle feeding. In both the Czech Republic and **Slovakia**, retail buyers push for GMO-free products and for products from animals that were not fed with GMO along with the strong influence of the neighboring anti-GMO countries has resulted in a political shift and a cultivation halt.

**Graph 1. Bt Corn Area in the European Union**



Source: FAS offices in the European Union

**Table 1. Bt Corn Area in the EU, by Member State**

in hectares	2012	2013	2014 (updated)	2015 (updated)	2016 (updated)	2017 (estimate)
<b>Spain</b>	116,307	136,962	131,538	107,749	129,081	124,227
<b>Portugal</b>	7,700	8,202	8,542	8,017	7,069	7,036
<b>Czech Republic</b>	3,050	2,560	1,754	997	75	0
<b>Romania</b>	217	834	771	2.5	0	0
<b>Slovakia</b>	189	100	411	400	112	0
<b>Poland</b>	4,000	0	0	0	0	0
<b>Total Bt corn area</b>	131,463	148,658	143,016	117,166	136,337	131,263
<b>Total corn area planted in the EU</b>	9,720,000	9,660,000	9,564,000	9,250,000	8,590,000	8,570,000
<b>Share of Bt corn in total corn area</b>	1.35%	1.54%	1.50%	1.27%	1.59%	1.53%

Source: FAS offices in the European Union

Additional information about the EU's corn market can be found in the [EU-28 Grain and Feed GAIN Annual Report 2017](#).

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

In March 2015, [Directive \(EU\) 2015/412](#) allowed MS to restrict or ban the cultivation of EU-authorized GE plants in their territories for non-scientific reasons. The Directive requires those MS in which GE crop cultivation takes place to take appropriate measures aimed at avoiding possible cross-border “contamination” into neighboring MS in which cultivation is prohibited. This effectively means that MS cultivating GE products bear the responsibility (and any liability) associated with cultivating GE crops.

The MS 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 product 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. MS 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.

To date, eighteen 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 approval pipeline at that time, apart from Denmark and Luxembourg that have only banned MON810 and three of the seven varieties in that pipeline.<sup>2</sup> Slovakia is currently in the process of updating their national law to opt out under Directive 2015/412. **Map 1** and the **Table 2** below provide an overview of the situation in regards to GE crops cultivation in the EU.

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<sup>2</sup> The varieties that were in the pipeline at the time of the Directive implementation 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 MS demands are available online on the [European Commission’s website](#).

**Table 2. Cultivation Situation in the different EU MS or Regions**

Situation	Countries and regions
 [N = New] Nine countries and four regions where cultivation was not banned before have opted out of GE corn cultivation or are in the process to do so under the new directive. This decision will not lead to a significant cultivation change as farmers in these countries/areas have not cultivated GE corn for various reasons, including the fact that the only event approved for cultivation is not well suited to local growing conditions, the threat of protests, and administrative constraints.	- Nine countries: Croatia, Cyprus, Denmark, <sup>*</sup> Latvia, Lithuania, Malta, the Netherlands, <sup>**</sup> Slovenia, Slovakia <sup>***</sup> - Four regions in two countries: Wallonia in Belgium; Northern Ireland, Scotland, and Wales in the United Kingdom
 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, <sup>*</sup> and Poland
 Two countries grow GE corn in 2017.	Spain and Portugal
 In the other countries and regions, cultivation is still allowed but no GE corn is grown for various reasons, including the fact the only event approved for cultivation is not well suited to local growing conditions, the threat of protests, administrative burden or marketing difficulties of the production.	- Six countries: Ireland, Romania, Sweden, Finland, Estonia and the Czech Republic - Two regions: Flanders in Belgium, England in the United Kingdom

<sup>\*</sup> 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

<sup>\*\*</sup> 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.

<sup>\*\*\*</sup> Slovakia is currently in the process of updating their legislation to opt out under Directive 2015/412.

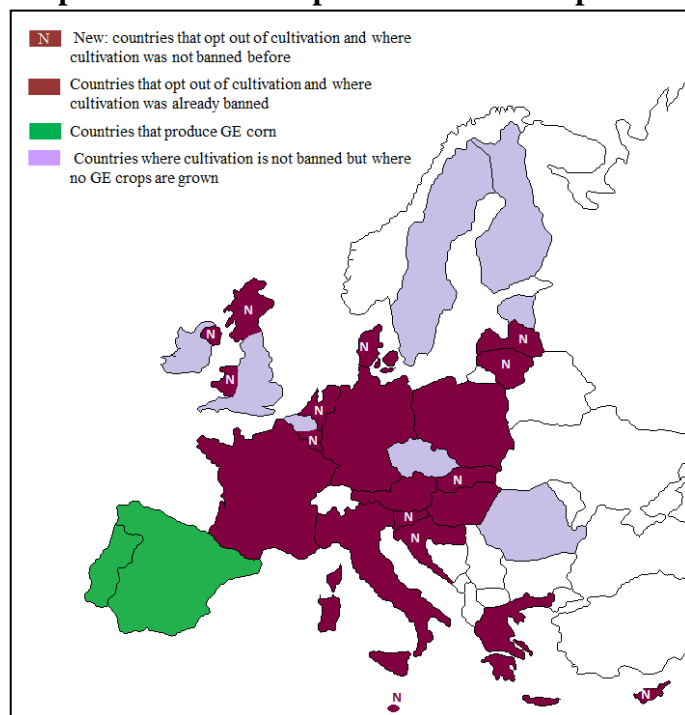
Source: FAS offices in the European Union

Moreover, on November 2, 2016 the German cabinet approved a draft legislation banning the cultivation of GE crops within Germany's borders. Until now, disagreement regarding whether the ban might cover the entire country, or be decided individually by each of the German states, has prevented this piece of law from entering into force.

The "opt-out" of cultivation law allows any MS to "opt out" of cultivating an approved GE crop (only MON 810 corn at the time of writing) for socio-economic as opposed to scientific reasons. The rationale behind introducing that law was to prevent non-GE MS invoking the safeguard clause by using "spurious science."

At the time the Directive was implemented, the EC asserted that the "opt-out" Directive would have a positive impact on authorizations given the progress of these crops through the authorization process. In March 2017, three GE corn crops for cultivation received "no opinion" from the Appeal Committee (authorization of BT11, 1507 and renewal of MON 810) and, at the time of writing, the College of Commissioners has yet to decide on these authorizations and authorization renewal. The cultivation opt-out did not lead to a change on farms as none of the countries that opted out in 2015 cultivated GE crops when the regulation was implemented, nor resulted in a change in the sense of votes on cultivation files.

### Map 1. EU MS that Opted Out of GE crops cultivation



Source: FAS offices in the European Union

In 2017 GE crops cultivation in the European Union is limited to two MS: **Spain** and **Portugal**.

While no ban on cultivation has been imposed in the **Czech Republic**, the country stopped producing GE corn in 2017 due to increasing difficulties to market their GE corn production. **Slovakia** also halted GE corn production in 2017. In this case it is more of a consequence of a political shift. The country is a signatory of the [Danube Soy Initiative](#), adhered to the [European Soy Declaration](#). It is our understanding that Slovakia is in the process of updating their legislation to opt out under Directive 2015/412.

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

### 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 protein deficient and a major importer of GE soybean and soybean meal (33 MMT), and corn products (7 MMT) per year, mainly used as a feed ingredients in the livestock and poultry sectors. European non-GE soybean production is expected to increase in the coming years but it remains marginal relative to total imports. The EU also imports more than 2.5 MMT of rapeseed products yearly.

Additional information about on EU's protein deficit can be found in the [EU-28 Oilseed and Products GAIN Report 2017](#).

Trade data do not differentiate between conventional and GE varieties. The graphs presented in this section therefore include both categories. **Table 3** 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 to the EU is estimated at 92 percent for soybeans, 95 percent for soybean meal, just over 20 percent for corn, and less than 20 percent for rapeseed.

**Table 3. Major Producers/Exporters Share of GE Crops in Total Production in 2016**

<b>Soy</b>	
Argentina	100%
Brazil	97%
Canada	94%
Paraguay	96%
<a href="#">Ukraine</a>	estimated at 60-70%
United States	94%
Uruguay	98%
<b>Rapeseed/Canola</b>	
Australia	23%
Canada	93%
Russia	0%
<a href="#">Ukraine</a>	0%
United States	90%
<b>Corn</b>	
Argentina	97%
Brazil	97%
Canada	92%
Russia	0%
Serbia	0%
<a href="#">Ukraine</a>	estimated at 5 - 10%
United States	92%
Uruguay	96%

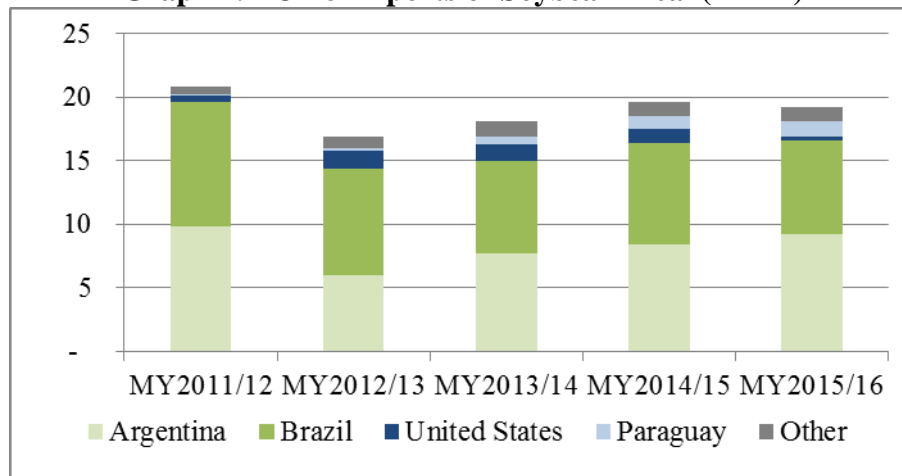
Source: [ISAAA Brief 52, 2016](#) and FAS GAIN reports.

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

According to the latest [EU-28 Oilseed and Products GAIN Annual Report](#), the EU needs to import on a yearly basis about 33 MMT of soybean and soybean products, mainly for animal feed. The EU imports around 65 percent of the soybean meal it consumes. The rest is produced by domestic crushing facilities, which uses more than 85 percent of imported soybeans.

