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Report Highlights:
The European Union's (EU) complex and lengthy policy framework for biotechnology creates a challenging environment for research and limits access to innovative tools for EU farmers. The EU produces very few genetically engineered (GE) crops but it imports large amounts of GE feed. In July 2018, the European Court of Justice issued its judgment that organisms created through innovative biotechnologies should be regulated as GE organisms in the EU. Scientists and the main farm organizations warn that this judgment could harm research and agriculture in the EU. This judgment also has potential to create trade disruptions in the future.

Executive Summary:

Commercial cultivation of GE crops in the EU is limited to 1.5 percent of the EU's corn area (130,000 hectares of GE corn in Spain and Portugal). The single variety authorized for cultivation is banned in nineteen Member States (MS). The threat of destruction by activists and difficult marketing conditions also discourage the cultivation of GE crops. The EU does not export any GE products but it imports more than 30 million metric tons (MT) of soybean products, 10 to 15 million MT of corn products, and 2.5 to 4.5 million MT of rapeseed products per year, mainly for feed. The share of GE products of total imports is estimated at 90 to 95 percent for soybean products, 20 to 25 percent for corn, and less than 20 percent for rapeseed. The EU's main suppliers are Argentina, Brazil and the United States. The United States is a major supplier of soybeans and corn processing by-products to the EU and a relatively minor supplier of soybean meal and corn. 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's policy framework for biotechnology developed under pressure from anti-biotech activists close to the antiglobalization movement creates an unnecessary burden that does not improve consumer protection and does not take into account recent scientific knowledge. The EU's unfavorable political and regulatory environments restrict public and private research in biotechnology, impede commercial production of biotech plants, and create trade disruptions. While the EU still conducts some research, most programs are limited to basic research. The private sector's interest in developing varieties of GE plants suitable for cultivation in the EU has waned. The plant-breeding sector was hopeful that innovative biotechnologies (also called "new breeding techniques") could help revive plant biotechnology in the EU. However, in July 2018, the Court of Justice of the European Union (CJEU) judged that organisms created through these techniques should be subject to the EU's outdated and lengthy policy framework. The vast majority of scientists are deeply concerned that this judgment will have significant negative consequences for innovation in the EU. In addition, professionals in the agricultural sector warn about its potential economic impact. The general public is not aware of agricultural applications of innovative biotechnologies.

Stakeholders that defend agricultural biotechnology at EU level are scientists and professionals in the agricultural sector, including farmers, seed companies, and representatives of the feed supply chain. For more than two decades, European consumers have been exposed to consistent negative messaging from anti-biotech groups. As a result, consumer attitudes towards GE products are mostly negative. However, the situation varies across countries, and in the United Kingdom and Spain there are examples of GE-labeled imported food products that achieve sales success. The EU's food industry and retailers adapt their product offerings to meet consumer perceptions. There are more and more initiatives to differentiate non-GE food products at the retail level by using voluntary GE-free labels. Several major supermarkets promote themselves as carrying only non-GE products.

Regarding animal biotechnology, the EU is active primarily in basic medical research. Some MS also conduct research for agricultural purposes, focusing their efforts on improving livestock breeding. No foods are produced from animal clones or GE animals; acceptance is low due to ethical and animal welfare concerns. Commercial cloning in the EU is limited to elite horses.

Acronyms used in this report are the following:

CGFM	Corn Gluten Feed and Meal
CJEU	Court of Justice of the European Union
DG SANTE	Directorate General for Health and Human Safety
DDGS	Distiller's Dried Grains with Solubles
EC	European Commission
EFSA	European Food Safety Authority
ENVI	Environment, Public Health and Food Safety Committee of the European Parliament
EP	European Parliament
ERA	Environmental Risk Assessment
EU	European Union
FAS	Foreign Agricultural Service of the United States Department of Agriculture
GAIN	Global Agricultural Information Network of the Foreign Agricultural Service
GE	Genetically Engineered (official terminology used by the U.S government)
GMO	Genetically Modified Organism (official terminology used by the EU, and used here when quoting specific regulatory language)
JRC	Joint Research Center of the European Commission
LLP	Low Level Presence
MS	Member States of the European Union
MT	Metric Ton
NBTs	New Breeding Techniques
OECD	Organization for Economic Cooperation and Development
PPP	Public-Private Partnership
RASFF	Rapid Alert System for Food and Feed
PAFF	Standing Committee on Plants, Animals, Food and Feed
UK	United Kingdom

Glossary:

"Genetic Engineering" means transgenesis.

"Innovative biotechnologies" is used here as a synonym for the European term "New Breeding Techniques" (NBTs) and is generally referred to as genome editing. It excludes traditional genetic engineering (transgenesis), known in Europe as genetically modified organisms (GMOs).

Table of Contents:

CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

A significant number of the internationally recognized public and private researchers in plant biotechnology are European. However, this research is not likely to lead to the commercialization in the EU of new biotech plants in the short term due to unfavorable political and regulatory environments:

- Several major **private developers** including BASF, Bayer, KWS, and Limagrain are European. However, the private sector's interest in developing varieties of GE plants suitable for cultivation in the European Union (EU) has waned. Repeated vandalism of test plots by activists, together with the uncertainty and delays of the EU approval process, makes genetic engineering an unattractive investment. EU companies have thus concentrated their efforts on non-European markets, and most of their research sites in plant biotechnology are now outside Europe. Several major private European developers have moved their research and development operations to the United States (Bayer in 2004, BASF in 2012, and KWS opened its new research center in the United States in 2015). The biotech industry's recent consolidation 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 coming 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. An international consortium including several EU research institutions and the United States Department of Agriculture's Agricultural Research Service (USDA ARS) developed a GE 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 for the possible commercialization of this tree.
    - As for **innovative biotechnologies**, several EU countries including Belgium, the Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Poland, Portugal, Spain, and the United Kingdom are using these techniques to develop new plant varieties. For example, in Belgium, a research consortium is developing cisgenic late blight resistant Bintje potatoes. In the Netherlands, Wageningen University conducts research on cisgenic potatoes and apples. However, these plants are unlikely to be commercialized in the EU in the coming years due to the uncertain regulatory environment, including the July 2018 judgment of the Court of Justice of the European Union. For additional information, please see Part B) Policy e) Innovative Biotechnologies.

- **Public-private partnerships** (PPPs): The EU has several PPPs in plant biotechnology. Most of them focus on industrial rather than agricultural applications. For instance, 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 ($4.2 billion, 25 percent of which is publicly funded) in research and innovation efforts between 2014 and 2020 with the purpose of replacing at least 30 percent of oil-based chemicals and materials with bio-based and biodegradable ones by 2030. Biotechnology is one of the fields of research covered by this PPP.

As for **medical applications of plant biotechnology**, some laboratory research is being conducted in the EU. In the laboratory, GE plants and plant cells are used to develop proteins of pharmaceutical interest. 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).

Additional examples of plant biotechnology research carried out by EU countries can be found in Part B) Policy d) Field Testing and individual country reports listed in Annex 2

b) COMMERCIAL PRODUCTION

- **Only two MS cultivate Bt corn in 2018.**

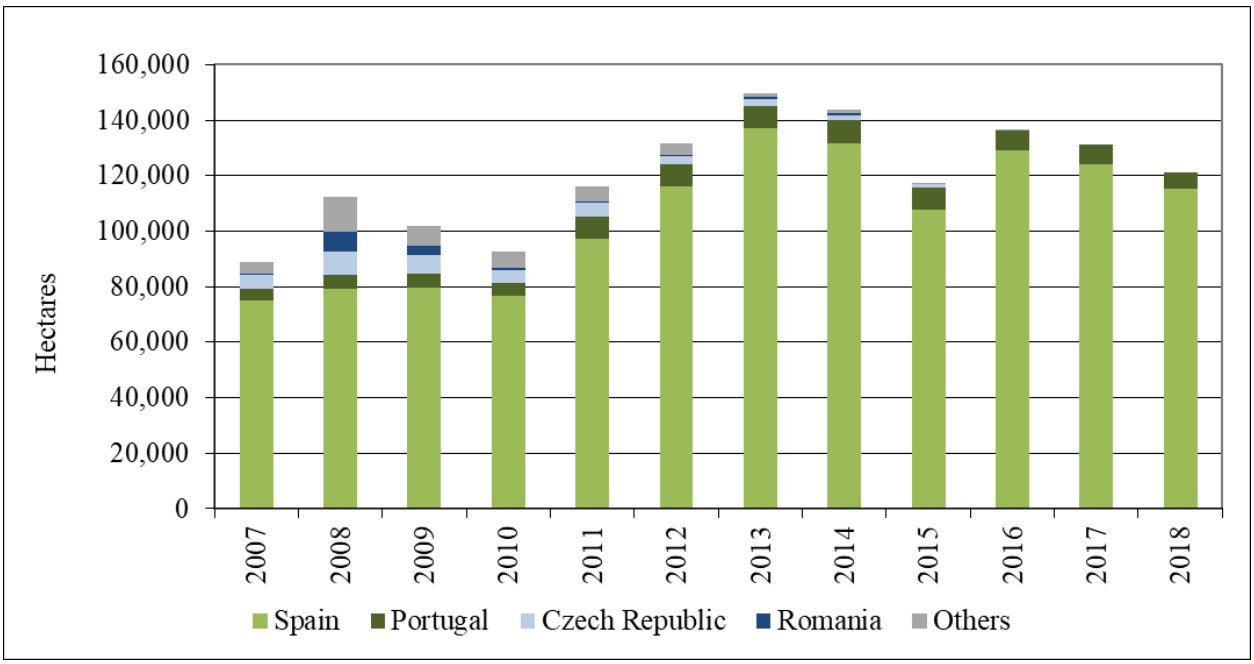
The only GE plant approved for cultivation in the EU is MON810 corn. It is a Bacillus thuringensis (Bt) corn resistant to the European corn borer (a pest).

Graph 1 and Table 1 below show how in 2018, the area planted in Bt corn in the EU decreased by 8 percent to 120,979 hectares. **Spain** represents 95 percent of the total area and **Portugal** the remaining 5 percent. MON810 is grown in areas were the corn borer represents a problem.

Bt corn produced in the EU is used locally as animal feed. 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 led some farmers to opt for conventional corn varieties.

Since 2017, the **Czech Republic** and **Slovakia** stopped cultivating Bt corn. Although the Czech government has a science-based approach to biotechnology, farmers stopped growing GE corn due to the difficulties marketing GE products. Domestic production of GE corn in the Czech Republic was used for biogas production and on-farm cattle feeding. In both the Czech Republic and Slovakia, retail buyers push for GE-free products and for products from animals that were not fed GE feed.

Graph 1. Bt Corn Area in the EU



Source: FAS offices in the EU

Table 1. Bt Corn Area in the EU

in hectares	2013	2014	2015	2016 (updated)	2017 (updated)	2018 (estimate)
Spain	136,962	131,538	107,749	129,081	124,197	115,246
Portugal	8,202	8,542	8,017	7,069	7,036	5,733
Czech Republic	2,560	1,754	997	75	0	0
Romania	834	771	2.5	0	0	0
Slovakia	100	411	400	122	0	0
Total Bt corn area	131,463	148,658	143,016	117,166	136,337	131,263
Total corn area planted in the EU	9,747,000	9,557,000	9,252,000	8,566,000	8,372,000	8,250,000
Share of Bt corn in total corn area	1.53%	1.50%	1.27%	1.59%	1.57%	1.47%

Source: FAS offices in the EU

- **Nineteen MS have "opted out" of GE crops cultivation since 2015.**

Since 2015, nineteen EU countries have "opted out" of GE crops cultivation for all or part of their territories under Directive (EU) 2015/412. This regulation, also called the "opt-out" Directive, allows any MS to "opt out" of cultivating an approved GE crop for socio-economic as opposed to scientific

reasons. The rationale behind introducing that law was to prevent MS from invoking the safeguard clause by using "spurious science." 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 MS votes on cultivation files during the authorization process. For more information on this Directive, please see EU-28 Biotechnology Annual Report 2017.

