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Report Highlights:

Despite efforts to boost local protein crop production, the EU remains heavily reliant on genetically engineered (GE) feed imports to sustain its livestock sector. Regulatory barriers, political challenges, and market resistance limit GE crop cultivation, hindering progress toward self-sufficiency. In July 2023, recognizing genome editing's growing role in agriculture, the European Commission proposed a regulatory framework for plants developed using new genomic techniques (NGTs). This framework categorizes plants into two groups based on their similarity to conventionally bred crops. While the European Parliament adopted the proposal, disputes over labeling, patentability, and risk assessments within the Council have delayed progress. Renewed efforts to achieve consensus and advance to trilogue negotiations are expected during the upcoming Polish and Danish Council Presidencies in 2025. Meanwhile, genome-edited products remain subject to the restrictive GMO Directive.

Executive Summary

The European Union (EU) imports large amounts of genetically engineered (GE) feed to sustain its livestock sector. The United States is one of the main suppliers of soybeans to the EU, most of which are GE. Despite efforts at the EU and Member State (MS) levels to grow protein crops in the EU and gain feed self-sufficiency, farmers in the EU will continue to need imports of safe, reliable, and affordable feedstuffs. The stakeholders that defend agricultural biotechnology at the EU level are scientists and professionals in the agricultural sector, including farmers, seed companies, and representatives of the feed supply chain.

Commercial cultivation of GE crops in the EU is limited to less than one percent of the EU's total corn area (around 70,000 hectares in Spain and 1,000 hectares in Portugal respectively in 2024). The single variety authorized for cultivation is banned in all or parts of nineteen MS. The threat of destruction by activists and difficult marketing conditions also discourages the cultivation of GE crops in general.

For over twenty years, the limited popularity of GE foods compared to traditional ones, coupled with persistent fear-mongering campaigns by anti-biotech groups, has led to predominantly negative sentiments among European consumers regarding GE products. In response, the EU's food industry and retailers are adjusting their product portfolios to align with consumer perceptions. A growing number of initiatives aim to distinguish non-GE food products at the retail level through the use of voluntary GE-free labels. Several prominent supermarkets position themselves as exclusively offering non-GE products.

The EU approval process for GE products consists of a scientific risk assessment phase and a more politically influenced risk management phase. The first is carried out by the European Food Safety Authority (EFSA). The latter is the responsibility of the European Commission (EC), with determining input from the MS. This arrangement displeases the European Parliament (EP), which condemns the Commission's decisions and is attempting to reform the risk management phase. In 2024, the EU issued a total of 9 approvals/renewals, compared to 13 approvals/renewals for GE crops 2023.

The EU is primarily active in basic medical research regarding animal biotechnology. 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 because consumer acceptance is low. Both genetic engineering and genome editing of microorganisms is widely used in laboratories all over the EU.

Since the 2018 European Court of Justice ruling classifying genome-edited organisms as GMOs under the existing GMO Directive, the EU has gradually moved toward addressing the limitations of the current regulatory framework. Following the European Commission's 2021 study recognizing the need for targeted legislation, the Commission proposed a new regulatory framework in July 2023, dividing NGT plants into two categories: Category 1, which includes plants that are similar to those produced through traditional breeding methods and are exempt from GMO regulations, and Category 2, which

includes plants with traits that cannot be achieved through conventional breeding, subjecting them to full GMO regulation. The Commission then forwarded the adopted proposal to the co-legislators—the European Parliament and the Council of the EU—for their evaluations and amendments.

In the first semester of 2024, the European Parliament adopted the proposal but introduced significant amendments, including mandatory labeling for all NGT products and a proposed ban on patentability, a measure that remains contentious. Meanwhile, the Council of the EU was unable to reach consensus under both the Spanish Presidency in the second half of 2023 and the Belgian Presidency in the first half of 2024. Despite efforts to address key demands, such as stricter risk assessments, enhanced labeling, and patent restrictions, the lack of agreement on crucial issues, particularly on patentability, has stalled progress.

During Hungary's Presidency in the second half of 2024, progress on the proposal stalled, as expected, due to Hungary's longstanding opposition to plant biotechnology. As Poland assumes the Presidency in January 2025, followed by Denmark in July, efforts to secure a Council consensus and initiate trilogue negotiations are expected to continue.

Until adoption, genome-edited products will remain under the restrictive GMO Directive, delaying scientific innovation and global regulatory alignment.

Acronyms Used in this Report:

CGFM	Corn Gluten Feed and Meal
ECJ	European Union Court of Justice
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
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
NGTs	New Genomic Techniques
OECD	Organization for Economic Cooperation and Development
PPP	Public-Private Partnership
RASFF	Rapid Alert System for Food and Feed
PAFF	European Commission's Standing Committee on Plants, Animals, Food and Feed
UK	United Kingdom
USDA	United States Department of Agriculture

Glossary:

"Genetic Engineering" is the use of transgenesis in plant or animal breeding. Transgenesis is the process of introducing an exogenous gene from one organism into another with the intent of enabling the latter to exhibit a new property. In Europe, these resulting organisms are known as "Genetically Modified Organisms" (GMOs).