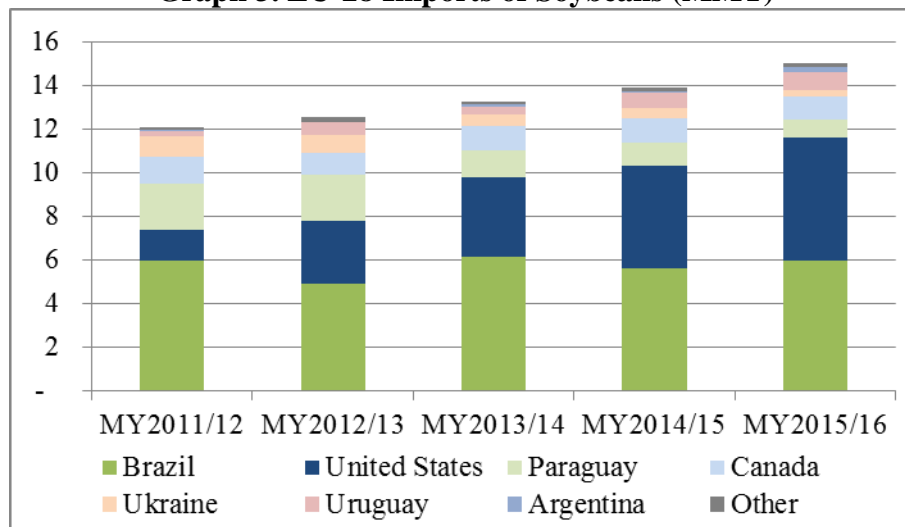
In the past five years, soybean meal imports amounted to 19 million MT, and soybean imports to 13 million MT per year on average (see graphs below). The EU's leading suppliers are Brazil, Argentina and the United States. The largest users of soybean meal (Germany, Spain, France, the Benelux, and Italy)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

**Graph 2. EU-28 Imports of Soybean Meal (MMT)**



Source: FAS based on Global Trade Atlas data

**Graph 3. EU-28 Imports of Soybeans (MMT)**



Source: FAS based on Global Trade Atlas data

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

As the global cultivation of GE crops expands (See **Table 3**), it is increasingly difficult for European importers to source non-biotech soybean products, as 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. Non GE soybean meal demand in the EU-28 includes the organic sector, some of the products sold under [Geographical Indications](#), and various GE-free labeling initiatives. Non GE soybean meal 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 2.4 million MT in 2016/17 to around 2.5 million MT in 2017/18, which is still low compared to the 33 million MT of soybeans and soybean products imported every year. The minor impact on imports is expected to be partly offset by a rising demand for feed.

Additional information about on EU-28 soybean production and soybeans and soybean products imports can be found in the [EU-28 Oilseed and Products GAIN Annual Report 2017](#).

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

- Under the 2014-2020 Common Agricultural Policy, some MS such as **France, Germany and Spain** have national strategies for protein crops, which aim to encourage crop rotation while reducing their dependence on imported protein.<sup>3</sup>
- Under the 2014-2020 Common Agricultural Policy, several countries have chosen to give farmers coupled supports for soybeans.
- Under the 2014-2020 Common Agricultural Policy, some MS consider soybeans as nitrogen fixing crop (Ecologic Focus Areas) for greening compliance.
- In 2014, the European [Focus Group](#) on protein crops published its [final report](#).<sup>4</sup> 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 constrained.

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<sup>3</sup> The Blair House Agreement (BHA) limits the EU oilseed planting area of mainly rapeseed, sunflower seed, and soybeans, for food and feed purposes to an adjusted maximum guaranteed area (MGA) for those producers benefiting from crop specific oilseed payments. The BHA is triggered by crop specific payments. With the elimination of the crop specific payments, the BHA is maintained as a mechanism but is not used. However, if the introduction of coupled support for oilseeds were to trigger the BHA, the Commission asserts that measures are in place to ensure that the MGA is not overused.

<sup>4</sup> 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.



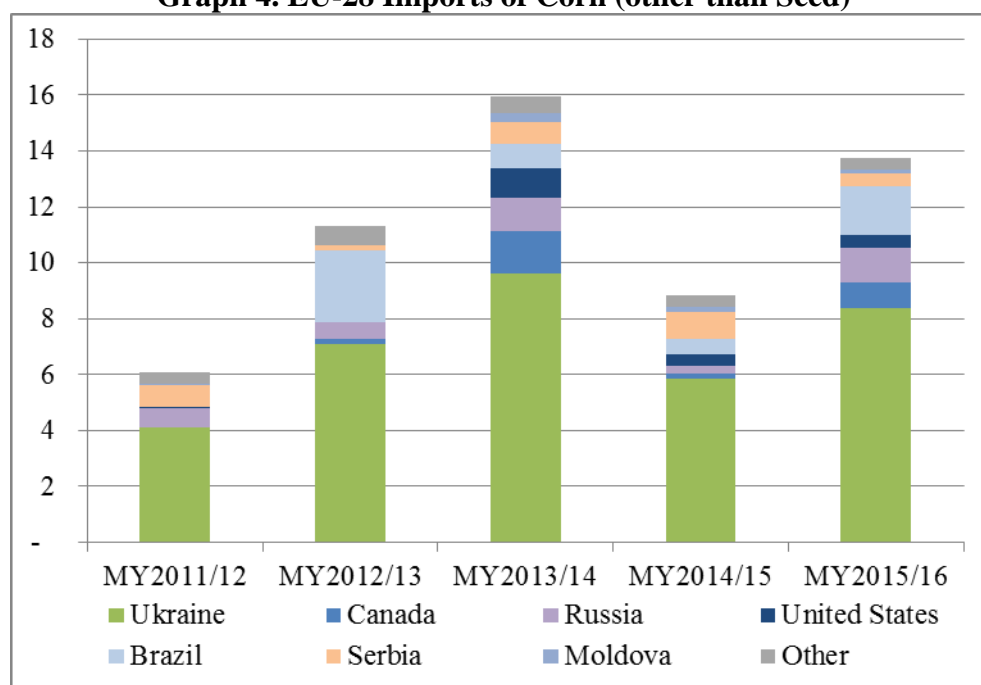
- The [Danube Soya Association](#), a non-governmental association supported by the Austrian government, promotes the production of non-biotech soybeans in the Danube region (Austria, Bosnia Herzegovina, Bulgaria, Croatia, Germany, Hungary, Romania, Serbia, Slovakia, Slovenia and Switzerland). According 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).
- On July, 17, 2017, on the sidelines of the Agriculture and Fisheries Council in Brussels, twelve MS, signed the [European Soy Declaration](#) which aims to boost soy production in the EU. While not an EU binding policy, Ministers of Agriculture of Austria, Croatia, Finland, France, Germany, Hungary, Luxembourg, the Netherlands, Poland, Romania, Slovenia and Slovakia signed the declaration and agreed to voluntarily implement the provisions of this declaration. The declaration also includes a provision on GMO-free feed, whereby signatories “support the further development of markets for sustainably cultivated non-GMO soybeans and soybean products.”
- For additional information see [Part B: Policy. N\) Related Issues](#).

- **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 largest importers of corn (Spain, the Benelux, Italy and Portugal) have important livestock and poultry sectors, but are limited in domestic grain production. Additional information about on EU’s grain market can be found in the [EU-28 Grain and Feed GAIN Annual Report 2017](#). We estimate the share of GE corn out of total corn imports to be just over 20 percent.

Over the past few years, Ukraine’s expansion market share of corn exports to the EU has been remarkable, resulting both from economic factors and from their non-biotech image. In MY2015/16, Ukraine accounted for over 60 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 (See **Table 3**).

**Graph 4. EU-28 Imports of Corn (other than Seed)**

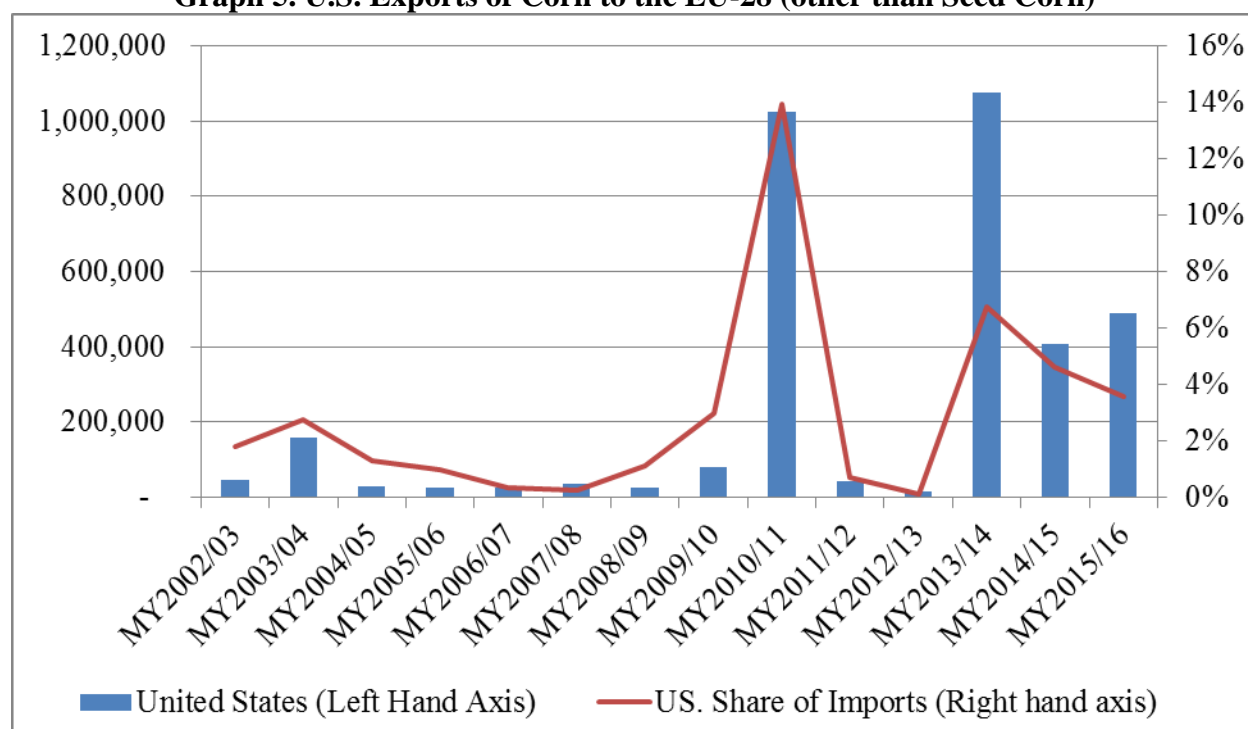


Source: FAS based on Global Trade Atlas data

While U.S. exports of corn to the EU, on average, amounted to 3 MT per year until 1997, since 1998, they were significantly reduced— with the only two exceptions in 2010/11 at 946,000 MT and in 2013/14 at 1.3 million MT. Over the past 15 years, U.S. corn imports to the EU represented on average less than 3 percent of EU’s total corn imports. (See **Graph 5**).

The beginning of GE corn plantings in the United States in 1998 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](#). The slow pace of approvals affects corn trade in particular due to the EU policy of approving stacks as a separate product. While so far, there is only one soybean stack being cultivated in the United States, most of the GE corn varieties produced in the United States are stacks. Imported U.S. corn is mainly used for animal feed and bioethanol production.