The table and the map below provide an overview of the situation regarding the implementation of the opt-out directive by the MS.

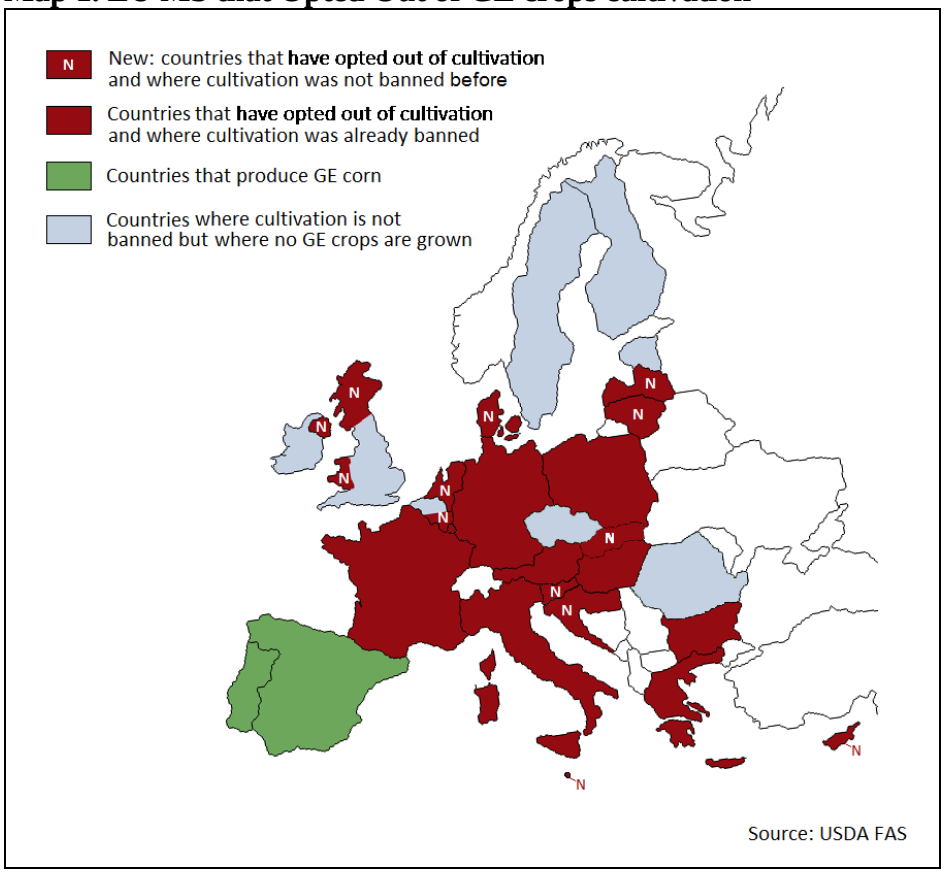
Table 2. Cultivation Bans in the EU

Situation	Countries and regions
N [N = New] Nine countries and four regions where cultivation was not banned before have opted out of GE corn cultivation under the 2015 Directive. This decision did not lead to a change on farms as none of the countries that opted out in 2015 cultivated GE crops for various reasons, including the fact that is not well suited to local growing conditions, the threat of protests, and administrative constraints.	- Nine countries: Croatia, Cyprus, Denmark,* Latvia, Lithuania, Malta, the Netherlands,* Slovenia, Slovakia* - 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,* and Poland
Two countries grow GE corn in 2018.	Spain, Portugal
In the other countries and regions, cultivation is still allowed but no GE corn is grown for various reasons, including the fact that is not well suited to local growing conditions, the threat of protests, and administrative burden.	- Six countries: Ireland, Romania, Sweden, Finland, Estonia and the Czech Republic - Two regions: Flanders in Belgium, England in the United Kingdom

* *Notes:*

- *Denmark and Luxembourg have only opted out of cultivation for MON810 and three from the seven varieties of corn that were in the pipeline at that time*
- *In the Netherlands, the government is developing its own assessment framework for GE crops cultivation. As a result of the assessment, if cultivation of a crop is allowed in the Netherlands, the government will lift any geographical restriction that may be in place.*
- *Slovakia is currently in the process of updating their legislation to opt out under Directive 2015/412.*
- *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.*

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



For further explanation on cultivation trends by MS, see USDA's Foreign Agricultural Service (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

Every year, the EU imports:

- More than 30 million MT of soybeans and soybean meal (including both GE and non-GE products);

- 10 to 15 million MT of corn and corn-processing byproducts (GE and non-GE);
- 2.5 to 4.5 million MT of rapeseed and rapeseed meal (GE and non-GE).

The share of EU imported GE products is estimated at 90 to 95 percent for soybean products, 20 to 25 percent for corn, and less than 20 percent for rapeseed.

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.

Table 3. Share of GE Crops in Total Production in the EU's Main Supplier Countries

Soy	
Argentina	100%
Brazil	97%
Canada	85%
Paraguay	96%
United States	94%
Rapeseed / Canola	
Australia	24%
Canada	95%
Russia	0%
Ukraine	estimated at 10 - 25% of exports
Corn	
Brazil	89%
Canada	100%
Russia	0%
Serbia	0%
Ukraine	estimated at 1 - 3% of exports
United States	92%
Vietnam	3%

Source: ISAAA and FAS GAIN reports

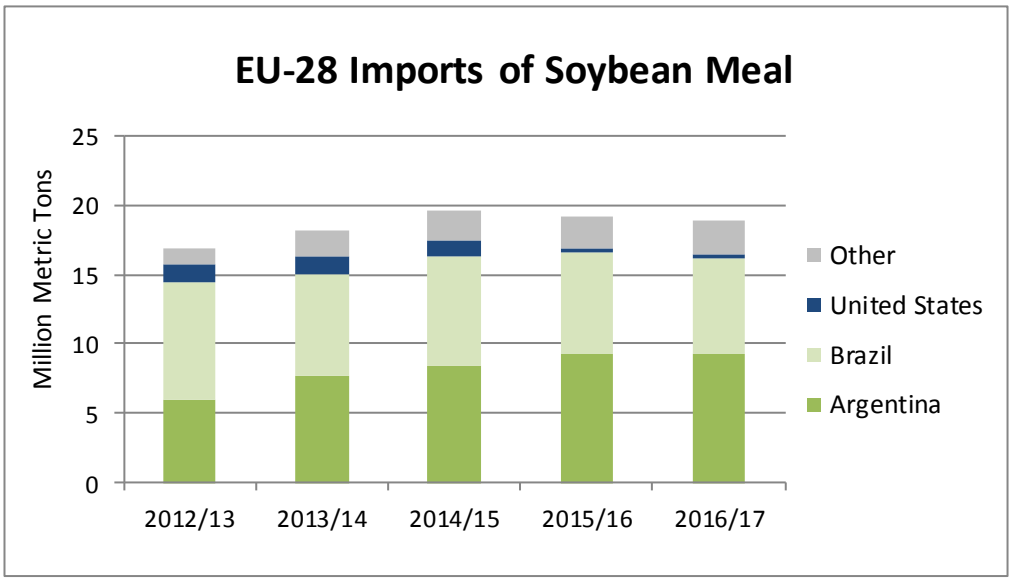
- **The EU imports more than 30 million MT of soybean products every year.**

The EU is protein deficient and does not produce enough to meet demand due to several reasons, including climate conditions. The EU needs to import more than 30 million MT of soybeans and soybean meal every year, mainly for animal feed. European non-GE soybean production is expected to increase in the coming years, but it remains marginal relative to imports.

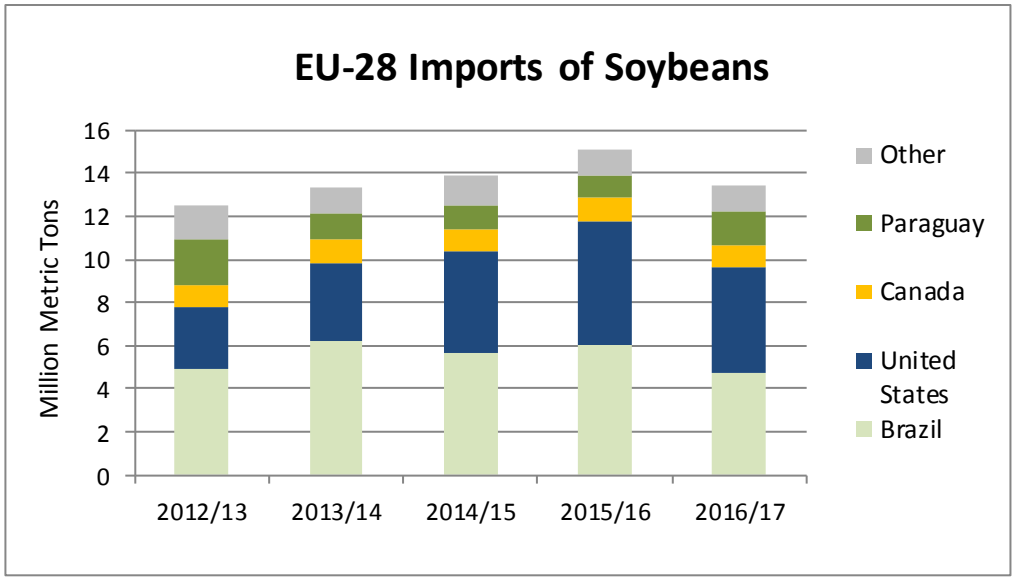
In the past five years, soybean meal imports amounted to 18.5 million MT and soybean imports to 13.7 million MT per year on average (see graphs below). The EU imports around 65 percent of the soybean meal it consumes. The rest is produced by domestic crushing facilities; more than 85 percent of the soybeans crushed in these facilities are imported.

The EU's leading suppliers by volume are Argentina, Brazil, and the United States. The largest users of

soybean meal (Germany, Spain, France, Benelux, and Italy) are also the main producers of livestock and poultry. They represent 65 percent of total EU consumption.



Source: FAS based on Global Trade Atlas data



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 10 to 15 percent of total meal consumption. Non-GE soybean meal demand in the EU 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 soybean products.**

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 production remains minor relative to total animal feed demand. EU soybean production is expected to be around 2.7 million MT in 2018/19, which is low compared to the more than 30 million MT of soybean products imported every year.

In 2014, the European Focus Group on protein crops published its final report.[1] 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 crop 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.

Several EU countries subsidize local non-GE protein production:

- 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. These strategies include incentives such as providing coupled supports to farmers or considering protein crops as nitrogen fixing crop (Ecologic Focus Areas) for greening compliance under the 2014-2020 Common Agricultural Policy (CAP).
- The Danube Soya Association, a non-governmental association supported by the Austrian government, promotes the production of non-GE 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.
- Since July 2017, thirteen MS have signed the European Soy Declaration, which aims to boost soybean production in the EU. For additional information, please see Part B) Policy n) Related Issues.

For more information, please see the European Commission's website.