"Innovative biotechnologies" is used here as a synonym for the European term "New Genomic Techniques" (NGTs) and "New Breeding Techniques" (NBTs) and is generally referred to as genome editing. It excludes traditional genetic engineering (transgenesis).

In this report, the European Union (EU) refers to the EU 27 Member States (MS). The United Kingdom (UK) is mentioned separately throughout the report.

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CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

Europe is home to many internationally recognized public and private researchers in plant biotechnology. However, strict political and regulatory barriers prevent this research from leading to the approval or cultivation of new biotech crops within the EU:

Large **private companies** like BASF, Bayer, KWS, and Limagrain are key players in European plant biotechnology. However, they face significant challenges in developing genetically engineered (GE) plant varieties for cultivation in the EU. Activist-driven vandalism of test plots, combined with uncertainties, delays in the EU approval process, and public perception challenges, has made genetic engineering a less attractive investment. To overcome these obstacles, many European companies have moved their research to other countries. Bayer shifted its research to the United States in 2004, followed by BASF in 2012 and KWS in 2015. This strategic move allows them to navigate regulatory frameworks more efficiently and pursue opportunities in a more conducive environment.
The exodus of research activities from Europe is not limited to the mentioned companies. HZPC, the largest Dutch seed potato producer, moved some of its research and field trials to Canada in 2021 due to the EU's stringent genome-editing rules. This relocation reflects the industry's response to regulatory challenges within the EU, particularly concerning innovative biotechnologies.

Numerous **public institutions and universities** are actively engaged in advancing research within the field of plant biotechnology. These institutions play a vital role in conducting foundational studies that drive scientific understanding and innovation in the field. Their efforts span a diverse range of objectives, from improving crop yields and creating pest-resistant varieties to exploring innovative approaches such as genome editing. Such initiatives are essential for tackling the challenges of shifting agricultural landscapes, adapting to climate change, and meeting the growing demand for sustainable and resilient crops.

- Public institutions focus on **fundamental research** but often place less emphasis on product development, the final step in the research pipeline. Limited funding and the high costs associated with navigating the EU regulatory approval process for genetically engineered plants further complicate this transition**.** Despite these challenges, international collaborations involving several EU research institutions showcase promising initiatives. For instance, an international consortium, including EU research institutions and the United States Department of Agriculture’s Agricultural Research Service (USDA ARS), successfully developed a genetically engineered plum tree called HoneySweet resistant to the plum pox virus. Field trials have demonstrated the feasibility of coexistence with conventional or organic plum production. However, the final approval for commercialization in EU Member States is anticipated to take several years.

- **Innovative biotechnologies**, such as genome editing, are gaining momentum among public institutions across many EU countries, including France, Germany, Italy, the Netherlands, Belgium, Spain, Hungary, Poland, Sweden, and Czechia, to develop new plant varieties. EU-SAGE, a network of scientists from 134 European institutes advocating for policies supporting genome editing for sustainable agriculture, has created a publicly accessible database of genome-edited crop plants, incorporating data from peer-reviewed scientific publications within and beyond the EU offering a detailed overview of advancements in genome-edited crops. However, the regulatory framework has posed challenges, especially following the July 2018 ruling by the Court of Justice of the European Union, which classified genome-edited plants under the same stringent regulations as GMOs, hindering their commercialization in the EU. Public institutions continue to navigate these evolving complexities while contributing valuable insights to the broader landscape of plant biotechnology. In 2023, the proposal by the European Commission to regulate genome-edited plants signaled a shift in regulatory dynamics. On June 13, 2023, the Italian government converted into law no. 68, with amendments, the "drought" decree of April 14, 2023, to tackle the country's severe water crisis. Specifically, the law provides for urgent provisions on agricultural genetics (art. 9 bis), authorizing field trials of innovative biotechnologies for experimental and scientific purposes until December 31, 2024.
- Overall, public institutions in Europe remain at the forefront of plant biotechnology research, striving to balance scientific exploration with the practical challenges of product development and regulatory considerations. Their work is instrumental in shaping the future of agriculture, fostering sustainability, and addressing global food security concerns. For additional information, please see Part B) Policy e) Innovative Biotechnologies.