**Graph 5. U.S. Exports of Corn to the EU-28 (other than Seed Corn)**



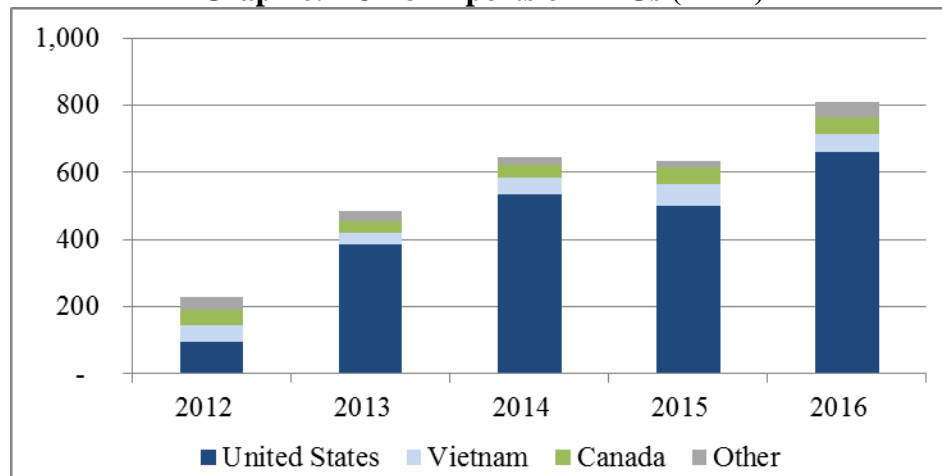
Source: FAS based on Global Trade Atlas data

- **The United States is the main supplier corn processing by-products to the EU.**

The EU imports between 250 and 850 thousand metric tons of DDGs and CGF per year<sup>5</sup>. The share of GE products out of total imports is estimated to be about 80 percent. The United States is the main supplier of DDGs and CGFM to the EU, with an average market share of 71 percent over the past five years (see **Graph 6** and **Graph 7** 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.

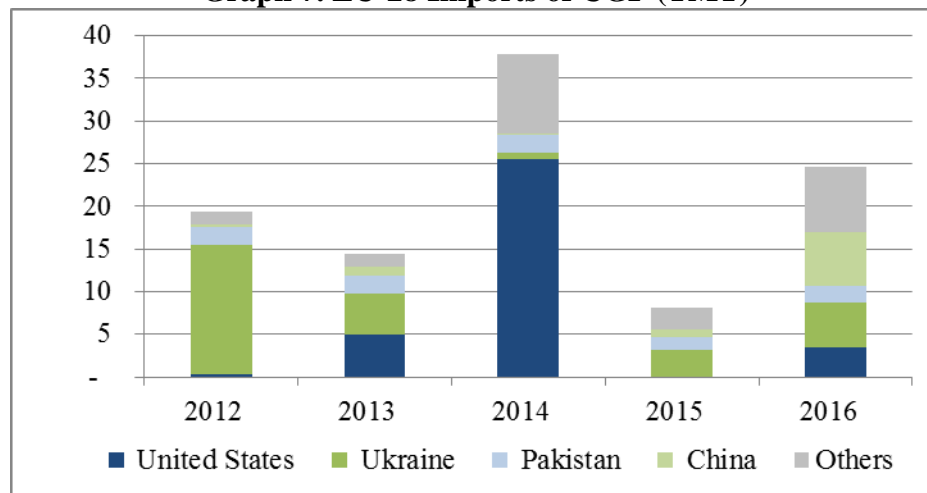
<sup>5</sup> DDGS is a corn byproduct of the distilling process; CGF is a corn byproduct of the wet-milling.

**Graph 6. EU-28 Imports of DDGs (TMT)**



Source: FAS based on Global Trade Atlas data

**Graph 7. EU-28 Imports of CGF (TMT)**



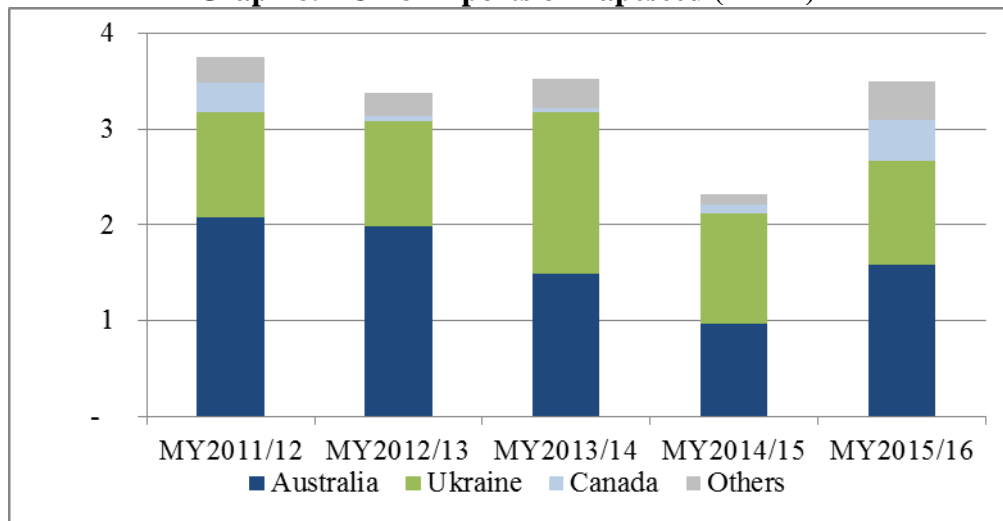
Source: FAS based on Global Trade Atlas data

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

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. The biodiesel industry is the main driver for the demand of rapeseed oil but food and industrial use are also influencing demand. In the last five years, the EU imported between 2.3 and 3.8 million MT of rapeseed and between 245,000 and 460,000 MT of rapeseed meal per year (see **Graph 8** and **Graph 9** below).

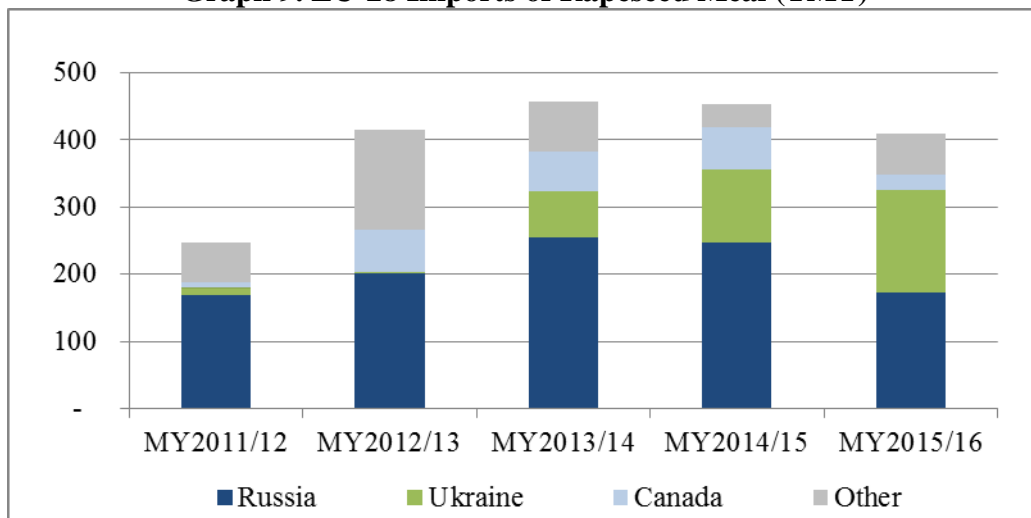
In MY2015/16, 12 percent of the EU's imports of rapeseed and 6 percent of its imports of meal came from Canada, where 95 percent of rapeseed is GE; and 45 percent of rapeseed came from Australia, where 21 percent of rapeseed is GE. (See **Table 3**)

**Graph 8. EU-28 Imports of Rapeseed (MMT)<sup>6</sup>**



Source: FAS based on Global Trade Atlas data

**Graph 9. EU-28 Imports of Rapeseed Meal (TMT)**



Source: FAS based on Global Trade Atlas data

#### 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 2016, it provided 750 million euros for [humanitarian food assistance](#) projects implemented by partner organizations in 61 countries. The aid does not include GE products.

<sup>6</sup> 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.

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

The EU is not a recipient of external food aid. However, some redistribution within the EU under the [Fund for European Aid to the Most Deprived \(FEAD\)](#) is carried out.

## **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. This has led to a widening gap between GE products deregulated and grown in the United States, and other biotechnology growing countries, and those approved in the EU, resulting in the partial or complete disruption of trade in affected commodities and processed products.

Although the legally prescribed approval time is 12 months (6 months for EFSA, 6 months for comitology), it takes an average of seven years (industry estimate) for the European Commission approval of a GE product. The USDA is currently tracking approximately 28 applications (cultivation, import, and renewal) of corn, soy, or rapeseed as they await the scientific review by the European Food Safety Authority (EFSA). Additionally, there are 14 applications (cultivation, import, and renewal) awaiting EU Commission action.

This represents a problem for commodity trading companies, as it limits their sourcing options and increases the risk in their operations with those countries where not-yet approved events are grown. 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 and do result in trade disruptions and price increases for protein-rich products which the EU needs for its animal feed sector.

Farmer's planting decisions are also affected by the EU delays. In major exporting countries it prevents farmers from choosing cutting-edge seed varieties. It can also prevent farmers in countries outside the EU from planting GE varieties so that they can remain or become an agricultural supplier to the EU.

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

For more information, see [Chapter 1 Part B c\) Approvals](#).

- **Low Level Presence**

The effect of these [asynchronous approvals](#) is reinforced by the EU's policy for low level or adventitious presence of events. Commodity trading companies see the risk to their operations increase when trading with countries where GE products are grown, yet are not-yet approved in the EU. The risk presented is that an unapproved GE crop could get inadvertently mixed with an approved GE product or a non-GE product creating a low level presence in the commodity supply chain.

For additional information see [low-level presence policy](#) section.

- **Cultivation Bans**

Eighteen MS have banned so far 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 MS to “opt out” of use of EU approved biotech crops**

In April 2015, Health and Food Safety Commissioner Andriukaitis announced his review of the EU biotech authorization process, which would allow MS to “opt out” of using EU-authorized GE plants. In October 2015, the European Parliament (EP) rejected the “opt out” for use proposal. Members of the EP 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 with the Council, although it remains highly unlikely that MS will vote on the proposal. Essentially, in the absence of an agreed proposal, the EC has asserted that the unwillingness of the EP and MS 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 proposed an amendment to [Directive 2001/18/EC](#) (“...on the deliberate release into the environment of genetically modified organisms”) regarding environmental risk assessment of GE Plants. The EC is obliged to update the Annexes to that Directive as regards the environmental risk assessment, with a view to incorporating and building upon the EFSA's 2010 guidance on the environmental risk assessment of GE plants by April 3, 2017.

The EC asserts that the proposal:

- reflects technical guidance that has already been implemented;
- implies no new requirements or fundamental changes;
- maintains a “case-by-case” approach.

The EC is currently working with MS to finalize the text. The draft amendment is expected to enter into force during the last quarter of 2017.