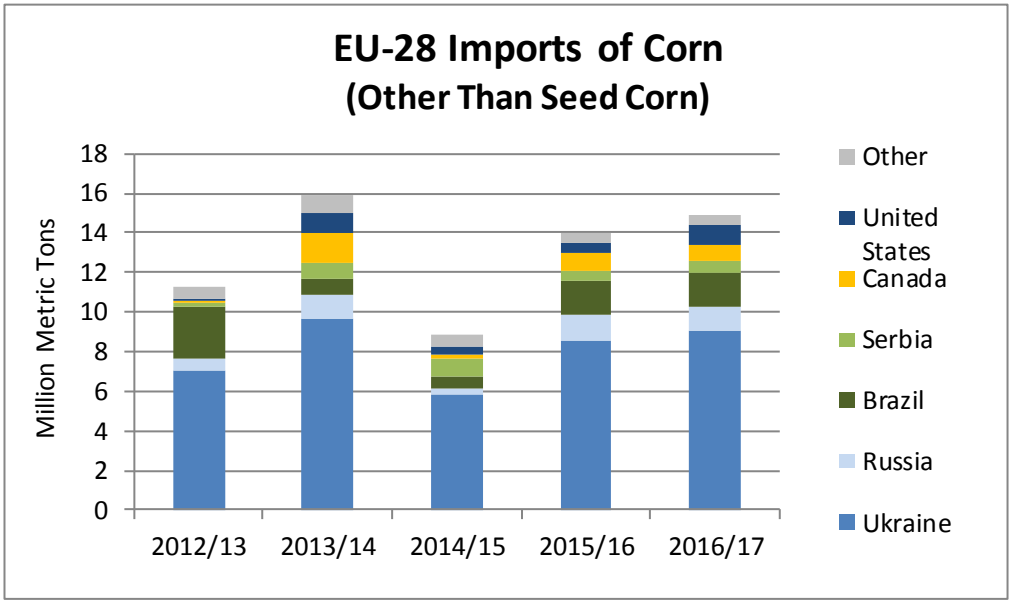
- **The EU imports 10 to 15 million MT of corn per year on average.**

The EU imports about 10 percent of the corn it consumes. The share of GE corn out of total corn imports is estimated to be just over 20 percent. The largest importers of corn (Spain, the Benelux, Italy and Portugal) have large livestock and poultry sectors, but are limited in domestic grain production.[2]

In the past five years, Ukraine has been the major supplier of corn to the EU; this country accounted for 61 percent of the EU's corn imports in 2016/17. No production of GE crops has been officially allowed

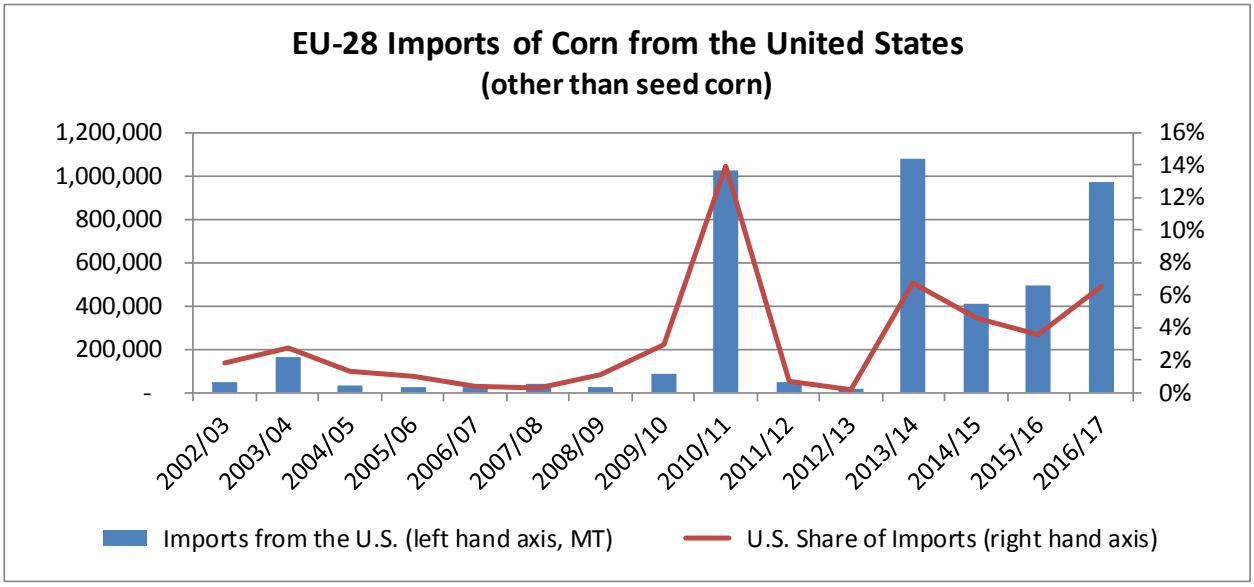
[1] This Focus Group is part of the European Innovation Partnership (EIP) "Agricultural Productivity and Sustainability," one of five EIPs which have been launched by the EC in a bid to step up innovation efforts.
[2] Additional information on EU's grain market can be found in the EU-28 Grain and Feed GAIN Annual Report 2018.

in the country, but experts estimate that one to three percent of Ukraine's exports of corn are GE.



Source: FAS based on Global Trade Atlas data

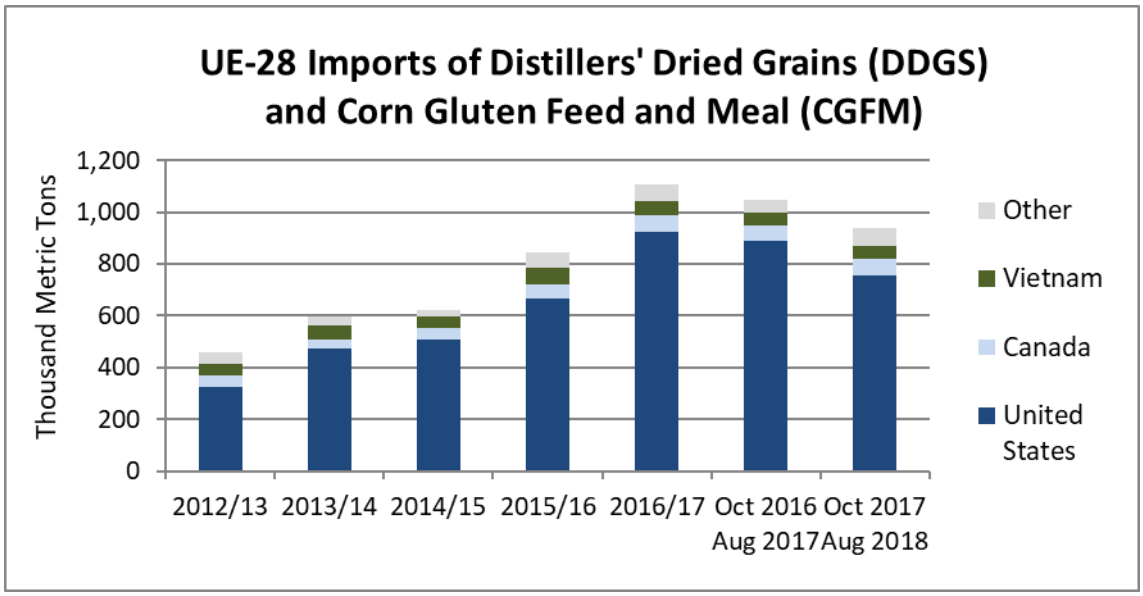
Over the past 15 years, the United States represented on average four percent of total EU imports of corn (see graph below). The beginning of GE corn plantings in the United States in 1998 resulted in a drastic decline in U.S. exports to the EU. This is due to the lag of GE traits approvals in the EU compared to approvals in the United States (asynchronous approval) and to the lack of a low-level presence policy in the EU. Moreover, 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.



Source: FAS based on Global Trade Atlas data

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

In 2016/17, the EU imported 1.1 million MT of Distiller's Dried Grains with Solubles (DDGS) and CGFM (see graph below).[3] The share of GE products of total imports is estimated at 80 percent. The United States is the main supplier of DDGS and Corn Gluten Feed and Meal (CGFM) to the EU, with an average market share of 79 percent over the past five years. The volume of imports varies from year to year depending on prices and on the pace of EU approvals of new GE corn varieties.



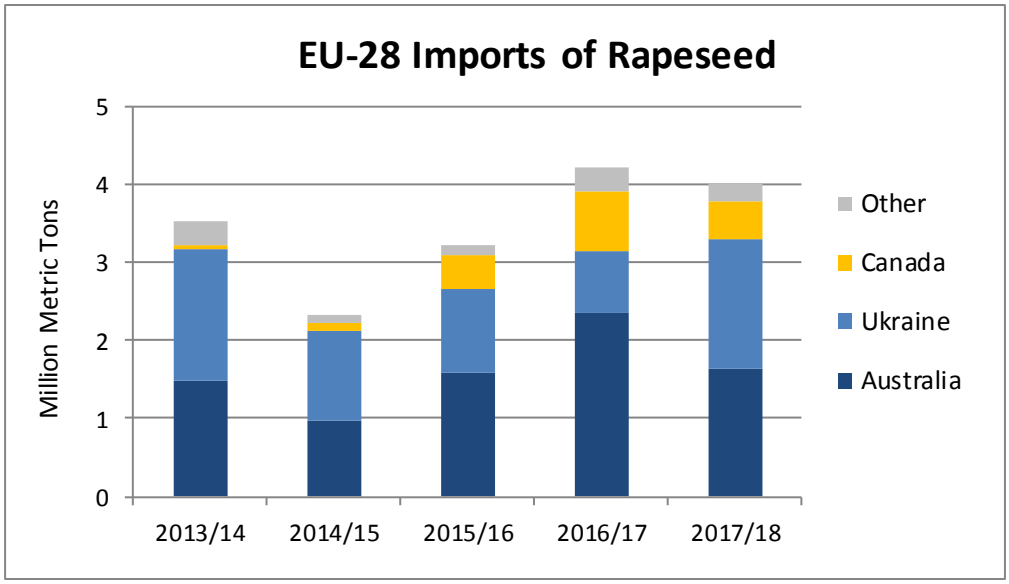
Source: FAS based on Global Trade Atlas data

- **The EU imports 2.5 to 4.5 million MT of rapeseed products every year.**

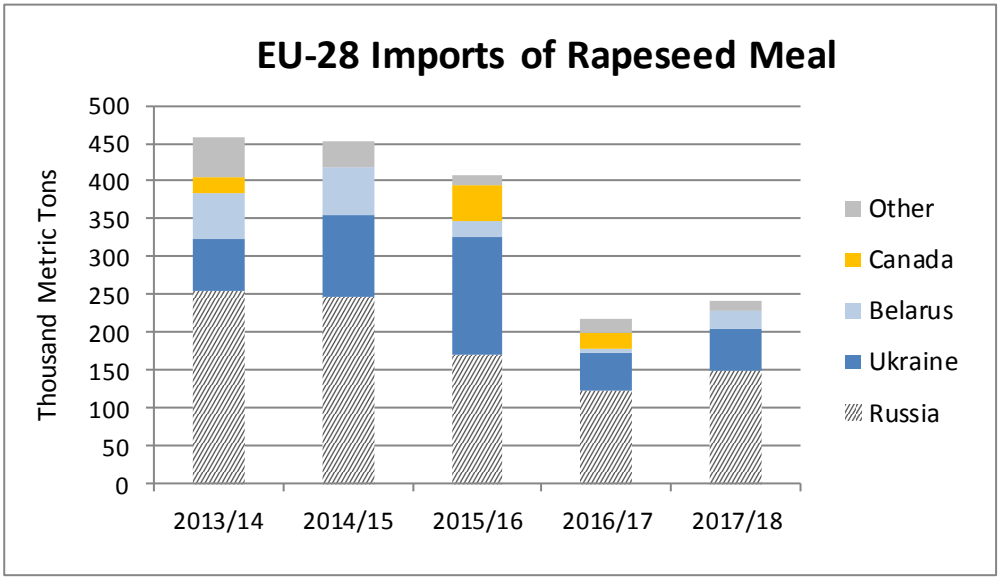
In the last five years, the EU imported on average 3.5 million MT of rapeseed and 356 thousand MT of rapeseed meal per year (see graphs below). The share of GE products of total imports is estimated at less than 20 percent. The three major suppliers of rapeseed to the EU (Australia, Ukraine and Canada) grow GE rapeseed (see table 3 above).