The EU has several **public-private partnerships (PPPs)** in plant biotechnology. These partnerships are crucial for fostering innovation, accelerating research and development, and addressing challenges in the plant biotechnology sector. They aim to bring together the expertise, resources, and capabilities of both the public and private sectors to advance scientific knowledge and contribute to the sustainable development of agriculture. These partnerships typically facilitate collaborative research projects, the development of innovative technologies, and the integration of bio-based approaches into various sectors, including agriculture. By combining public and private resources, PPPs in plant biotechnology can accelerate the translation of research findings into practical applications, contributing to the competitiveness of the European bioeconomy. One notable example is the **Circular Bio-based Europe Joint Undertaking (CBE JU)**, a €2 billion partnership between the European Union and the Bio-based Industries Consortium (BIC) that funds projects advancing competitive circular bio-based industries in Europe. CBE JU is operating under the rules of Horizon Europe, the EU's research and innovation program, for the 2021-2031 period. The partnership is building on the success of its predecessor, the Bio-based Industries Joint Undertaking (BBI JU), while addressing the current challenges facing the industry. The partnership was established by the Council regulation (EU) 2021/2085.

Advancements in **medical applications of plant biotechnology** have been notable, with a focus on plant molecular farming for the production of therapeutic proteins and vaccines. Research institutions

and biotech companies across the region are actively involved in developing plant-based expression systems, exploring the scalability, cost-effectiveness, and simplified distribution of plant-based vaccines. The production of pharmaceutical proteins through genetic engineering of plants is also a significant area of investigation. Collaborative efforts, often supported by EU funding programs, foster research initiatives between academic institutions, biotech firms, and pharmaceutical companies. These endeavors adhere to the regulatory frameworks set by the European Union to ensure the safety and efficacy of novel biotechnological products. As the landscape of plant biotechnology evolves, continuous exploration and collaboration within Europe contribute to the advancement of medical applications, providing potential solutions for healthcare challenges. For the most recent and specific developments, it is advisable to consult recent publications, academic journals, and official reports from European institutions and organizations involved in plant biotechnology research.

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 2023.**

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

Table 1 below demonstrates that the area planted with Bt corn in the EU decreased sharply over recent years, dropping to approximately 70,000 hectares in 2024, representing less than 1 percent of the total corn area. This decline reflects a combination of factors, including reduced availability of MON810 seeds due to regulatory and market challenges, as well as an overall reduction in total corn plantings across the EU. **Spain** accounts for 99 percent of the Bt corn area, while **Portugal** represents the remaining 1 percent. MON810 cultivation remains limited to regions where the corn borer poses a significant threat to production, emphasizing its role as a targeted solution in pest-prone areas.

Bt corn produced in the EU is primarily used as animal feed locally. In Spain and Portugal, feed grain elevators typically do not maintain separate production lines for GE and non-GE corn because practically all marketed feed contains GE soybeans as a source of protein, leading to default labeling as 'contains GE products.' However, the corn processing industry utilizes GE-free corn for production intended to enter the food chain. In many cases, this corn is sourced through identity-preserved programs. The food corn processing industry offering better prices is prompting some farmers to choose conventional corn varieties.

Since 2017, both the Czech Republic and Slovakia have discontinued the cultivation of Bt corn (Romania ceased in 2016). Despite the Czech government maintaining a science-based approach to biotechnology and actively conducting field trials, farmers have halted the cultivation of GE corn due to challenges in marketing these products.

Table 1. Bt Corn Area in the EU (ha)

	2019	2020	2021	2022	2023	2024
Spain	107,130	98,152	96,606	67,620	46,327	69,411
Portugal	4,718	4,216	4,313	2,290	1,898	931
Total Bt corn area	111,848	102,368	100,919	69,910	48,225	70,342
Total corn area planted in the EU	8,910,740	9,254,040	9,247,000	8,838,730	8,298,970	8,907,040
Share of Bt corn in total corn area	1.25%	1.14%	1.09%	0.79%	0.58%	0.79%

Source : FAS EU offices and EUROSTAT

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

Since 2015, 19 EU countries have "opted out" of GE crop 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.[1]