- **New guidance document on the risk assessment of GE plant material at low levels in feed and food not intended for import to the EU**

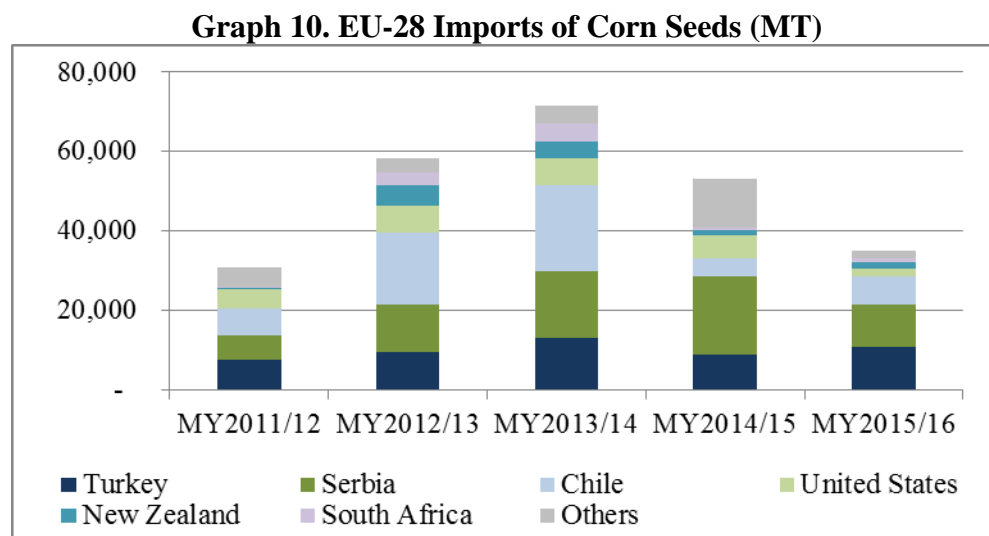
On Monday, May 8, 2017, the European Food Safety Authority (EFSA) launched a public consultation on a draft guidance document on the risk assessment of GE plant material at low levels in food and feed material that are not intended for import into the European Union. EFSA invited all interested parties to submit comments on the revised draft guidance document by June 30, 2017.

Additional information can be found in [EFSA's website](#).

The guidance was agreed by the GMO Panel at EFSA in September 2017 but has not yet been published at the time of writing.

- **Zero tolerance for adventitious presence in seeds**

Seed trade is affected by the zero tolerance of adventitious presence. The fact that the EU-28 only allows cultivation of MON810, serves as a trade barrier for U.S. seed exports containing or with adventitious presence of other GE events. A threshold level for adventitious GE material presence has not yet been set. As a consequence, the EU-28 is forced to either produce its corn seeds domestically or import seeds from a limited number of origins (Turkey, Serbia, Chile, United States, New Zealand and South Africa among other) where seed is produced under restrictive conditions that prevent from cross-contamination with not-yet approved for cultivation events.



Source: FAS based on Global Trade Atlas data



- **Marketing Bans**

**Austria** imports GE soybeans and soybean products. However, the country has implemented its own cultivation and marketing bans on EU approved GE crops. Since 2007 the following GE crops are banned for import and processing by Austrian Law: Monsanto GT73 rapeseed, Monsanto MON 863 corn, Bayer Ms8 rapeseed, Bayer Rf3 rapeseed and Bayer Ms8XRf3 rapeseed. **Bulgaria** has two regulations (amendments to the Food Act) imposing requirements on labeling and a ban on sales of foods containing GE products in schools, kindergartens and nurseries.

## **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).

The responsible government ministries at the Member State 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 somewhat conflicted relationship with agricultural biotechnology since it was introduced over 30 years ago. The European Commission (EC) continues to pursue inconsistent and unpredictable approaches regulating the technology. This is due in part to the strong emotional and ideological stance taken by EU consumers and anti-biotech non-governmental organizations (NGOs) on biotechnology, legislation adopted by the EC. As a result, the process surrounding the approval for cultivation and use of GE crop varieties has suffered. Conversely, the EU's agriculture industry relies on significant imports of GE feed for its large livestock sector. The United States, Canada, Brazil, and Argentina help to fill this need, and do so primarily with GE corn and soybean varieties. These conflicting issues continue to reflect the 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 MS 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 use<sup>7</sup>**

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

- An application<sup>8</sup> is sent to the appropriate national competent authority of a MS. That competent authority acknowledges receipt of the application in writing to the applicant within 14 days of receipt, and transmits the application to EFSA.
- EFSA informs other MS and the 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.

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<sup>7</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council

<sup>8</sup> The application must include:

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

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

- EFSA 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 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](#).

#### • **EC Proposal to Amend Comitology Rules**

As reported in [GAIN Report E1708 "EC Proposes Changes in Comitology Rules in Effort to Hold MS more Accountable,"](#) on February 14, 2017, the EC proposed to amend the comitology rules as provided by [Regulation \(EU\) 182/2011](#).

The proposal, which is subject to co-decision by Council and Parliament, aims to make MS take responsibility for decision making by:

- making only votes cast in favor or against count in the Appeal Committee;
- allowing a second referral to Appeal Committee at the Ministerial level;
- making public MS' votes cast;
- allowing referral to the Council of Ministers.

Although the proposal would, in theory, apply to all areas of EU law-making, it is clearly aimed primarily at the decisions made in the sensitive biotechnology sector. If adopted, the proposal would add up to six months to the decision-making process. Post analysis suggests that the adopted proposal on its own would not significantly impact voting patterns, and the College of Commissioners would still decide on authorizations. To date, there has been no significant

movement by the legislature on the proposal. More specifically, MS do not seem enthusiastic to discuss or progress the issue.

- **Authorization for cultivation of biotech events<sup>9</sup>**

The appropriate competent authority of each MS must provide written consent before an event can be commercially released for cultivation. 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.<sup>10</sup>
- 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 MS within 30 days following their receipt.
- Those MS may present observations through the Commission or directly within 30 days.
- The national competent authority has 45 days to evaluate the other MS comments. If, as is typically the case, these comments are not in line with the national competent authority's scientific opinion, the case is brought to EFSA which has three months from receipt of the documentation to give its opinion.
- The Commission then presents a draft decision reflecting EFSA's opinion to the Regulatory Committee for vote.
- As is the case for placing biotech events on the market for food and feed use, 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 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. 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.

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<sup>9</sup> Directive 2001/18/EC of the European Parliament and of the Council

<sup>10</sup> 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.

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

Moreover, [Directive \(EU\) 2015/412](#) allows MS 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**

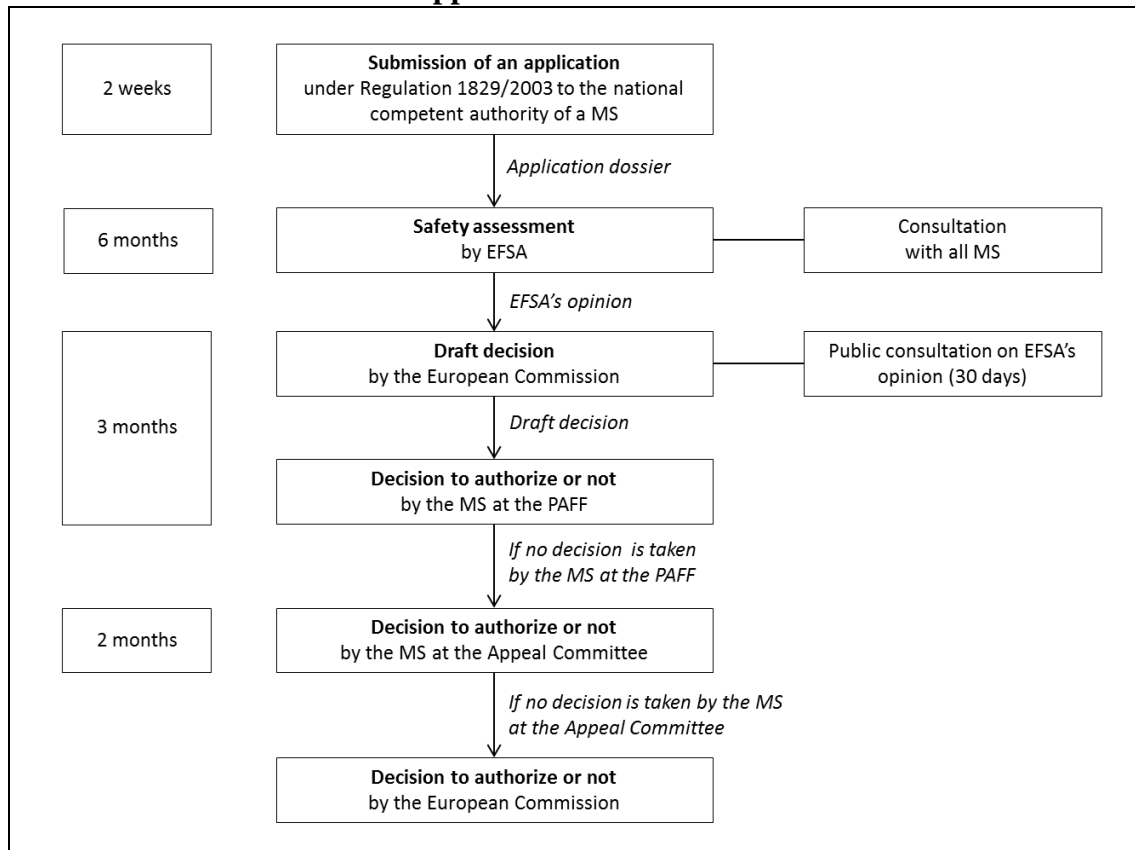
See [Chapter 1 Part A f\) Trade Barriers](#)

#### **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, for the events approved in 2017, it took an average of 48 months (industry estimates) for a GE product to be reviewed by EFSA and nearly seven years to pass through the approval process from start-to-finish. In contrast, the average approval process takes about 25 months in Brazil and the United States and 35 months in Korea.