Although the EU is the world's largest producer of rapeseed, local demand exceeds domestic supply and large quantities of rapeseed are imported for crushing. Rapeseed meal is used for feed in the livestock sector. The biodiesel industry is the main driver for rapeseed oil demand but food and industrial use also have an influence.

[3] DDGS are a corn by-product of the distillation process; CGFM is a corn by-product of wet-milling.



Source: FAS based on Global Trade Atlas data



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 European Commission's (EC) Humanitarian Aid and Civil Protection department 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. 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 is carried out under the Fund for European Aid to the Most Deprived.

f) TRADE BARRIERS

Please see the following sections of this report:

- Timeline followed for approvals;
- Low-level presence policy;
- Countries that have opted out of cultivation.

Moreover, some countries have marketing bans on EU approved GE crops:

- In Austria, since 2007, one variety of GE corn and four varieties of GE rapeseed are banned for import and processing.
- Bulgaria has a ban on sales of foods containing GE products in schools, kindergartens and nurseries.

For more information, please see individual country reports listed in Annex 2.

PART B – POLICY

a) REGULATORY FRAMEWORK

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 in the Member States 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 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.

Over time, EFSA's guidance documents have become more rigid as they have been codified into law. This has the effect of:

- reducing the ability of risk assessors, researchers and developers to adopt the most scientifically sound approaches as knowledge and experience expand over time;
- preventing risk assessors from taking a flexible, hypothesis-driven, weight-of-evidence approach;
- adding unnecessary costs and burdens on applicants for data and information that have scant scientific justification or predictive value; and
- contributing directly to ever lengthening and unnecessary delays in the risk assessment process – which now averages six years overall for EFSA's opinion on a biotech product.

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 on biotechnology taken by EU consumers and anti-biotech groups. 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. For more information on anti-biotech groups in the EU and on their influence on regulatory decisions, see Part F) 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 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, applicants tend to avoid this procedure because cultivation applications are unpredictable and slow the whole process; applicants prefer to submit an application for food and feed only.

- **Authorization for placing biotech events on the market for food or feed use**[4]

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

- An application[5] 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.

- 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

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

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

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

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.

- **Authorization for cultivation of biotech events**[6]

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.[7]

- Using the information exchange system that has been set up by the EC, the competent authorities of the MS send to the Commission, within 30 days of receipt, a summary of each notification received.

- The Commission must forward these summaries to the other 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

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

[7] The notification includes *inter alia*:
- A technical dossier supplying the information necessary for carrying out an environmental risk assessment.
- The environmental risk assessment and the conclusions, together with any bibliographical reference and indications of the methods used.

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

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.

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.

- **European Commission updated annexes on environmental risk assessment of GE plants for import and cultivation**

The Commission Directive (EU) 2018/350 amending Directive 2001/18/EC regarding the environmental risk assessment (ERA) of GE plants was published in March 2018. The EC was obliged to update the Annexes of Directive 2001/18/EC with a view to incorporating and building upon EFSA's 2010 guidance on the ERA of GE plants.

The Commission asserts that this amendment:
- reflects technical guidance that has already been implemented;
- implies no new requirements or fundamental changes;
- maintains a "case-by-case" approach.

Background

On October 13, 2017, EU Regulatory Committee 2001/18 adopted the amendments proposed by EFSA to certain annexes of Directive 2001/18/EC as regards the ERA of GE plants. The United States provided comments to the EU after they notified the WTO of its intent to amend the annexes in November and December 2016, as TBT and SPS notifications respectively.

In November 2010, EFSA's GMO Panel published guidance for the ERA of GE plants submitted within the framework of Regulation (EC) No. 1829/2003 or under Directive 2001/18/EC. Although the conceptual basis of this guidance is generally consistent with the ERA approach used in various global

regulatory approaches, the details of this guidance and subsequent EFSA guidance documents frequently ask for data and related information that is not predictive for the decisions that are to be made under the respective regulations or directives.

An ERA should reflect the need to approach cases on their individual merits (case by case) and ensure that regulatory measures be science-based, least restrictive and least burdensome to achieve the regulatory objectives. The EU has incorporated some of the EFSA guidance into the regulations, thereby removing some of the benefits of flexibility that most good guidance can provide in a regulatory framework.

This continues the unfortunate trend for ERAs and food safety. It suggests a need for information that has not proven to be predictive of the actual characteristics of biotech products as they relate to its safety, i.e. the aspects of safety that are supposed to be under review according to the objectives of the relevant regulation.

- **EC Proposal to Amend Comitology Rules**

On February 14, 2017, the European Commission (EC) proposed to amend the comitology rules as provided by Regulation (EU) 182/2011.[8] 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 Appeal Committee;
- allowing a second referral to Appeal Committee at Ministerial level;
- making public Member States' 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. The issue has been discussed at the European Parliament (EP) and there has been discussion by MS at Council. However, MS do not seem enthusiastic to progress the issue. Although several EP Committees have delivered their opinions, the EP's Committee on Legal Affairs that is responsible for this proposal has not yet adopted a position.

Background

Since 2014, Commission President Jean-Claude Juncker has asserted that the Commission is repeatedly "forced" to take a decision when the MS cannot decide amongst themselves. President Juncker is referring to the failure of standing committees composed of MS representatives to find a qualified

[8] See GAIN report "EC Proposes Changes in Comitology Rules in Effort to Hold MS more Accountable"

majority in favor or against proposals for the authorization of several politically sensitive GE events. MS that either vote against or abstain do not base their votes on scientific evidence, but rather to reflect their national socio-economic political concerns. In such cases, it is left to the Commission to take the final decision on adopting the proposal or not. In efforts to change this dynamic, Juncker vowed to change procedures on the Commission's implementing powers to better reflect political positions in the Council. Members of the European Parliament (MEPs) have called the current process "flawed" for GE event approvals, and since 2015 have been voting for non-binding political resolutions opposing all GE event approvals until a reform is made.

The EU's current comitology or decision-making framework is designed for MS to take decisions on the Commission's proposals for implementing acts, and only if everything else fails does the Commission take a final decision. However, in the case of GE products and glyphosate, some MS have chosen to oppose or abstain from voting not for reasons of adverse impact of GE events or pesticides on human or animal health or the environment, but for political reasons. By offering "no opinion" under the current comitology rules, MS can blame the Commission for making the final decisions on these sensitive issues.

Within this context, the European Commission's 2017 Work Program included an initiative to "modernize" the comitology procedures and to change them to avoid the Commission having to take the final decision when MS fail to reach an agreement or express a "no opinion."

On February 14, 2017, the European Commission published a legislative proposal to amend the EU's comitology rules (EU 182/2011), in a stated effort to make MS more accountable for EU legislation. These proposed changes would apply to all areas of EU law-making, which means that other sectors such as pharmaceutical products, food safety and other important EU policy areas could be affected in the future. However, to date, only approval decisions for GE products and glyphosate have failed to reach a qualified majority for or against ("no opinion"). In these cases, the Commission has been obliged to take "unpopular" but science-based decisions.

Most political experts believe that the do not have the political will to adopt the Commission's proposal on comitology. However, if it were to be adopted, Post's analysis suggests that reviews would still fail to reach a qualified majority "against" GE import and cultivation authorizations, and thus the Commission would still have to make the final decision. Even with the anticipated departure of the pro-biotech United Kingdom (UK) from the EU in March 2019 (Brexit), the adoption of the comitology proposal would not result in a qualified majority being reached "against" GE authorizations. However, if the German government had changed its vote from "abstain" to "against" as a result of including the Green party in its post-September 2017 election they could have a qualified majority against, but so far Germany has still been abstaining.

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

See Part A) f) Trade Barriers

vi. Timeline followed for 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 supplier countries and those approved in the EU, resulting in the partial or complete disruption of trade in affected commodities and processed products.

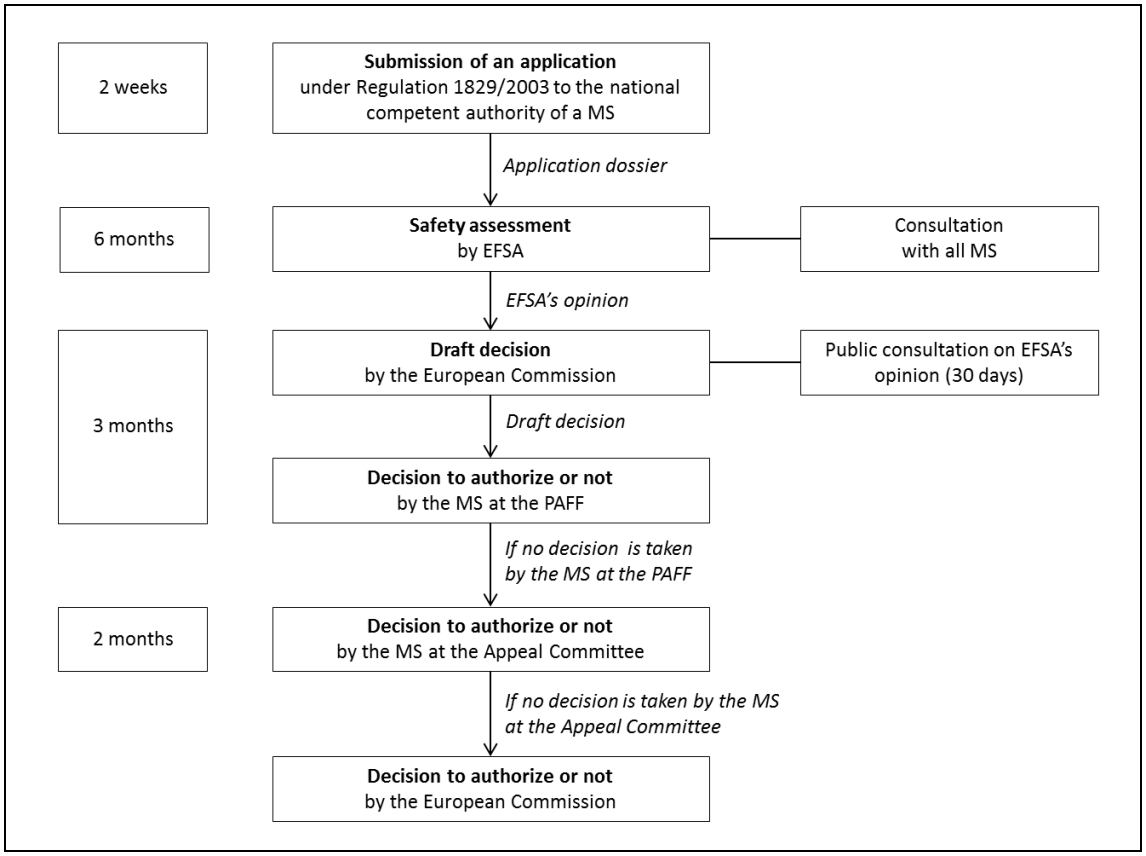
This represents a problem for commodity trading companies, as it limits their sourcing options and increases the risk in their operations with those countries where not-yet approved events are grown. Shipments of agricultural commodities destined for the EU have been rejected when traces of such events 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 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 asynchronous approvals prevent 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 timelines that should be followed for approvals according to the EU regulations are given in the charts below. The EU's regulatory review process, should legally endeavor to take twelve months: six months to undergo an environmental, human and animal health safety assessment by the regulatory European Food Safety Authority (EFSA) and six months for the European Commission to approve. However, in practice GE events approved in the EU in 2017 took an average of seven and a half years from application to EFSA to market access granted by the European Commission. In contrast, the average approval process takes about two years in Brazil and the United States and three years in Korea. The main bottleneck of the EU's lengthy approval process lies with EFSA. Despite 25 years of history of safe use of GE products globally, and EFSA's extensive institutional record of regulating GE products, it took the organization an average of five and a half years to deliver its safety assessments for the events approved in 2017. Many of the GE applications now under EFSA's review are stacked traits that EFSA has already reviewed as single applications, and even with this hands-on experience, EFSA's regulatory review timelines continue to grow.