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

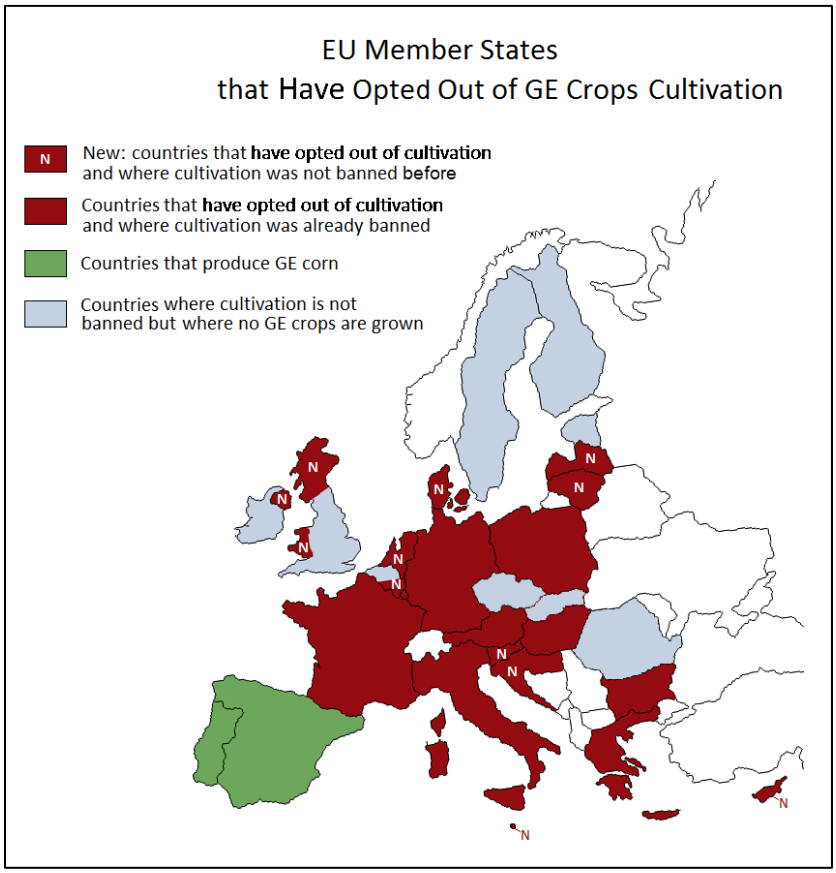
[1] For more information on this Directive, please see EU-28 - Biotechnology Annual Report 2017.

Table 2. Cultivation Bans in the EU + UK

Situation	Countries and regions
 [N = New] Eight 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.	- Eight countries: Croatia*, Cyprus, Denmark*, Latvia, Lithuania, Malta, the Netherlands, Slovenia - 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	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.	- Seven countries: Ireland, Romania, Sweden, Finland, Estonia, Slovakia*, and the Czech Republic - Two regions: Flanders in Belgium, England in the United Kingdom

- Before opting out, Croatia did not have a countrywide ban on cultivating GE crops. However, Croatia's previous law on "GMOs" prohibited the release of GE plants in protected areas and their buffer zones, in areas of organic farming, and in regions important for ecotourism. The law served as a legal tool to exclude most of the country from planting GE plants.
- Denmark and Luxembourg have opted out of cultivating MON810 and three out of the seven varieties of corn that were in the pipeline at that time.
- The coalition agreement of the German government, published in spring 2018, stated that the ban on the cultivation of GE plants (opt-out) would be regulated nationwide, but the legislation has not yet come into force. The plans of the current German Government, elected in December 2021, remain unclear. Some federal states, such as Bavaria in 2019 and Hesse in 2023, have banned the cultivation of genetically modified plants in their federal nature conservation laws.
- Slovakia did not officially opt out, but the legislation significantly discourages the cultivation of GE crops.

Map 1. EU MS + UK that Opted Out of GE Crops Cultivation



Source: USDA/FAS

Some of the MS that have "opted out" of GE crops cultivation have incorporated Directive (EU) 2015/412 into their national law; others MS are still in the process of this action.

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

c) EXPORTS

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

d) IMPORTS

Every year, the EU imports:

- More than 30 million metric tons (MT) of soybeans and soybean meal (including both GE and non-GE products);
- Around 20 million MT of corn and corn-processing byproducts (GE and non-GE);
- Between 4 to 8 million MT of rapeseed and rapeseed meal (GE and non-GE).

As trade data does not differentiate between conventional and GE varieties, the graphs presented in this section include both categories. However, the share of EU imported GE products can be roughly estimated to be around 90 percent for soybean products, about 20 percent for corn, and less than 25 percent for rapeseed based on share of GE crops in total production in the EU's main supplier countries (**Table 3).**

Table 3. Share of GE Crops in Total Production in the EUs Main Supplier Countries

Soy	
Argentina	100%
Brazil	98%
Canada	95%
Paraguay	99%
Ukraine	estimated at 50 to 65% of exports
United States	95%
Rapeseed / Canola	
Australia	20%
Canada	95%
Russia	0%
Ukraine	estimated at 10 to 12% of exports
Corn	
Brazil	88%
Canada	100%
Russia	0%
Serbia	0%
Ukraine	estimated at <1% of exports
United States	92%
Vietnam	3%

Source: ISAAA Report 55 and FAS/Kyiv pre-war estimates (2021)