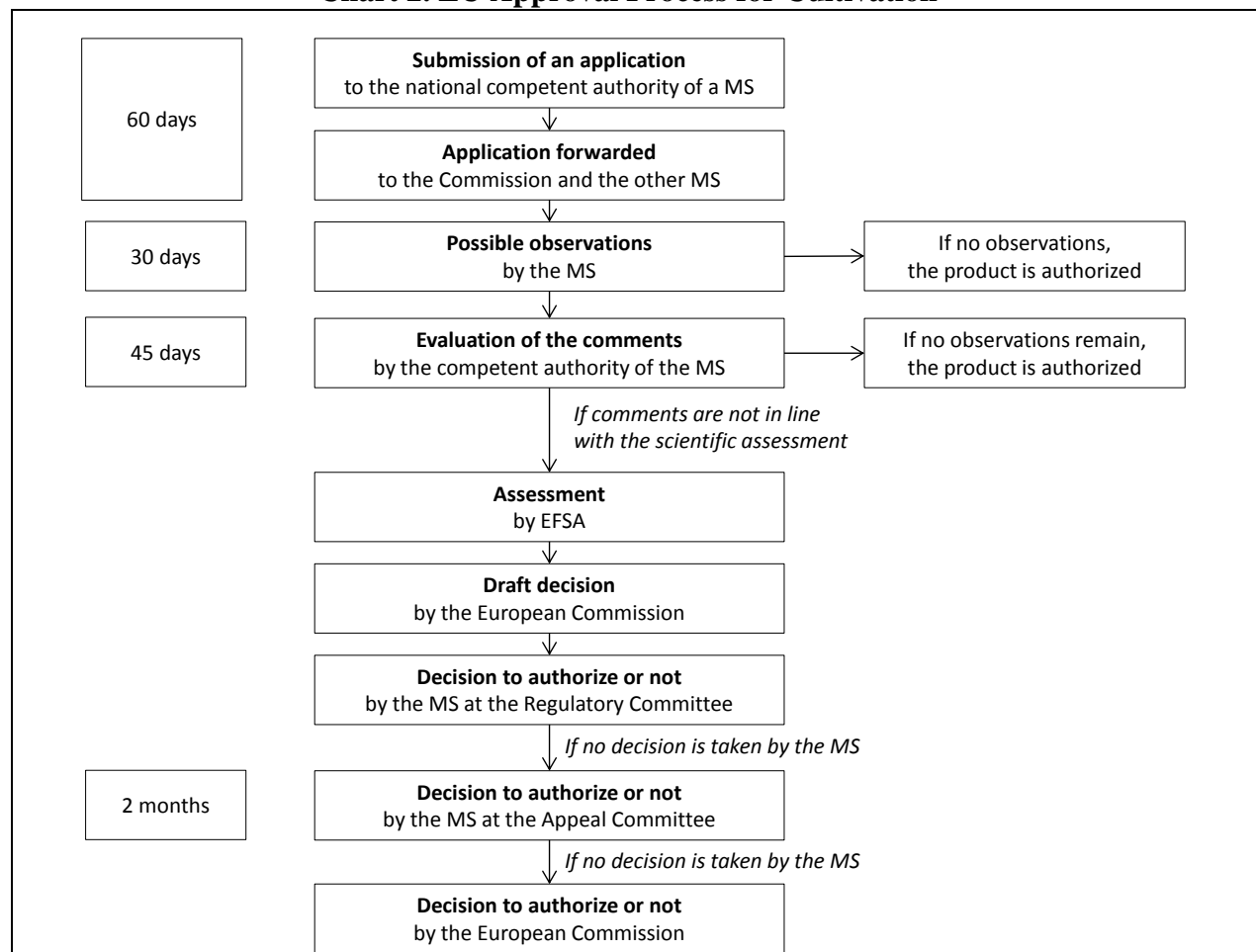
Each year, more biotech applications have been submitted than authorization decisions made, creating a growing backlog both in EFSA and at the Commission. Industry groups are putting pressure on the EC and MS to adhere to the legally prescribed approval process. Three EU industry groups (COCERAL, FEFAC, 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 procedures are graphically outlined below.

**Chart 1. EU Approval Process for Food and Feed.**



Source: USDA FAS

**Chart 2. EU 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 2017, the EC adopted five new authorizations for GE crops for food or feed use: On July 4, 2017, three GE corn events (Dow herbicide tolerant; Syngenta insect resistant/herbicide tolerant; Monsanto insect resistant - renewal) and two GE cotton events (Bayer insect resistant/herbicide tolerant; Dow insect resistant/ herbicide tolerant) were approved for import and processing.



All the GE events approved in 2017 have undergone the full authorization procedure, including a favorable scientific assessment by EFSA. They received "no opinion" from the MS 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

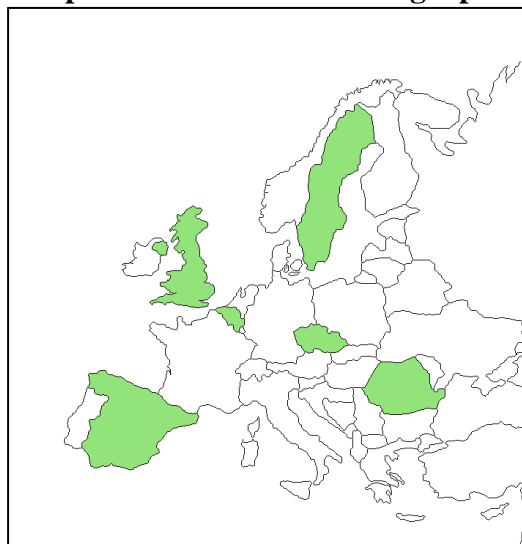
The approval process of stacked events is the same as in the case of single events.

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

Field trials are permitted in eleven MS<sup>11</sup>. However, only six MS conducted open-field testing in 2017: Belgium<sup>12</sup>, the Czech Republic, Romania, Spain, Sweden, and the United Kingdom. Repeated destruction by activists, a burdensome authorization process or the unattractive investment environment for seed companies are pointed out as the main disincentives in MS that allow field trials but none were carried out.

#### Map 2. Countries Conducting Open Field Trials in 2017



In 2017, ten different GE crops (arabidopsis, corn, canola, camelina, plum pox virus resistant plum tree, potatoes, tobacco, rice, wheat and poplar trees) are being tested in open field trials in the EU. Spain leads the number of accumulated notifications of open field releases. France and Germany have historically reported a high number of notifications, however there have been no field trials notifications since 2012 and 2010. 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. Other MS with significant accumulated numbers of open field trials notifications conducting field trials in 2017 include Sweden, Romania and the Czech Republic.

Source: FAS Offices in the European Union

<sup>11</sup> Belgium, Germany, Czech Republic, Denmark, Finland, Portugal, The Netherlands, Romania, Spain, Sweden and the United Kingdom.

<sup>12</sup> Belgium did not communicate any new field trial in 2017; however, a new trial with GE poplars for bioethanol production is still ongoing.

The number of projects actually conducted may be lower than the number of notifications.

The [list of the notifications](#) for deliberate release of GE plants into the environment is available on the JRC website.

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

## **e) INNOVATIVE BIOTECHNOLOGIES** <sup>13</sup>

Since the beginning of the twentieth century, several tools have broadened the possibilities for breeding new plant varieties, including mutagenesis and hybrid seed technology. During the last 20 years, additional applications of biotechnology and molecular biology have emerged, and several new breeding techniques (NBTs) have been developed. NBTs make crop improvement quicker and more precise. They can complement or substitute for genetic engineering. In addition, most NBTs have potential to address consumer concerns about GE crops by creating plants that could also have been obtained by conventional breeding.

EU scientists, plant breeders, biotech industry and MS (MS) urged the European Commission to clarify the legal status of the NBTs and their application since the current EU GMO-legislative framework, EU [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 necessary for these techniques and its products, even in cases where no foreign DNA is contained in the resulting end product or where these products are completely indistinguishable from conventionally bred crops.

The legal analysis on whether or not certain New Breeding Techniques (NBTs) fall under the scope of the EU legislation on Genetic Engineering (GE) was expected to facilitate the harmonization of MS approaches to regulate or not regulate Innovative Biotechnologies (IBs), but it would not deliver a final and binding opinion on the interpretation of EU law. After multiple delays, the Commission confirmed in January 2017 that the legal analysis has been put on hold until the European Court of Justice (ECJ) rules on the [four questions](#) that were raised by the French Supreme Court. The first hearing at the ECJ was held at the beginning on October 3, 2017. It takes between one year and a half and two years for the ECJ to answer MS' questions and the ruling is expected by 2018/2019. In these questions, the term “mutagenesis” includes only oligonucleotide-directed mutagenesis (ODM) and site-directed nucleases (SDN), which means that it is very unlikely that the ECJ would provide a comprehensive clarification at EU level in the foreseeable future on any of the other techniques. On September 7, 2017, the [Netherlands presented a policy discussion paper](#) to the Commission and MS whereby certain NBT applications would be excluded from the GMO designation of EU [Directive 2001/18/EC](#), similar to other genetic alteration technologies that are presently excluded; this would be

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<sup>13</sup> “Genetic Engineering” means transgenesis. “Innovative biotechnologies” is a synonym of New Breeding Techniques (NBTs) and excludes transgenesis.

accomplished by revising the directive's annex. At the time of writing, this proposal remains a proposal.

In parallel with the legal discussion on NBTs, the EC initiated a scientific review by the [Science Advisory Mechanism \(SAM\)](#). The Commission mandated the SAM to provide an explanatory note on "New techniques in agricultural biotechnology," which was published at the end of March 2017. The aim of the SAM is to support the Commission with high quality, timely and independent scientific advice for its policy-making activities and was set in place by Commission President Juncker after the position of Chief Scientific Advisor (Anne Glover) was abolished. [The scoping paper](#) was published late December 2016, and clarifies that the explanatory note will be scientific not legal and will be based on reviews of existing scientific sources.

The Commission appears to be waiting for the ruling from the ECJ before progressing with its regulatory approach(es) to NBTs. However, the Commission continues to hold [public dialogues on the challenges and opportunities NBTs may deliver](#).

On September 28, 2017, the European Commission organized a high-level conference on ["Modern Biotechnologies in Agriculture – Paving the way for responsible innovation."](#) The aim of the conference "was to stimulate an informed and open debate among all stakeholders on how the EU can benefit from modern biotechnologies and innovation in the food and agricultural sector while maintaining high safety standards." The Commission framed the discussion around embracing innovation in line with public needs and values and invited European policy makers, relevant industry stakeholders, representatives of civil society, scientists, and government experts as panelists. From ongoing discussions by panelists and the audience it was clear that for good or bad, biotechnology is perceived as risky in the EU and that strong labeling and transparency are essential components of the path forward. Many are looking to science to help provide regulatory clarity on NBTs, but as EU Commissioner for Health and Food Safety Vytenis Andriukaitis noted in his opening remarks at the conference, the problem is that there is no single vision in the EU and science will not deliver a black and white answer because science is about risk and uncertainty. How the EU addresses this for NBTs is not yet clear.

For more information see GAIN Report: [Dutch Proposal to Legislate NBTs](#).

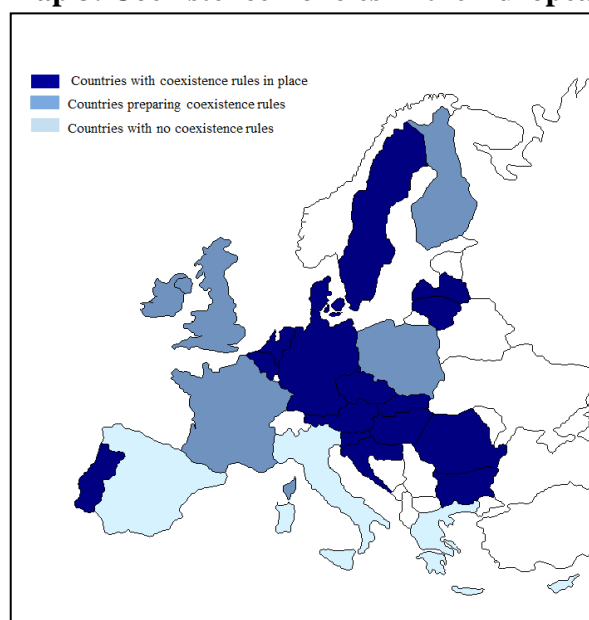
To know more about the situation in each country, see [Part C b\) Market Acceptance](#).