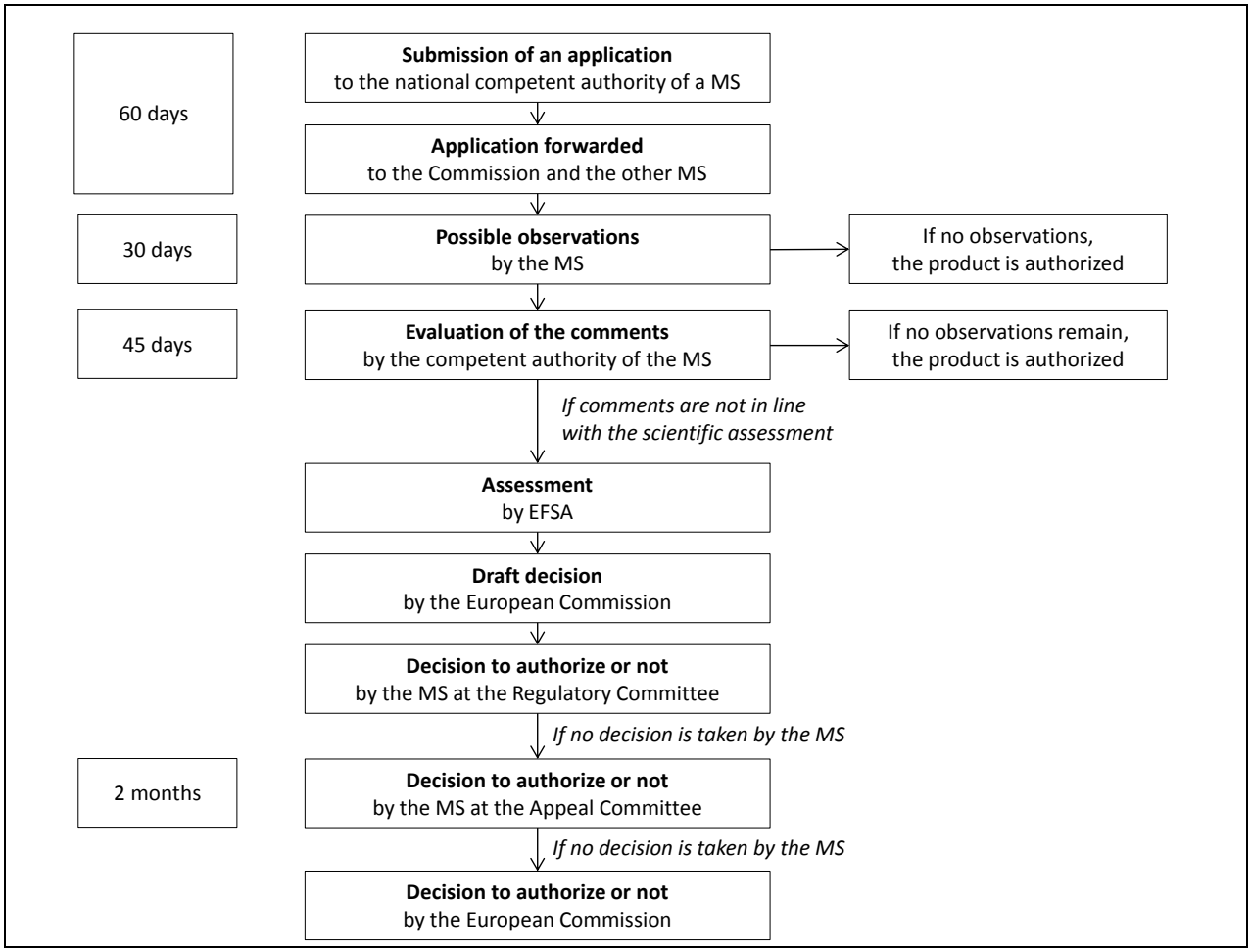
The very first step of applying for GE approval in the EU usually takes longer than six months. Applicants submit their GE dossier to EFSA and then wait a few months – even up to four years – for EFSA to review the application and perform a "completeness check." Upon successfully passing EFSA's dossier review, the six-month clock begins. EFSA working groups then review the dossier to undertake environmental, human and animal-health safety assessments; at any time they can "stop the clock" to ask the applicant to provide additional information – answers to questions and/or requests for additional studies. The EFSA clock is re-started when the applicant has submitted its responses or completed the studies requested. Thus, EFSA may argue that they can meet the six-month timeframe, but this is because they have unlimited timeouts. There is no public record on the frequency of the timeouts, but the biotechnology advocacy organization EuropaBio estimates that between 2011 and 2013, EFSA stopped the clock around five times per dossier on average. Between 2015 and 2017, EFSA is believed to have stopped the process more than ten times for each dossier on average.

Chart 1. EU Approval Process for Food and Feed



Source: USDA FAS

Chart 2. EU Approval Process for Cultivation



Source: USDA FAS

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.

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.

An 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.

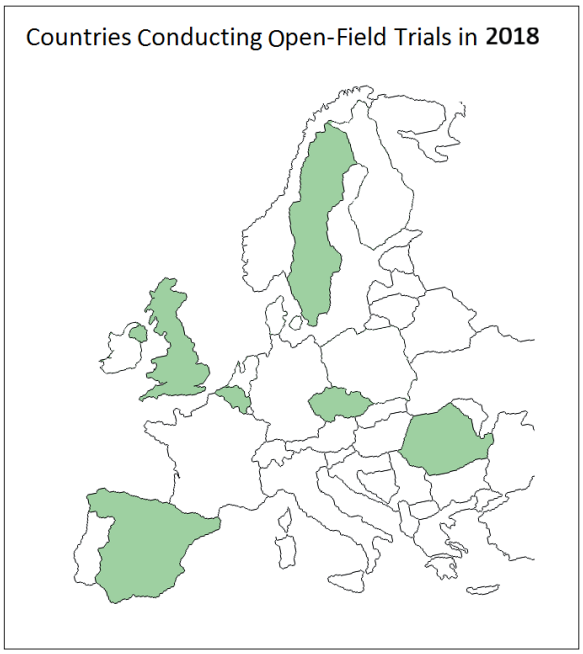
c) STACKED EVENT APPROVALS

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.

The EU approves a stacked product separately from the singles it has already reviewed (unlike the approval process for most GE products in the United States); this policy slows the pace of approvals for corn and may become a problem for soybeans as stacked soybeans are becoming common.

d) FIELD TESTING

Field trials are permitted in eleven MS.[9] However, only seven MS conduct open-field testing in 2018: Belgium, the Czech Republic, the Netherlands, 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 where none was carried out.



Source: FAS Posts

The list of the notifications for deliberate release of GE plants into the environment is available on the website of the European Commission's Joint Research Center (JRC).

Spain leads the number of accumulated notifications of open field releases. France and Germany have historically reported a high number of notifications, but there has not been any since 2012 and 2010 respectively. Some public institutions that conduct laboratory research go into partnership with private companies to carry out field trials in other countries, such as the United States. Other MS with significant accumulated numbers of notifications include Sweden, Romania and the Czech Republic. The number of projects actually conducted may be lower than the number of notifications.

For more information on field testing in selected countries, please see USDA FAS country reports listed in

[9] Belgium, Germany, Czech Republic, Denmark, Finland, Portugal, the Netherlands, Romania, Spain, Sweden and the United Kingdom.

Annex 2.

e) INNOVATIVE BIOTECHNOLOGIES [10]

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 innovative techniques have been developed. These techniques make crop improvement quicker and more precise. They can complement or substitute for genetic engineering. In addition, most of these techniques 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, and some Member States urged the European Commission to clarify the legal status of innovative biotechnologies and their application since the current legislative framework, EU Directive 2001/18/EC, does not reflect the progress made in the development of new techniques.

On July 25, 2018, the CJEU judged that organisms created through many newer genome editing techniques are to be regulated as GMOs in the EU. This judgment subjects such organisms, and food and feed products containing these organisms, to the expensive and lengthy approval process as well as traceability, labelling and monitoring obligations of the EU. That has significant potential negative consequences for EU innovation and EU agriculture. This judgment also has potential to create trade disruptions in the future.

The European Commission is expected to decide how to implement the CJEU judgment in the coming years; the Commission has requesting input from the Member States and asked them to answer questions on this subject. The Member States are still debating on this issue.

For more information on the reactions of EU stakeholders to the CJEU judgment, please see Part C) Marketing b) Market Acceptance/Studies.

Background

In 2007, the EU began a process to consider the regulation of emerging techniques in agricultural biotechnology termed "new breeding techniques" (NBTs). Most of the plants produced through these techniques lack foreign DNA or protein in the final plant and result in similar products as those developed through unregulated breeding techniques. Developers requested government clarification as to whether certain classes of products of genome editing techniques would fall outside the scope of biotechnology regulations developed for traditional genetic engineering.

On October 3, 2016, the French Supreme Court (Conseil d'Etat) sent the following four legal questions about innovative biotechnologies and mutagenesis to the CJEU:

- Are the organisms produced through mutagenesis GMOs under Directive 2001/18/EC? Which of these organisms should be regulated as GMOs under Directive 2001/18/EC?

[10] "Genetic Engineering" means transgenesis. "Innovative biotechnologies" is a synonym of New Breeding Techniques (NBTs) and excludes transgenesis.

- Are the organisms produced through mutagenesis GMOs under Directive 2002/53/CE?
- If organisms produced through mutagenesis are not regulated as GMOs under Directive 2001/18/EC, does it mean that the Member States are not allowed to set their own regulations for these organisms?
- Is the exclusion of mutagenesis from Directive 2001/18/EC consistent with the precautionary principle?

On January 18, 2018, the Advocate General of the CJEU released an advisory opinion on whether some gene editing technologies are exempt from EU Directives 2001/18/EC and 2002/53/CE (referred to as the laws on GMOs). In the non-binding opinion, the Advocate General advised that:

- organisms derived from classical mutagenesis and innovative techniques considered to be mutagenesis are GMOs;
- the technique of classical mutagenesis is exempt from the GMO legislation, and innovative techniques that are similar to mutagenesis and do not introduce foreign DNA are also exempt;
- EU Member States have discretion legislating in this sphere, as the EU has not developed legislation on mutagenesis;
- the mutagenesis exemption is consistent with the application of the precautionary principle.

Although the Advocate General's opinions are typically given considerable weight, in the ruling of July 25, the CJEU found that organisms produced with newer mutagenesis methods are subject to the regulatory obligations of EU Directive 2001/18/EC. As such, they will be subject to the EU's expensive and lengthy risk assessment and review requirements as they are applied to the cultivation and import of GE varieties.