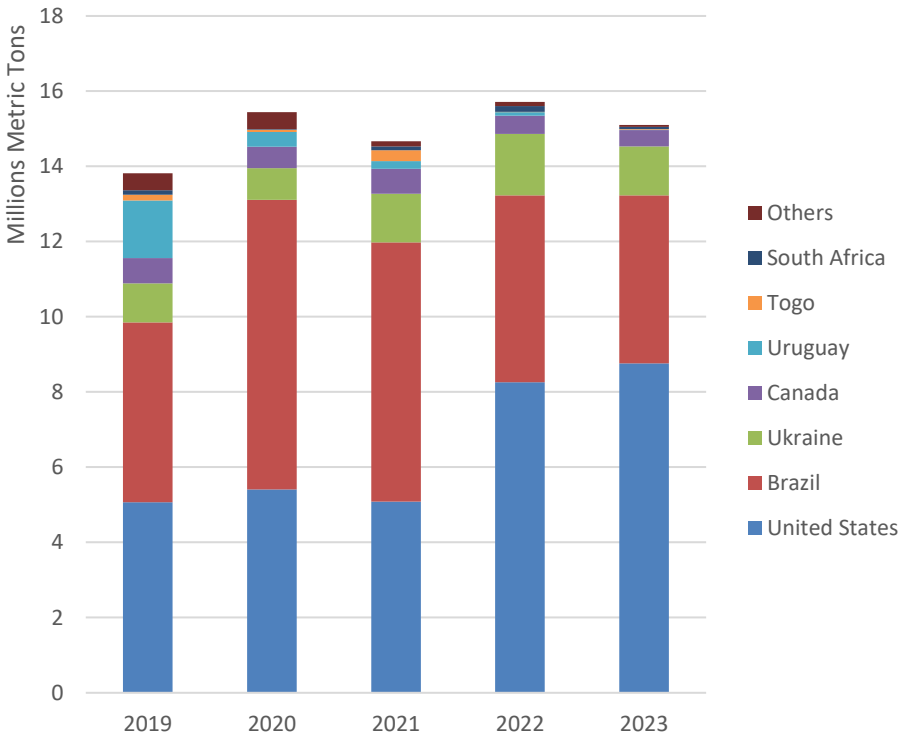
- **The EU imports around 30 million MT of soybean products every year.**

The EU is protein deficient and does not produce enough to meet animal feed demands. Therefore, it must import on average 30 million MT of soybeans and soybean meal every year, used mainly in animal feed.

In the past five years, soybean imports averaged around 14 million MT per year and soybean meal imports around 16 million MT (see **Graphs 1 and 2** below for a breakdown). The EU currently imports around 75 percent of its soybean supply, a slight decrease from previous years, reflecting modest growth in domestic production. This growth is supported by favorable margins, reduced input needs due to soybeans' nitrogen-fixing properties, and steady demand for non-GMO feed and food, although pesticide restrictions in the EU may limit potential yield improvements[2]. The majority of soybeans are crushed by domestic crushing facilities.

The EU's current leading suppliers by volume for soybeans are the United States and Brazil. Its largest suppliers by volume for soybean meal are Brazil and Argentina. The largest users of soybean meal (Germany, Spain, France, Benelux[3], and Italy) are also the main producers of livestock and poultry.[4]

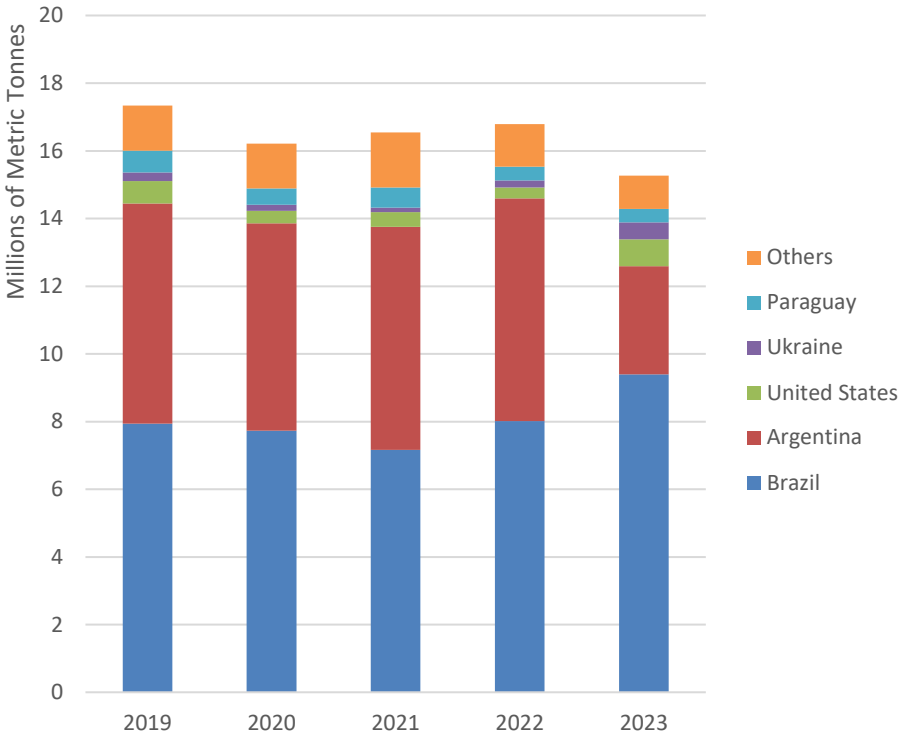
Graph 1. EU Imports of Soybeans (by Calendar Year)



Source: Trade Data Monitor (EUROSTAT)

[2] See the most recent GAIN update on EU oilseeds.
[3] Belgium, the Netherlands, and Luxembourg
[4] As referenced in EU-27 Agricultural Biotechnology Annual 2020.