## **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.

**Map 3** below shows that most MS have adopted or are preparing internal coexistence rules.

### Map 3. Coexistence Policies in the European Union



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.

However, Spain transposed [Directive \(EU\) 2015/412](#) into National Law, establishing that in those cases where GE corn cultivation takes place near to borders with other MS where GE cultivation is banned, the Ministry of Agriculture decide the measures to be put in place to avoid cross-border contamination.

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

Source: FAS Offices in Europe

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 MS and a number of third countries including the United States.

**Austria, France, Germany, Hungary, and the Netherlands** have legislation and/or guidelines in place to facilitate GE-free labeling. **Sweden** has adopted legislation that explicitly prohibits such labeling. In the **UK, Spain and Portugal** there is no formal government position, however there are a number of private initiatives for GE-free labeling. **Italy** has a number of private-operator led schemes. In the **Czech Republic and Slovakia** retail buyers of meat and mainly milk products are requiring farmers’ guarantee that their livestock is not fed with GE crops. In **Poland**, public consultations are underway on a government bill for labeling of products without the use of genetically modified organisms (GMOs). “GMO-free” labeling will likely be a voluntary label, which will most likely be used by food manufacturers and processors, feed manufacturers and traders of food products.

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”<sup>14</sup> on the market is the submission of an application. This application must include a monitoring plan for environmental effects.<sup>15</sup> The duration of the monitoring plan may be different from the proposed period for the consent.

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<sup>14</sup> “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.

<sup>15</sup> Directive 2001/18/EC: Article 5 and Annex III for experimental releases, Article 13 and Annex VII for placing on the market



2. Where appropriate, the application must include a proposal for post-market monitoring regarding use as food or feed.<sup>16</sup>
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.<sup>17</sup>
4. The results of the monitoring must be made publicly available.<sup>18</sup>
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.<sup>19</sup>

- **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 points of entry or border inspection points when consignments are not accepted for import.

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

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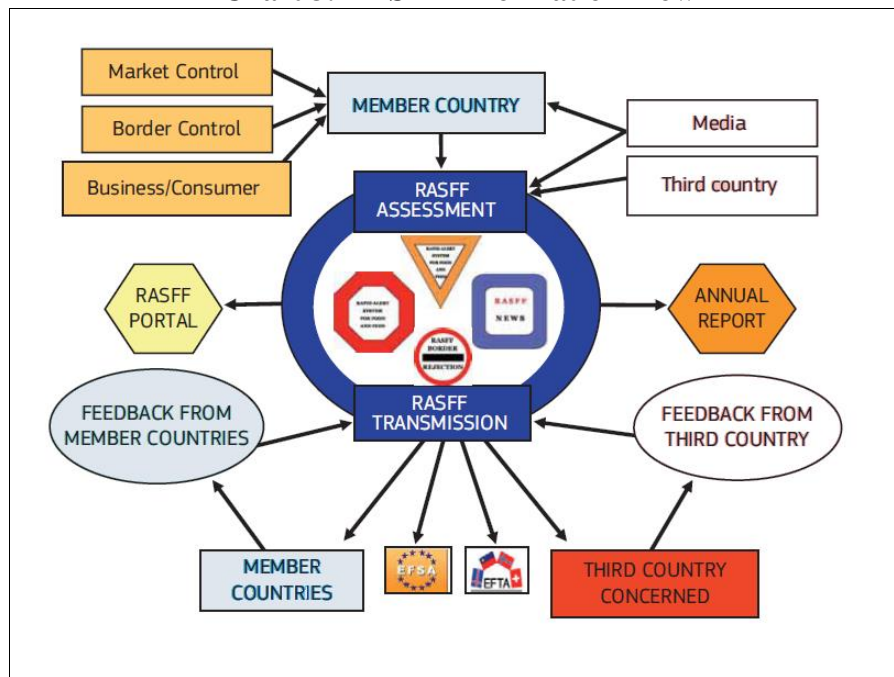
<sup>16</sup> Regulation (EC) No 1829/2003 Articles 5 and 17

<sup>17</sup> Directive 2001/18/EC Article 20

<sup>18</sup> Directive 2001/18/EC Article 20 - Regulation (EC) No 1829/2003 Article 9

<sup>19</sup> Directive 2001/18/EC Article 17 - Regulation (EC) No 1829/2003 Articles 11 and 23

**Chart 3. RASFF Information Flow**



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 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.

Additionally, there is no technical solution that defines zero for seeds. For additional information see [Part A f\) Trade Barriers](#).

## j) ADDITIONAL REGULATORY REQUIREMENTS

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

## k) INTELLECTUAL PROPERTY RIGHTS

### • Comparison Between Plant Variety Rights and Patents

Several intellectual property systems apply to inventions relating to plants in the EU. **Table 4** compares plant variety rights (also referred to as plant breeders' rights) and patents.

**Table 4. Plant Variety Rights Compared to Patents**

	Plant variety rights	Patents
<b>What does the property right cover?</b>	Plant breeders' rights cover a <b>plant variety</b> , defined by its whole genome or by a gene complex.	Patents cover a <b>technical invention</b> . 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.
<b>Conditions to be met</b>	Plant varieties can be granted variety rights provided that they are clearly distinguishable from	Patents can only be granted for inventions that are new, involve an inventive step, and are susceptible of industrial application. <sup>20</sup>

<sup>20</sup> 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

	any other variety, sufficiently uniform in their relevant characteristics, and stable.	
<b>Scope of the protection</b>	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.
<b>Exemptions</b>	<ul style="list-style-type: none"> <li>- Breeders' exemption allows free use of a protected variety for further breeding and free commercialization of new varieties (except for essentially derived ones).</li> <li>- There is an option for producers to use farm-saved seed under certain conditions.</li> </ul>	At EU level, according to the European Patent Office, a plant is protected for all its uses. <sup>21</sup>
<b>Duration</b>	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.
<b>Responsible office</b>	The Community Plant Variety Office ( <a href="#">CPVO</a> ) is responsible for the management of the plant variety rights system.	The European Patent Office ( <a href="#">EPO</a> ) examines European patent applications.
<b>Number of applications</b>	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.	<ul style="list-style-type: none"> <li>- The EPO receives between 500 and 800 applications relating to plant biotechnology each year.</li> <li>- 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).</li> <li>- On average, just under one third of applications relating to biotechnology<sup>22</sup> 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, anti-biotech NGOs or special interest groups.</li> </ul>
<b>Legal basis</b>	All the legislations in place are available on the CPVO website. They include <a href="#">Regulation (EC)</a>	The legal basis for patenting biotechnological inventions in the EU include: <ul style="list-style-type: none"> <li>- the European Patent Convention (<a href="#">EPC</a>), an</li> </ul>

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.

<sup>21</sup> This point has been controversial in some EU countries.

<sup>22</sup> all biotechnology applications (not only plant biotechnology ones)

	<p><a href="#">No 2100/94</a> on plant variety rights.</p> <p>The <a href="#">UPOV website</a> gives the text of the UPOV Convention (International Convention for the Protection of New Varieties of Plants) and the legislation of MS that has been notified in accordance with it.</p>	<p>international treaty ratified by all MS that provides the legal framework for the granting of patents by the EPO;</p> <ul style="list-style-type: none"> <li>- the <a href="#">case law</a> of the EPO boards of appeal, that rules on how to interpret the law;</li> <li>- Directive <a href="#">98/44/EC</a> 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;</li> <li>- national laws that implement EPC and Directive 98/44/EC (in place in all MS since 2007, see USDA FAS country reports).</li> </ul>
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Source: FAS Offices in the European Union

- **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](#)) 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 July 2017 the European Patent Office ([EPO](#)) published in their Official Journal, a Decision to amend the Implementing Regulations to the European Patent Convention, establishing that European patents shall not be granted in respect of plants or animals exclusively obtained by means of an 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).

- **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 CBP 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 SANTE.

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."<sup>23</sup>

## **m) INTERNATIONAL TREATIES/FORUMS**

Individual MS generally express similar position on biotechnology in international forums.

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

All MS 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 SANTE is the IPPC official contact point in the EU. The EU has not taken any position related to plant biotechnology in the IPPC recently.

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<sup>23</sup> See ESA's [press release](#)

## n) RELATED ISSUES

### • Risk Assessment and Communication of Evidence

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:

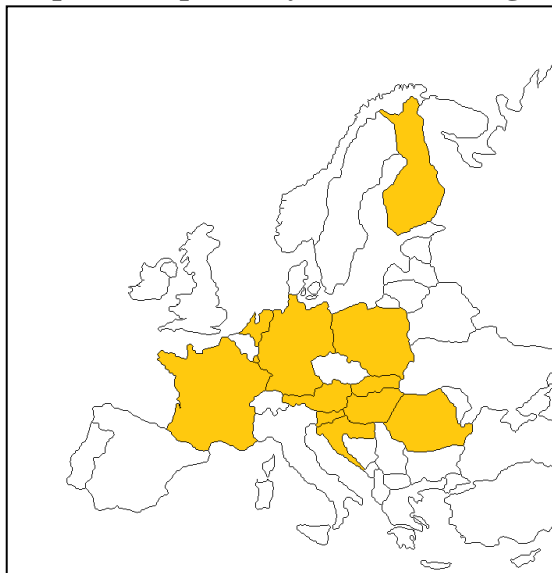
- There is no indication that the performance of 90-day feeding studies (following OECD or EFSA guidelines and current practice) with whole food or feed would provide additional information on the safety of maize MON810.
- Alternative in vitro methods are very promising but cannot yet replace animal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

### • European Soy Declaration:

#### Map 4. European Soy Declaration Signatories



On July, 17, 2017, on the sidelines of the Agriculture and Fisheries Council in Brussels, twelve MS, signed the [European Soy Declaration](#) which aims to boost soy production in the EU. While not an EU binding policy, Ministers of Agriculture of Austria, Croatia, Finland, France, Germany, Hungary, Luxembourg, the Netherlands, Poland, Romania, Slovenia and Slovakia signed the declaration and agreed to voluntarily implement the provision of this declaration. The declaration also includes a provision on GMO-free feed, whereby signatories “support the further development of markets for sustainably cultivated non-GMO soybeans and soybean products.” It also endorses product labeling systems similar to [Danube Soya](#) and [Europe Soya](#).

Source: FAS Offices in the European Union

- **GE-free Zones:**

Aside from the cultivation opt out and cultivation bans in place, some EU municipalities/provinces/regions/federal states have declared themselves GE free zones and are members of the “[European Network of GMO-Free Regions](#).” These zones are created by political declaration. Most of these areas are located in regions where the type of agricultural production cannot benefit from the current GE events available for cultivation in the EU. There is no legal enforcement mechanism connected to this declarations that would prevent a farmer from growing GE plants in these zones unless they are under the umbrella of a cultivation ban or the territory has officially opted out from cultivation.