Directive 2001/18/EC exempts certain genetic modification techniques, notably "mutagenesis." In plant breeding, mutagenesis is a long established technique that uses chemical, radiation or other physical stimuli to induce mutations. Plant breeders then evaluate whether the genetic alternations have yielded beneficial properties. If so, these plants are selected for use in breeding programs. The Directive's exemption of mutagenesis implies that plants developed through these common breeding techniques may be used in the EU without additional GMO-related regulation. However, the Directive does not legally define "mutagenesis," and the CJEU found that newer techniques are not covered by the "mutagenesis exemption."

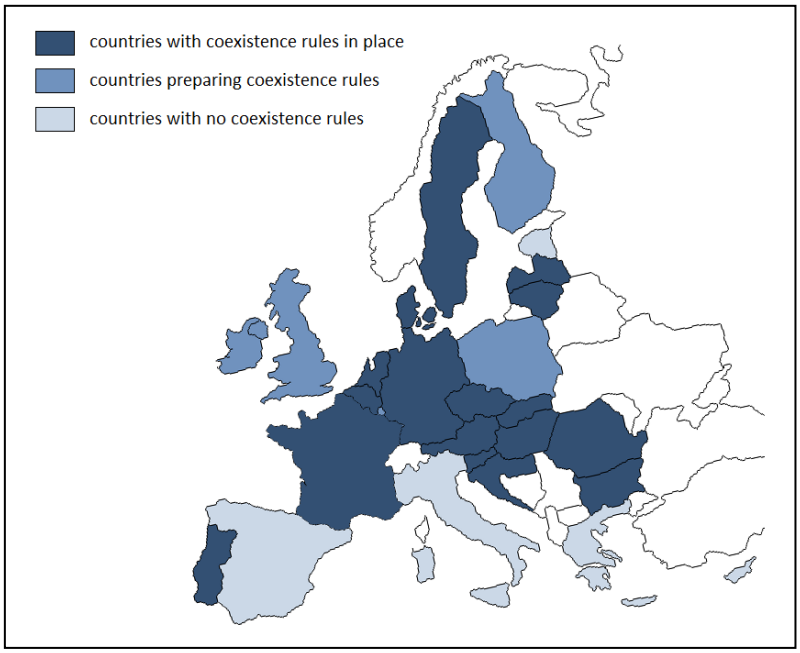
More specifically, the CJEU stressed in its judgment that "the number of applications" (i.e. frequency of use) and a "long safety record" are essential components of the "mutagenesis exemption." Organisms produced with the newer mutagenesis techniques are therefore not exempt from the obligations of Directive 2001/18/EC. The judgment neither defined the threshold for "the number of applications," nor what constitutes a "long safety record."

On Tuesday, September 25, 2018, Pilar Ayuso from the European Peoples' Party (Spain), a Member of the European Parliament (MEP), sponsored an event at the EP themed innovation in agriculture. Speakers at the event stressed the importance of agricultural innovation and the negative impact on its future resulting from the CJEU's judgment.

f) COEXISTENCE

Coexistence rules of GE plants with conventional and organic crops are not set by EU authorities but by MS national authorities. At the 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. Coexistence Policies in the European Union



The countries that produce or used to produce GE crops have enacted specific legislation on coexistence. Map 3 shows that most MS have adopted or are preparing internal coexistence rules (source: FAS Offices in the EU).

For example:
In Spain, coexistence at the farm level is managed by following the good agricultural practices defined by the National Association of Seed Breeders and in 2017, a decree was enacted to avoid possible cross-border contamination into neighboring Member States not growing GE crops. In some parts of the EU such as Southern Belgium and Hungary, coexistence rules are very restrictive and limit the cultivation of GE crops.

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. Although products undergo a safety assessment, labels are simply there to inform consumers. However, these labels are often interpreted as warnings, and producers expect such 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 (see the low-level presence policy section of this report);
- 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 GE-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 2018, **Austria, the Czech Republic, France, Germany, Hungary, Italy, and Poland** have legislations and/or guidelines in place to facilitate GE-free labeling. **Sweden** has adopted legislation that explicitly prohibits such labeling. In **Greece, Spain, Portugal, and the United Kingdom**, there is no formal government position but there are a number of private initiatives for GE-free labeling. In the **Czech Republic** and **Slovakia** retail buyers of meat and milk products are requiring farmers' guarantee that their livestock is not fed with GE crops.

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. 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[11] on the market is the submission of an application. This application must include a monitoring plan for environmental effects.[12] The duration of the monitoring plan may be different from the proposed period for the consent.
2. Where appropriate, the application must include a proposal for post-market monitoring regarding use as food or feed.[13]
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

[11] "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.
[12] Directive 2001/18/EC: Article 5 and Annex III for experimental releases, Article 13 and Annex VII for placing on the market
[13] Regulation (EC) No 1829/2003 Articles 5 and 17

received the original notification may adapt the monitoring plan after the first monitoring period.[14]

4. The results of the monitoring must be made publicly available.[15]
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.[16]

- **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.

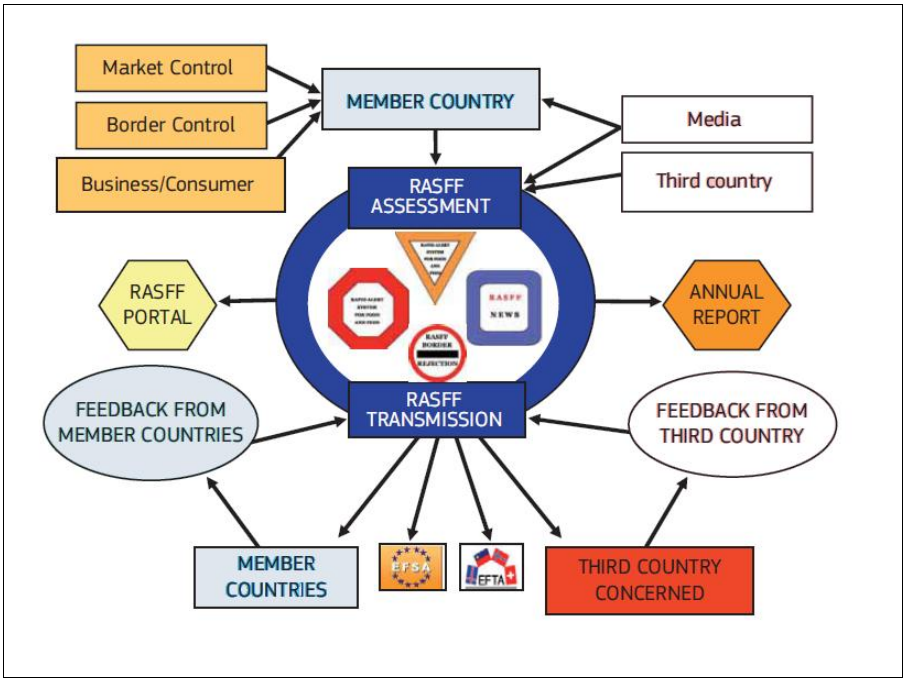
Whenever a member of the RASFF network (the EC, EFSA, a MS, Norway, Liechtenstein, or Iceland) has any information relating to the existence of a risk to human health deriving from food or feed, this information is immediately transmitted to the other members of the network. The MS shall immediately notify the RASFF of any decision 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.

Chart 3. RASFF Information Flow

[14] Directive 2001/18/EC Article 20
[15] Directive 2001/18/EC Article 20 - Regulation (EC) No 1829/2003 Article 9
[16] Directive 2001/18/EC Article 17 - Regulation (EC) No 1829/2003 Articles 11 and 23



Source: RASFF 2013 annual report

i) LOW LEVEL PRESENCE (LLP) 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:

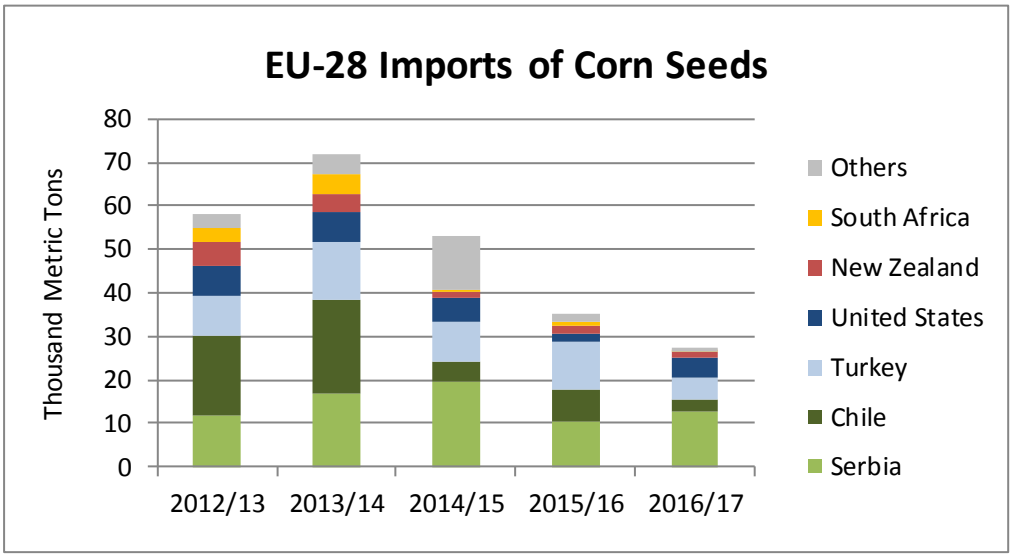
- Low Level Presence (LLP), defined as the detection of low levels of GE crops that have been approved in at least one country, but not in the importing country. Most of these incidents are associated with asynchronous approval systems.
- Adventitious Presence (AP), defined as the unintentional presence 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).

• Thresholds for adventitious presence in feed, food and seeds

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.

In 2016, the 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.

As for **seeds**, a threshold level for adventitious GE material presence has not yet been set. The EU is forced to either produce its seeds domestically or import seeds from a limited number of origins (Serbia, Chile, Turkey, United States, New Zealand and South Africa among others) where seed is produced under restrictive conditions that prevent any presence of not-yet approved events (see chart below about imports of corn seed).



Source: FAS based on Global Trade Atlas data

- **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**

In May 2017, 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 2017. The guidance was agreed by the GMO Panel at EFSA in September 2017 but has not yet been published at the time of writing. Additional information can be found on EFSA's website.

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.[17] 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**

[17] In Spain, total area is calculated based on GE seed sales records, and it is publicly available on the Ministry of Agriculture's website.

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

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

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

	on the CPVO website. They include Regulation (EC) No 2100/94 on plant variety rights. The UPOV website gives the text of the UPOV Convention (International Convention for the Protection of New Varieties of Plants) and the legislation of MS that has been notified in accordance with it.	biotechnological inventions in the EU include: - the European Patent Convention (EPC), an international treaty ratified by all MS that provides the legal framework for the granting of patents by the EPO; - the case law of the EPO boards of appeal, that rules on how to interpret the law; - Directive 98/44/EC on the legal protection of biotechnological inventions, that has been implemented into the EPC since 1999 and shall be used as a supplementary means of interpretation; - national laws that implement EPC and Directive 98/44/EC (in place in all MS since 2007, see USDA FAS country reports).

Sources: CPVO, EPO

- **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) amended the Implementing Regulations to the European Patent Convention, establishing that European patents shall not be granted for plants or animals exclusively obtained by means of "essentially biological processes." "Essentially biological processes" means naturally occurring processes such as the crossing of whole genomes and the subsequent selection of plants or animals.

l) 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."[20]

m) INTERNATIONAL TREATIES/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.