Graph 2. EU Imports of Soybean Meal (by Calendar Year)



Source: Trade Data Monitor (EUROSTAT)

The demand for non-GE soybean meal in the EU is largely driven by the organic sector, products sold with Geographical Indications, and various GE-free labeling initiatives. This market relies on a combination of domestically produced soybeans and imports, primarily from Brazil and India. As domestic production expands, European non-GE soybean output is expected to grow further in the coming years, contributing to the supply for these specialized markets.

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

Reducing the EU's dependence on imported soybean products has been a key focus of various initiatives aimed at promoting sustainability, self-sufficiency, and alternative protein sources. The EU's current potential for soy production, however, remains modest compared to total animal feed demand, with an estimated 3 million metric tons produced in the 2023/24 marketing year, a small percentage of overall needs.

In November 2018, the European Commission released a report on The Development of Plant Proteins in the European Union which raised concerns about feed and food security, especially in light of global trends. The report emphasized the critical role of plant proteins—such as soybeans, rapeseed, sunflower seeds, and lentils—within the EU agri-food sector. It analyzed the dynamics of supply and demand for these proteins and explored strategies for their sustainable production, considering both economic and environmental factors.

Building on this report, the EU has initiated key measures to reduce its reliance on imported soybean products. Research and innovation funding have been strategically allocated to developing sustainable, high-yielding soybean varieties suited for European climates. This aligns with the objectives outlined in the European Commission's report, which highlighted the need for policy tools and novel proposals to unlock the economic and environmental potential of protein crops in the EU.

In tandem with these initiatives, the Circular Bio-based Europe Joint Undertaking, operating under Horizon Europe, plays a pivotal role in advancing circular bio-based industries within the EU. This initiative contributes significantly to the development of sustainable and locally sourced protein alternatives, aligning with the broader goals of promoting self-sufficiency and environmental sustainability in the region's protein production landscape.

However, the 2018 report did not address the potential impact of EU restrictions on agricultural biotechnology, which could impede progress in breeding more resilient and climate-adapted protein crops. While discussions on a European protein strategy have been ongoing for years, tangible progress has been limited. In response, the European Economic and Social Committee (EESC) published an an opinion in 2022, reaffirming the importance of enhancing EU protein autonomy while addressing sustainability, food security, and supply resilience.

The Common Agricultural Policy under the new strategic plans (2023 – 2027) includes measures to support protein crops in the EU. These include a 25 percent increase in coupled income support for protein crops compared to 2022, promoting carbon storage, reducing greenhouse gas emissions, and incentivizing sustainable farming practices. The CAP recognizes the importance of protein crops in achieving environmental and climate objectives, aligning with the EU's broader goals for sustainability and self-sufficiency.

In line with these efforts, several EU member states have called for an EU-wide plant protein strategy to enhance domestic production and reduce reliance on imports. These countries emphasize the role of plant-based proteins in strengthening environmental resilience and ensuring food security across the region.

Several EU countries also subsidize local non-GE protein production:

- Germany: In 2023, Germany committed €8.6 million to its protein crop strategy, an increase of €3 million from 2022. This funding is part of a broader commitment, as the federal government has already allocated €41.6 million to this strategy, with continued support for protein crops through 2027.
- Spain: From 2023 to 2027, Spain will allocate €51 million annually to support protein crops, an increase over the funding from the previous 2014–2020 period.
- The Donau Soya Organization, a non-governmental association supported by the Austrian government, promotes non-GE soybean production in the Danube region, which spans Austria, Bosnia and Herzegovina, Bulgaria, Croatia, Germany, Hungary, Romania, Serbia, Slovakia,

Slovenia, and Switzerland. The region has the potential to produce 4 million metric tons of soybeans.

- Since July 2017, fifteen 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.

In October 2024, the Joint Research Centre (JRC) the European Commission's science and knowledge service providing independent scientific advice and support to European Union (EU) policy, released a report emphasizing the need for a comprehensive approach to improving EU protein sustainability, advocating for both supply-side and demand-side measures. Key findings indicate that transitioning to more plant-based diets, alongside better livestock management, could reduce GHG emissions and nitrogen surplus, while lowering dependence on imported feed protein. The report also highlighted potential economic challenges, forecasting a reduction in agricultural Gross Value Added (GVA), underscoring the importance of coordinated policy efforts to meet environmental, economic, and societal goals.