- **Court of Justice of the European Union’s Judgement on Adoption of Emergency Measures**

On September 13, 2017 the Court of Justice of the European Union (CJEU) [found](#) that MS may not adopt emergency measures regarding GE food and feed unless it is evident that there is a serious risk to health or the environment (Case C-111/16 *Giorgio Fidenato and Others*). Consequently, the CJEU ruled in favor of three Italian farmers who were prosecuted for having cultivated the EU-approved GE maize MON 810 in breach of a national decree issued July 12, 2013 prohibiting its cultivation in the Italian territory.

More specifically, the judgement refers to the Italian Government’s request to the EC to adopt emergency measures to prohibit the cultivation of MON 810 corn in light of new scientific studies carried out by two Italian research institutes. In the event, the EC concluded that there was no new science-based evidence to support the Italian Government’s request. Despite this, the Italian Government issued a decree prohibiting the cultivation of MON 810 on Italian territory.

## **PART C – MARKETING**

### **a) PUBLIC/PRIVATE OPINIONS**

In the EU, different types of **civil society organizations** have protested agricultural biotechnology since it was first introduced in the 1990s. These groups 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. **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.

**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. A majority of the EU farmers support the use of GE varieties due to the proven yield gains and lower input use. The main factors that prevent them from doing so currently are:

- (a) There is only one GE crop authorized for cultivation in the EU, other farmers would grow GE crops if other traits more adapted to their agronomic conditions were made available.
- (b) Eighteen MS have implemented a ban on it; some farmers in these countries would grow GE crops if they were allowed to
- (c) The threat of protests or destruction by activists, given that public field registers detailing the location of commercially grown GE crops are compulsory in most MS, with the notable exception of Spain.
- (d) In some EU MS, there is an increased interest in non-GE products, retail requirements or public/private initiatives such as the EU Soy Declaration discourage the cultivation and marketing of GE crops.
- (e) Farmers in some EU MS are inclined to supply GE-free market niches at a premium value rather than competing on volume.

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. The EU policy on biotechnology represents a challenge for commodity trading companies, as it limits their sourcing options, and increases the risk in their operations with those countries where not-yet approved events are grown.



**Public opinion** generally expresses distrust of private international biotech companies. For nearly two decades, European consumers have been exposed to consistent negative messaging from anti-biotech 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. 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.

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. 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.

The EU’s **Food industry** adapts 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, food manufacturers continue to reformulate in order to avoid the “Contains GMOs” claim. As always, the situation varies across countries, and in the United Kingdom and Spain there are increasing examples of GE-labeled imported food products that achieve sales success.

Most food **retailers**, especially major supermarkets, promote themselves as carrying only non-GE products. There are several initiatives in EU MS to differentiate themselves at the retail level by using voluntary GE-free labels. For instance, in the Czech Republic and Slovakia retail buyers of meat and mainly milk products are requiring farmers’ guarantee that their livestock is not fed with GE crops. Some retailers 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.



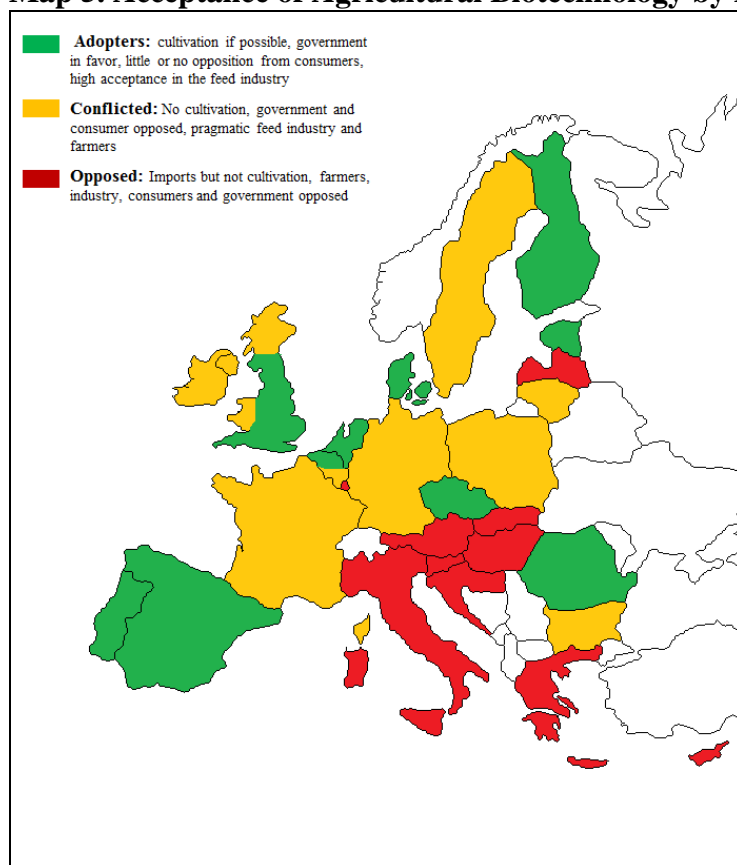
## b) MARKET ACCEPTANCE/STUDIES

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

There are three major categories of MS depending on their acceptance of plant biotechnology, as illustrated in **Map 5** 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 growers of Bt corn (such as **Spain and Portugal**) and the **Czech Republic**, which no longer grows GE corn due to marketing constraints, despite the government’s support of science based biotechnology decision making. Within this group we include other MS that would possibly produce GE crops if other traits more suitable for their conditions were approved for cultivation in the EU and/or have a significant dependency on imported feedstuffs (**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. The **United Kingdom** departure from the EU is scheduled for March 2019 (Brexit) will reduce the size of this pro innovation group of countries.
- In the “**Conflicted**” MS, most scientists, farmers, and the feed industry are willing to adopt the technology, but consumers and governments, influenced by anti-biotech groups, reject it. For instance, **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, when the feed industry decided not to use GE ingredients. 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**” MS, most stakeholders and policy makers reject the technology. Most of these countries are located in Central and South Europe (**Austria, Croatia, Cyprus, Greece, Hungary, Italy, Malta, and Slovenia**). **Latvia and Luxembourg** are also Opposed MS. In these countries, the government generally supports organic agriculture and geographical indicators, however, a minority of farmers in these countries are supportive of growing biotech crops. Beginning in 2017, **Slovakia** is in the “Opposed” group due to a political shift.

## Map 5. Acceptance of Agricultural Biotechnology by Member State – 2017



Source: FAS offices in the European Union

- **A debate on IBs is emerging in some EU countries**

MS can be arranged into four 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. On request of the Cibus Company, in 2014, the **Spain's** National Biosafety Commission (CNB) studied Cibus rapeseed (an herbicide tolerant rapeseed obtained through oligonucleotide-mediated mutagenesis) and concluded that the Cibus Rapeseed should be excluded from the scope of Directive 2001/18. In the **Netherlands**, the government sees innovative biotechnologies as an important propagation tool for the domestic plant breeding sector (See [Dutch Proposal to Legislate NBTs](#)). However, there is some opposition from anti-biotech groups in these countries. In **Italy**, the Minister for Agriculture advocated for innovation involving cisgenesis and genome editing, recently stating that these techniques are a different from transgenesis, and consequently they should not be regulated at such. The **Belgian** Region of Flanders has a small but innovative plant breeding sector that has focused on IBs because of the cumbersome regulations for developing and approving GE crops.

- Several MS can be seen as conflicted in that their position is not yet clear, but pro and con forces are active in the country. The **Czech Republic, France and Germany** are in this situation. In France, The Ministry of Agriculture and the Ministry of Environment have conflicting views on how innovative biotechnologies should be regulated. Both are waiting for the answers of the European Court of Justice to the questions asked by the French Supreme Court in October 2016. Research on IBs is being carried out in France, and the French Parliament released a pro-science report on innovative biotechnologies. At the same time, anti-biotech groups have conducted several actions against innovative biotechnologies. In 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 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, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovenia, Slovakia, and Sweden.**

- **Studies**

**Table 5** references relevant studies on the perception of GE plants and plant products in the EU.

**Table 5. Studies on GE plants and products perception in the EU**

<b>Report</b>	<b>Comment</b>
<a href="#">Eurobarometer Survey on Biotechnology</a>	The most recent Eurobarometer survey about biotechnology by the European Commission (2010)
<a href="#">Europeans and Biotechnology in 2010, Winds of Change?</a>	A report to the European Commission’s Directorate General for Research
<a href="#">Eurobarometer Survey on Food-Related Risks</a>	The most recent Eurobarometer survey about consumers’ perceptions of food-related risks by the European Commission (2010)
<a href="#">Comparing Perceptions of Biotechnology in Fresh versus Processed Foods</a>	A 2013 cross-cultural study carried out by the Food and Resource Economics Department from the University of Florida

Source: FAS Offices in the European Union

## CHAPTER 2 – ANIMAL BIOTECHNOLOGY<sup>24</sup>

### PART D – PRODUCTION AND TRADE

#### a) PRODUCT DEVELOPMENT

Basic research with GE animals is carried out by most MS, including: Austria, Belgium, the Czech Republic, Denmark, France, Germany, Hungary, Italy, the Netherlands, Poland, Slovakia, Spain, and the United Kingdom.

Most of these countries focus their efforts on developing 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 a laboratory environment.

Some of these countries (namely Poland, Hungary the United Kingdom and Spain) also use animal biotechnology to carry out research for agricultural purposes:

- to improve animal breeding (high yielding sheep, dairy cows and swine genomics, poultry resistance to avian flu).
- to study the immunization of livestock animals
- to study the molecular processes of reproduction in farm animals.
- For biological control of agricultural pests

GE animals used in basic, advanced research or [commercial production](#) in different EU MS include: Flies, nematodes, moths, tropical frogs, tropical fish, mice, rats, hens, cats, rabbits, goats, sheep, cows and horses.

In **Poland**, the Department of Animal Reproduction and Biotechnology, ascribed to the National Institute of Animal Breeding, conducts scientific and experimental studies in embryo cloning and somatic cell cloning of animals (pigs, rabbits, goats, cattle, cats, horses) as well as animal transgenesis.

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<sup>24</sup> Animal genetic engineering and genome editing result in the modification of an animal's DNA to introduce new traits and change one of more characteristic of the species. Animal cloning is an assisted reproductive technology and does not modify the animal's DNA. Cloning is therefore different from the genetic engineering of animals (both in the science and often in the regulation of the technology and /or products derived from it). Researchers and industry frequently use cloning when creating animals via other animal biotechnologies. For this reason, cloning is included in this report.

In **Hungary**, the [Agricultural Biotechnology Institute](#) of the [NARIC](#) has three research groups working on applied embryology and stem cell research, ruminant genome and rabbit genome biology.

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 medfly to protect fruits, nuts and vegetables from infestation, GE pink bollworm to improve cotton pest control, 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.

In **Spain**, in 2017 the Public Agricultural Research Institute (INIA) has notified Spain's National Biosafety Commission (CNB), as the mandatory prior step to conduct GE confined research, their activities to study the molecular processes of reproduction on GE rabbits, goats and sheep. Research on animal genome editing is being carried out in Spain by public Institutions such as the National Center for Biotechnology (CNB). Basic research with CRISPR-Cas9 in mice has been carried out since 2013. Additional information can be found in the [link](#).