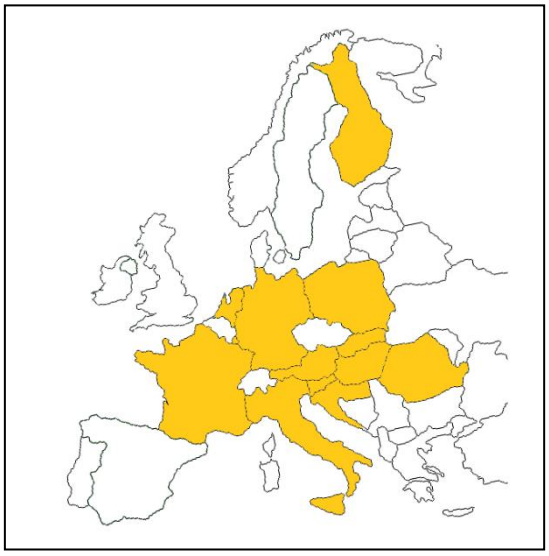
All MS have signed the International Plant Protection Convention (IPPC), an international treaty that works to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. DG SANTE is the IPPC official contact point in the EU. The EU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

[20] See ESA's press release

n) RELATED ISSUES

- **European Soy Declaration**

Map 4. European Soy Declaration Signatories



Since July 2017, thirteen MS have 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, Italy, 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 GE-free feed, whereby signatories "support the further development of markets for sustainably cultivated non-GE 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, or 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 declarations. Most of them 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.

- **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 this "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 European Commission to withdraw the proposal (with 577 votes for, 75 against and 38 abstentions) which the Commission declined to do. This prompted the EP to ask the Commission to make a new proposal. The Commission has asserted however that there is no "Plan B". After rejection by the EP, the proposal is now formally on the table with the Council, although it remains highly unlikely that MS will vote on the proposal. Essentially, in the absence of an agreed proposal, the Commission 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.

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; it is now difficult for elected officials 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. They receive less media attention than opponents to biotechnology.

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 the following:

(a) There is only one GE crop authorized for cultivation in the EU. More farmers would grow GE crops if other traits more adapted to their agronomic conditions were made available.
(b) Nineteen MS have implemented a ban on the only GE crop authorized for cultivation. Some farmers in these countries would grow GE crops if they were allowed to.
(c) The threat of protests or destruction by activists frightens many farmers, 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 MS, retail requirements or public/private initiatives such as the EU Soy Declaration discourage the cultivation and marketing of GE crops.
(e) In some MS, there is an increased interest in non-GE products and farmers 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.

For nearly two decades, European **consumers** have been exposed to consistent negative messaging from anti-biotech groups 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 (Spain and Portugal), consumer perception is less negative. 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 objections 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.

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

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 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.**

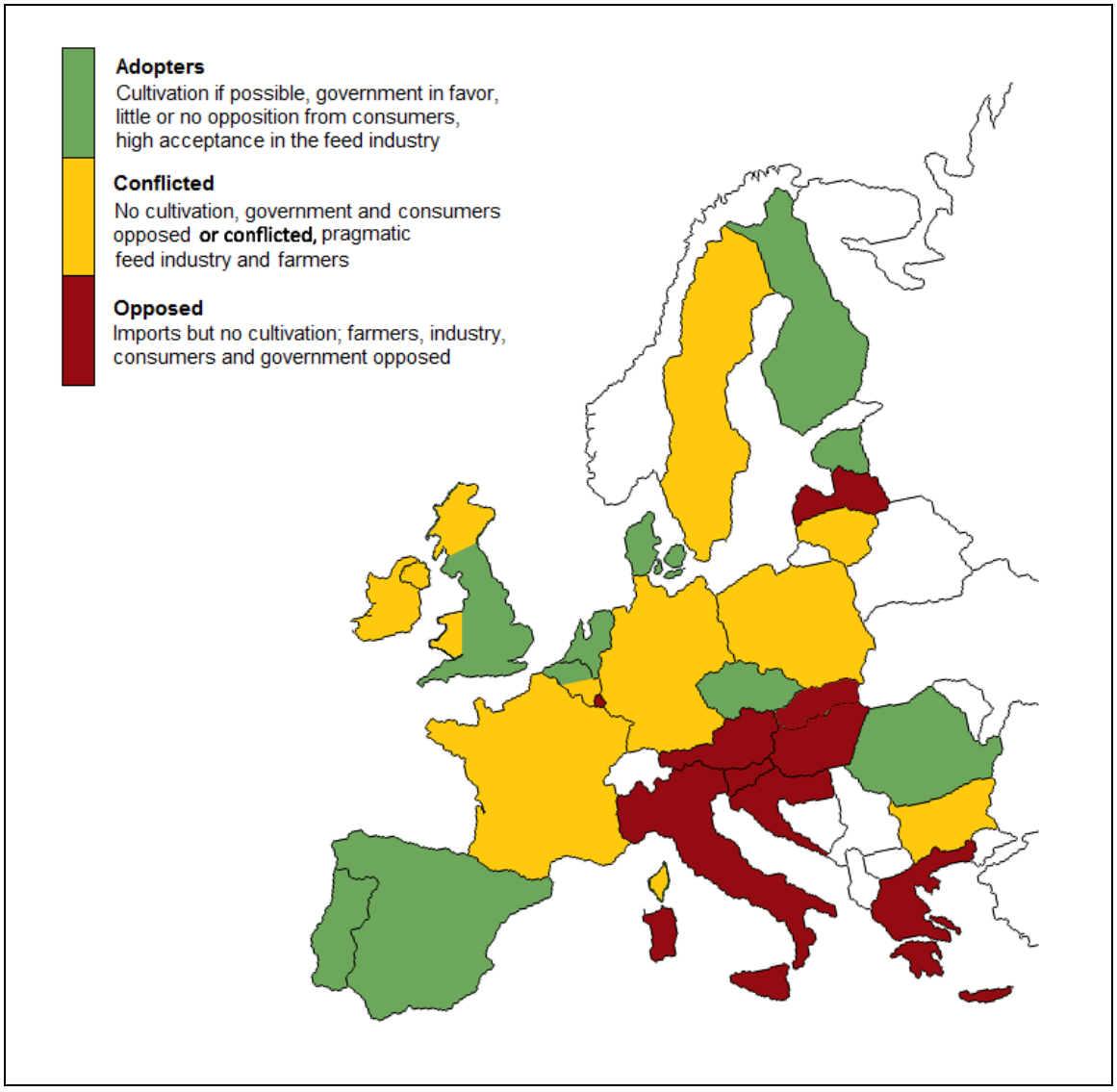
There are three major categories of MS depending on their acceptance of agricultural applications of genetic engineering, as illustrated in Map 5 below.

- The "**Adopters**" have pragmatic governments and industries generally open to the technology. This category includes growers of GE corn (**Spain and Portugal)**, as well as 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 (**the Czech Republic, Denmark, Estonia, Finland, the Netherlands, Flanders in Northern Belgium, Romania, and England in the United Kingdom**). The **United Kingdom**'s departure from the EU 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 indications. A minority of farmers in these countries are supportive of growing biotech crops. **Slovakia** has been in the "Opposed" group since 2017 due to a political shift.

Map 5. Acceptance of Agricultural Biotechnology by Member State – 2018



Source: FAS offices in the European Union

- **A debate on innovative biotechnologies is emerging in the EU**

Looking at the various stakeholders across Europe, there are some differences between countries, but overall the general trends are as follows:

- **The vast majority of scientists are deeply concerned** about the recent CJEU judgment. They warn that it could put an end to a promising field of research in the EU. Several groups of leading EU scientists have released position papers. For example:
    - On November 13, 2018, the European Commission's Chief Scientific Advisors published a statement providing "a scientific perspective on the regulatory status of products

derived from gene editing, and the implications for the GMO Directive." They state that "when reasons other than scientific evidence inform decision making, such as those based on ethical, legal, social and economic considerations, these should be clearly identified and communicated as such in a transparent way. At the same time, relevant and robust scientific evidence should be provided to inform decision-making and good regulation. This is essential to generate good policy and regulation, to maintain public trust in science, and to reduce the potential reputational risk to the EU, if it appears that the EU is not employing the best scientific evidence to generate good public policy." They add that the GMO Directive should be revised to reflect current knowledge and scientific evidence and that the features of the final product itself must be examined regardless of the underlying technique used to generate that product. This statement draws in large part on the Advisors' Explanatory Note on New Techniques in Agricultural Biotechnology published in April 2017.

- On October 24, 2018, leading scientists representing more than 85 European plant and life sciences research centers and institutes released a position paper.[21] They state that "European agricultural innovation based on precision breeding will come to a halt because of the high threshold that this EU GMO legislation presents. This will hinder progress in sustainable agriculture and will give a competitive disadvantage to plant breeding industries in Europe. The impacts on our society and economy will be enormous. From a scientific point of view, the ruling makes no sense. Crops containing small genome edits are at least as safe as crops obtained through classical mutagenesis or conventional breeding. But more importantly, we find the ruling irresponsible in the face of the world's current far-reaching agricultural challenges. The ruling proves that current EU GMO legislation is outdated and not in line with recent scientific evidence."
- On October 17, 2018, two associations of plant scientists[22] sent an open letter to the European Commission. They state that it is "urgent to decide on the regulatory status of plants derived from these technologies, in the interest of research, of all European seed companies, the competitiveness of European agriculture at the global level, and European consumers."

- **Anti-biotech groups are opposed to innovative biotechnologies.** They are already campaigning against these technologies in several countries including France, Germany, Greece, Hungary, Italy, the Netherlands, Spain, and the United Kingdom.

- **Professionals in the agricultural sector** (farmers, seed companies, and the feed supply chain including importers) **support the use of innovative biotechnologies** and are concerned about the possible negative economic impact of the CJEU decision. Some small farmers' organizations are close to anti-biotech groups but they only represent a small share of EU farmers.

- **There is low awareness of agricultural applications of innovative biotechnologies among the general public**. The EU's **food industry and retailers have not expressed a position yet**;

[21] Th signatories are researchers from Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Lithuania, the Netherlands, Poland, Portugal, Romania, Spain, Slovakia, Sweden, and the United Kingdom

[22] French *Association Française des Biotechnologies végétales* (AFBV) and German *Wissenschaftlerkreis Grüne Gentechnik* (WGG)

they adapt their product offerings to consumer perceptions.

For further explanation on the situation in each MS, see USDA FAS country reports, listed in Annex 2.

- **Studies**

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

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

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

CHAPTER 2 – ANIMAL BIOTECHNOLOGY[23]

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**

[23] 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.

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 (Poland, Hungary, Spain, and the United Kingdom) 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 research in the EU include flies, nematodes, moths, tropical frogs, tropical fish, mice, rats, hens, cats, rabbits, goats, sheep, cows and horses.

Below are some **examples** of research projects in animal biotechnology carried out in the EU:

- 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 (pigs, rabbits, goats, cattle, cats, horses) as well as animal transgenesis.
- In **Hungary**, the Agricultural Biotechnology Institute of the NAIK has three research groups working on applied embryology and stem cell research, ruminant genome and rabbit genome biology.
- In the **United Kingdom**, the Oxitec company 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 fruit, 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, and 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 ten 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 2018, the Center for Swine Studies reported research activities on GE hogs. In 2017, the Public Agricultural Research Institute (INIA) notified the National Biosafety Commission (CNB) to study the molecular processes of reproduction on GE rabbits, goats and sheep. Basic research with CRISPR-Cas9 in mice has been carried out since 2013; research on animal genome

editing is carried out by public institutions such as the National Center for Biotechnology (CNB).