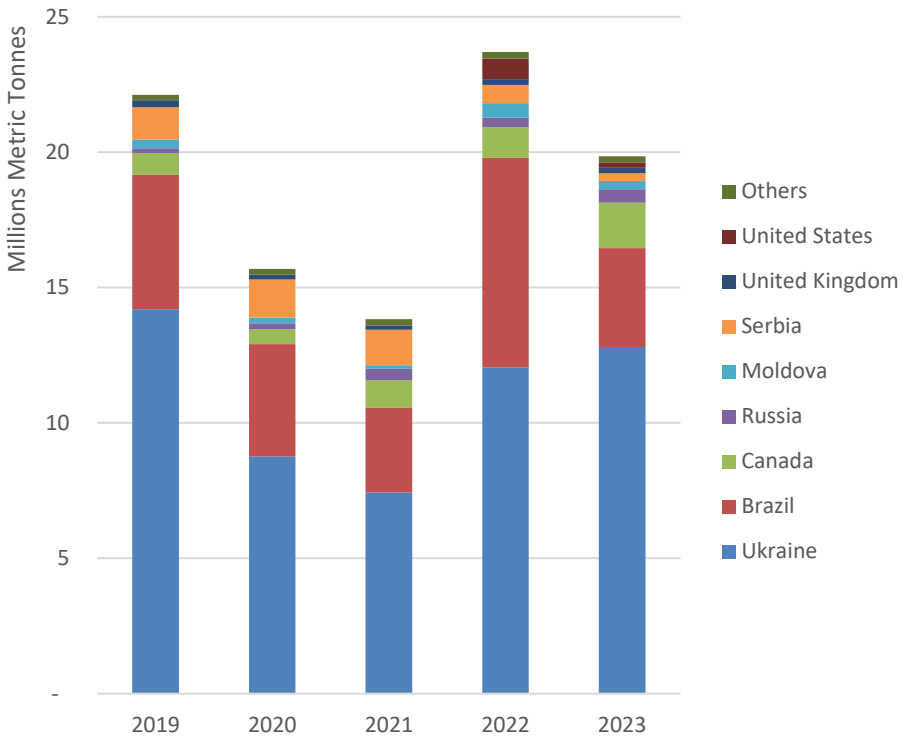
For more information, please see the European Commission's website.

- **The EU imports between 15 to 23 million MT of corn per year.**

Over the past five years, corn imports averaged 19 million MT. The EU currently imports about 20 percent of its total corn supply. Based on share of GE crops in total production in the EU's main supplier countries, it can be estimated that just over 20 percent of total corn imports are GE. The largest importers of corn (Spain, Benelux, Italy, and Portugal) have large livestock and poultry sectors but are limited in their domestic grain production.[5] In the past five years, Ukraine has been by far the EU's major supplier of corn; it accounted for more than 60 percent in 2023.[6] GE crop production is not officially allowed in Ukraine but there are reports of unregistered GE production of corn, rapeseed, and soybeans[7].

[5] Additional information on EU's grain market can be found in the EU-27 Grain and Feed GAIN Annual Report 2024.
[6] EUROSTAT
[7] Additional information can be found in the last GAIN Ukraine Biotechnology and Other New Production Technologies Report.

Graph 3. EU Imports of Corn (by Calendar Year)



Source: Trade Data Monitor (EUROSTAT)