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

## **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. In the policy paper of April 4, 2014, the Dutch Cabinet stated that the application of biotechnology in animal breeding for recreation and sport is prohibited, but permitted for biomedical purposes (see [4/11/2014 Report - Dutch Government Reveals Its Biotech Policy](#) for more information).

In September 2017, the British Company Oxitec announced they will build a new mosquito egg production unit. For additional details see [Oxitec Press Release](#).

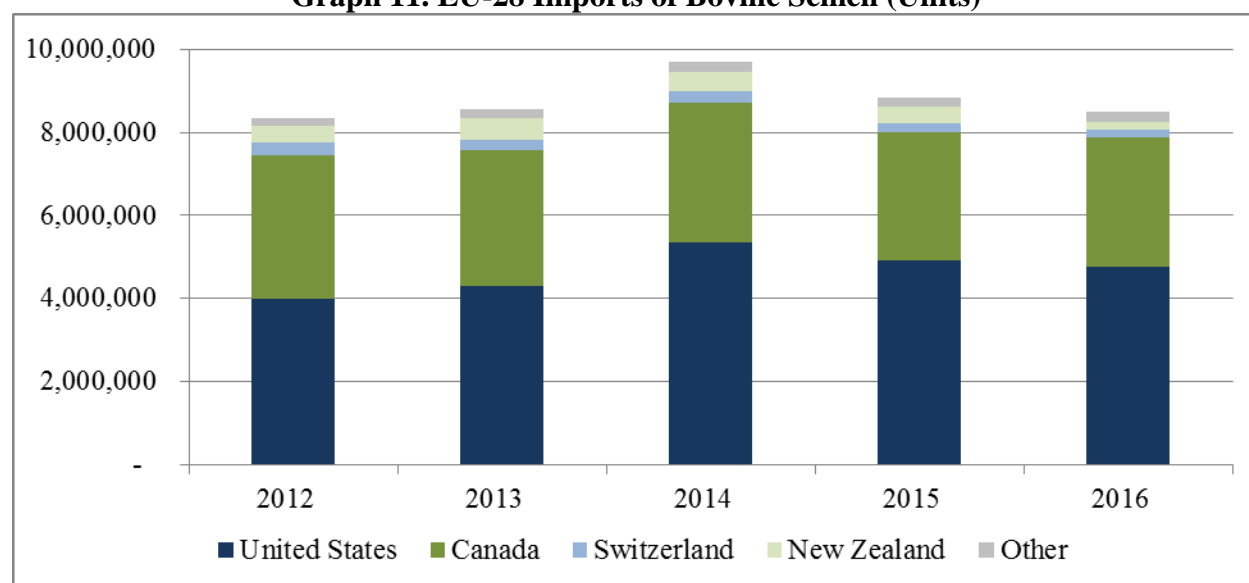
### c) EXPORTS

The UK exports GE mosquito eggs for development and subsequent release in Brazil and the Cayman Islands. This trade is expected to increase with the announcement of a new mosquito egg production unit. See [Commercial Production](#) Section above.

### d) IMPORTS

The EU has most likely imported semen and embryos from cloned animals. The specific quantity of these imports is not available. The United States is largest extra EU-28 supplier of bovine semen, with an average market share of over 50 percent of the EU's bovine semen imports, followed by Canada, which accounts for nearly 40 percent of the import market in quantity.

**Graph 11. EU-28 Imports of Bovine Semen (Units)**



Source: FAS based on Global Trade Atlas data. (HS Code 051110)

### e) 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 Authorities

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.

Additional information on GE animals, relevant documents and reports can be found in [EFSA's site](#).

## **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 BIOTECHNOLOGIES** <sup>25</sup>

There have been no developments or legislative activities on animals produced through innovative biotechnologies (also called “new breeding techniques”) at the EU level recently beyond what is reported under [Part B e\) Innovative Biotechnologies](#).

However, some MS have launched internal debates. For instance, on March 29, 2017, the French Parliamentary Office for the Evaluation of Scientific and Technological Choices (Office parlementaire d'évaluation des choix scientifiques et technologiques, OPECST) released a draft pro-science report on innovative biotechnologies. This report recommends supporting research on particular fields and to carry out amendments in some international regulations. For additional information see [France - Annual Biotechnology Report -2017](#)

## **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](#)).

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

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<sup>25</sup> “Innovative biotechnologies” is a synonym of New Breeding Techniques (NBTs). It excludes transgenesis.



- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and animals resulting from such processes<sup>26</sup>

## e) INTERNATIONAL TREATIES/FORUMS

The EU is member of the Codex Alimentarius along with its 28 MS. The Codex has working groups and develops guidelines on biotech animals. For example it has developed guidelines for the conduct of food safety assessment of foods derived from GE animals. The EU and its MS draw up EU position papers on the issues discussed in the Codex.

The 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 MS.

Twenty-two<sup>27</sup> out of the current 28 MS 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

The EU's livestock breeding interest has showed a limited interest in cloning so far, and does not favor the commercialization of GE animals and clones for food or agricultural purposes. However, in the some pragmatic MS, the EU livestock industry has better perception and interest in animal genomics and marker assisted selection for animal breeding.

There is limited interest in animal biotechnology among the general public although, if asked, people are generally more hostile to it than to plant biotechnology, due to ethical concerns. Media varies among the different MS. Coverage occasionally includes reports on decisions taken at the EU level, in the United States or Canada regarding to regulation or marketing of such products (*e.g.* GE salmon).

Opinions vary with the intended use. 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.”

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<sup>26</sup> Source: [European Patent Office](#)

<sup>27</sup> Non-OECD EU MS include: Bulgaria, Croatia, Cyprus, Lithuania, Malta, and Romania

Food use is widely rejected; medical applications are the most accepted. The use of animals for medical research aimed at finding cures for diseases or the recovery of endangered species is generally regarded favorably. Public awareness of biotech insects is low.

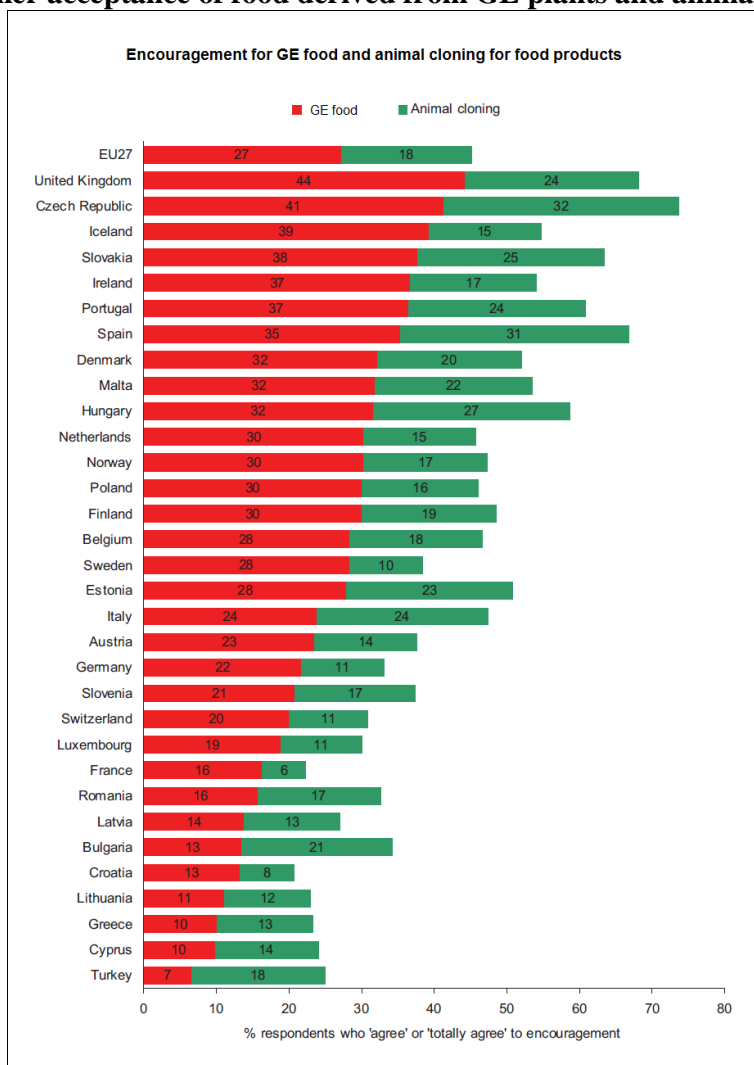
There are a number of organizations actively campaigning against the technologies, including animal welfare NGOs, local food groups, and biodiversity activists. .

#### **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. 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.” **Graph 12** below reflects the combination of consumer acceptance of food derived from GE plants and animal cloning in each MS.

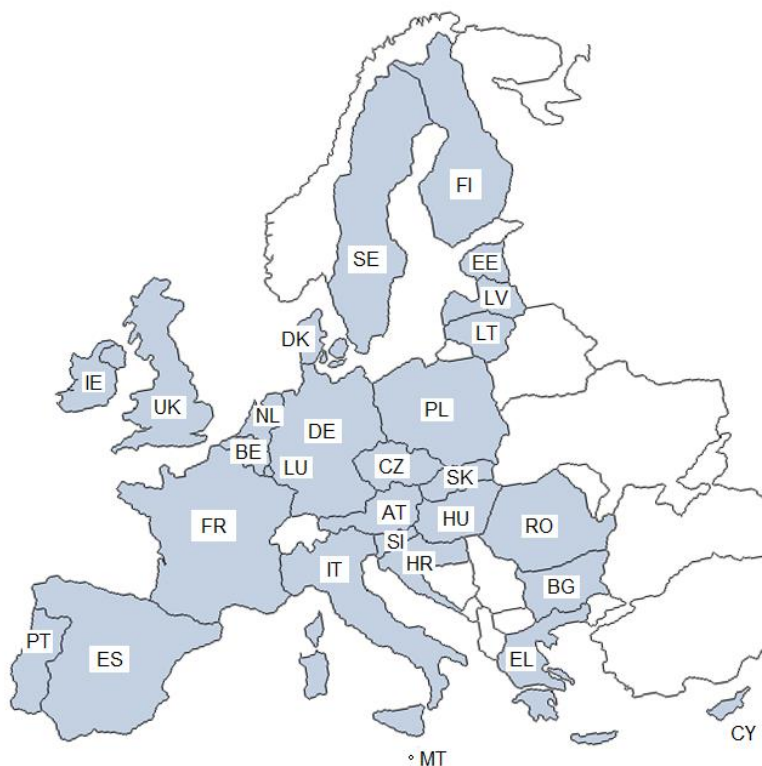
**Graph 12. Consumer acceptance of food derived from GE plants and animal cloning by MS**



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

## ANNEX 1 – 28 MS OF THE EUROPEAN UNION

### 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 <sup>28</sup>

<sup>28</sup> The UK's departure from the EU is scheduled for March 2019 (Brexit).

## **ANNEX 2 – RELATED REPORTS**

USDA Foreign Agricultural Service writes comprehensive reports about individual EU MS. 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](#).