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.

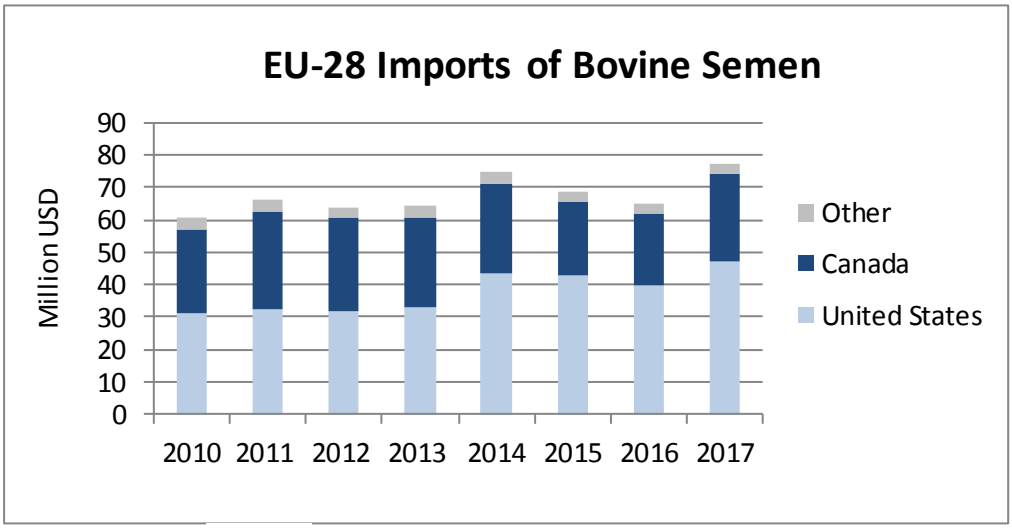
In 2018, the Oxitec company (based in the United Kingdom) has launched several new initiatives to produce **biotech mosquitoes** in order to combat disease-spreading mosquitoes. For additional details, please see Oxitec's Press Releases.

c) EXPORTS

The UK exports GE mosquito eggs for development and subsequent release in Brazil and the Cayman Islands. For additional details, please see Oxitec's Press Releases.

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 the largest supplier of bovine semen to the EU with an average market share of over 50 percent in quantity, followed by Canada (40 percent).



Source: FAS based on Global Trade Atlas data

e) TRADE BARRIERS

The main barriers to using animal biotechnology to improve animal breeding are the public and political opposition to it, due to 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 Part B iv).

Moreover, EFSA published a guidance on the environmental 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 on EFSA's website.

ii. Political factors influencing regulatory decisions

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

iii. Legislations and regulations with the potential to affect U.S. trade

The current EU regulation on novel foods (Regulation (EU) 2015/2283) was published in December 2015. Most of its provisions apply from January 1, 2018. It repealed 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 [24]

Recent policy developments on animals produced through innovative biotechnologies (also called "new breeding techniques") are reported under Part B) e) Innovative Biotechnologies.

c) LABELING AND TRACEABILITY

EU regulations (EC) No 1829/2003 and (EC) No 1830/2003 require food and feed produced from GE animals to be labeled as such (see 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 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;
- 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.[25]

e) INTERNATIONAL TREATIES/FORUMS

[24] "Innovative biotechnologies" is a synonym of New Breeding Techniques (NBTs). It excludes transgenesis.
[25] Source: European Patent Office

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[26] out of the current 28 MS of the EU are members of the Organization for Economic Cooperation and Development (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 Part B) l) Cartagena Protocol).

PART F – MARKETING

a) PUBLIC/PRIVATE OPINIONS

The EU's livestock industry does not favor the commercialization of clones or GE animals for agricultural purposes. However, in the some EU MS, the livestock industry is interested 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 coverage is low; it occasionally includes reports on regulatory decisions taken at the EU level or on the marketing of such products in extra-EU countries.

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 significant share of the population would still reject it as being "unnatural."

Food use is widely rejected; medical applications are the most accepted one. 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.

A number of organizations are actively campaigning against the technologies in the EU, including animal welfare activists, local food groups, and biodiversity activists.

b) MARKET ACCEPTANCE/STUDIES

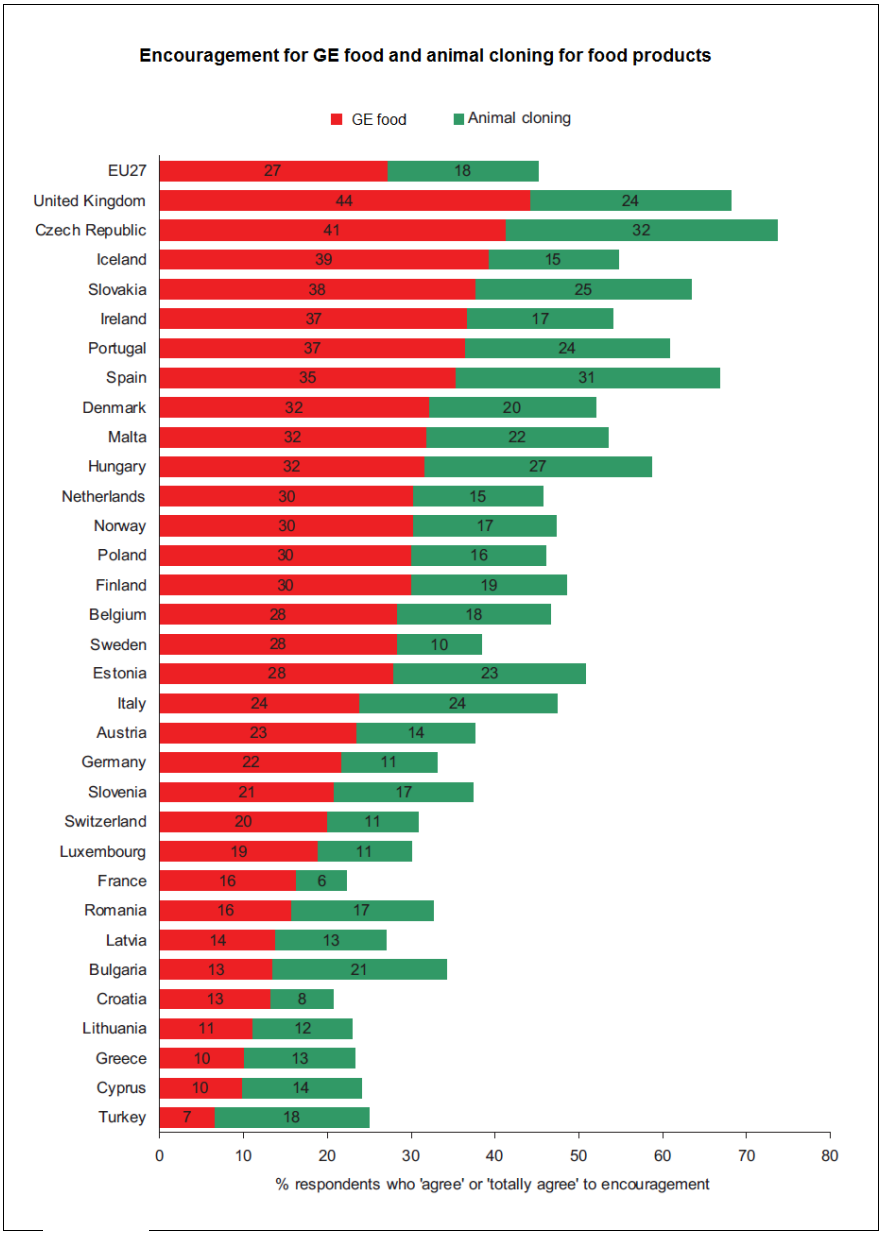
There is little public awareness of animal biotechnology in the EU, but overall, market acceptance is

[26] Non-OECD EU MS include: Bulgaria, Croatia, Cyprus, Lithuania, Malta, and Romania

low among policy makers, industry, and consumers due to animal welfare concerns. Animal biotechnology is a controversial issue that is not widely discussed.

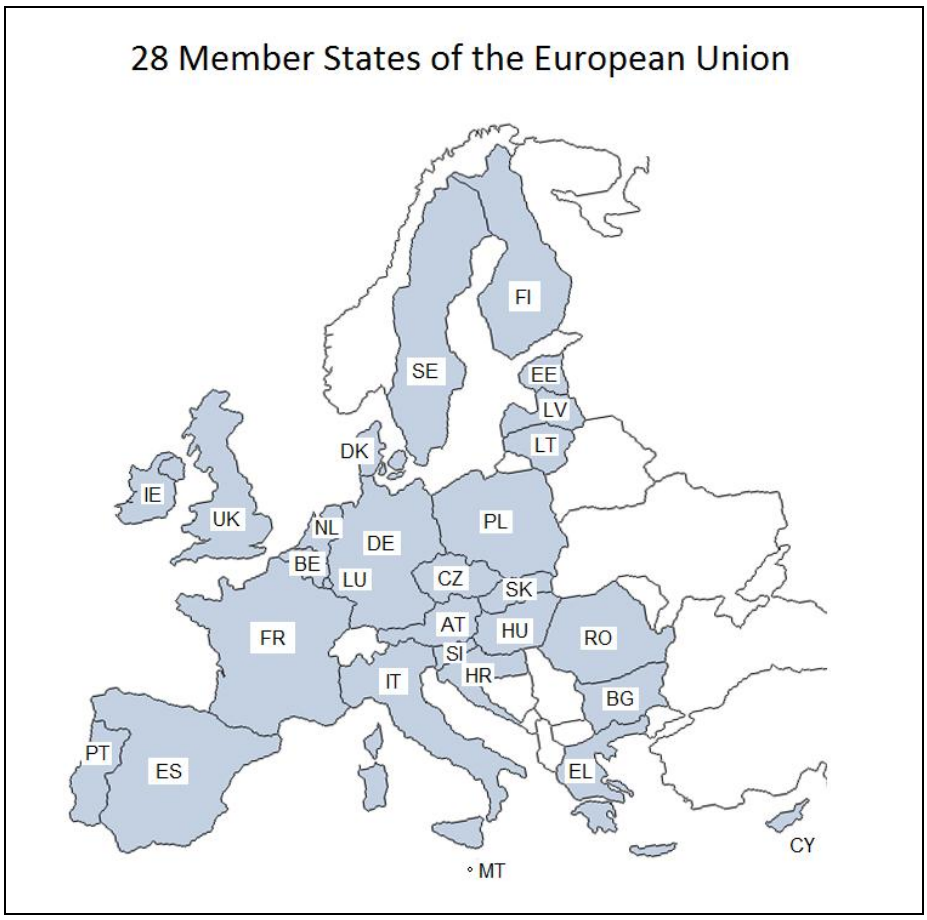
The latest European survey on biotechnology dates back to 2010. According to this survey, "cloning animals for food products is even less popular than GM food with 18 percent of Europeans in support" and the main explanation is that "the idea of the 'natural superiority of the natural' captures many 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



AT	Austria	IE IT	Ireland
BE	Belgium	LT	Italy
BG	Bulgaria	LU	Lithuania
CY	Cyprus	LV	Luxembourg
CZ	Czech Republic	MT	Latvia
DE	Germany	NL	Malta
DK	Denmark	PL	The Netherlands
EE	Estonia	PT	Poland
EL	Greece	RO	Portugal
ES	Spain	SE	Romania
FI	Finland	SI	Sweden
FR	France	SK	Slovenia
HR	Croatia	UK	Slovakia
HU	Hungary		United Kingdom[27]

[27] 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 in the GAIN database and on the Foreign Agricultural Service website.