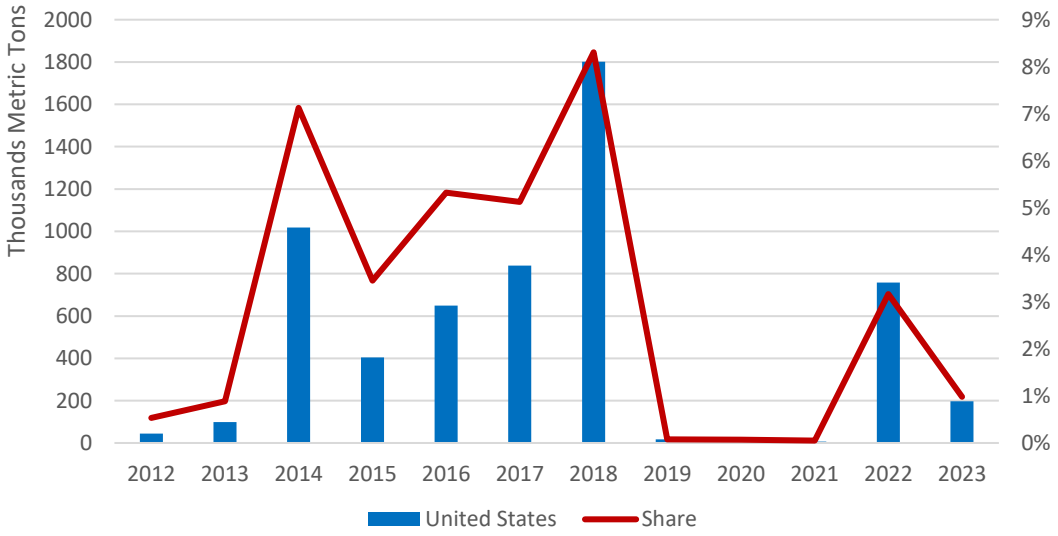
Over the past 10 years, on average, the United States represented 3 percent of total EU imports of corn (see **Graph 4**). The beginning of GE corn plantings in the United States in 1998 resulted in a drastic decline in U.S. exports to the EU. This is due to the lag of GE traits approved in the EU compared 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 a result of multiple transgenic events[8] in one variety. These varieties are referred to as stacks. The approval process for stacked GE traits in the EU is particularly complex. Each transgenic event within a stack must be individually assessed and authorized before the stack itself can be evaluated. This sequential and resource-intensive approach not only delays approvals but also increases regulatory uncertainty for exporters. Consequently, the challenges associated with asynchronous approvals and the stringent EU regulatory framework continue to significantly limit U.S. corn exports to the EU market.

Imported U.S. corn is primarily used for animal feed and bioethanol production, with Spain serving as the EU's primary importer. In MY 2017/18, Spanish imports of U.S. corn recovered briefly but ceased in June 2018 due to a 25 percent retaliatory EU tariff imposed in response to U.S. steel and aluminum tariffs. However, these imports resumed in MY 2021/22 following the phase-out of retaliatory duties and the need to replace Ukrainian corn supplies disrupted by Russia's invasion.[9]

[8] A transgenic event is the DNA sequence incorporated into the target genome.
[9] Please see the USDA EU Grain Summer Update 2024 for more info

In MY 2022/23, access to Ukrainian corn and an abundance of Brazilian corn significantly reduced U.S. exports to negligible levels. According to the USDA's Export Sales Report, over 500,000 MT of U.S. corn were committed for export to the EU in MY 2023/24. As of November 20, 2024, the current marketing year (2024/25) shows 221.1 thousand MT in outstanding sales to the EU.

Graph 4. EU Imports of Corn from the United States and Share on Total (by Calendar Year)



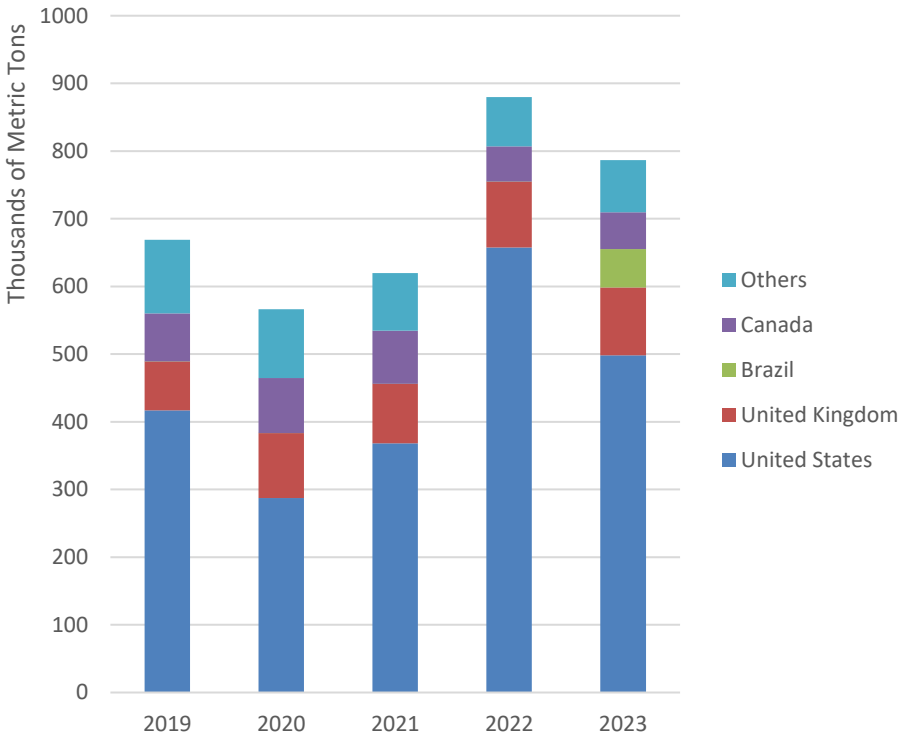
Source: Trade Data Monitor (EUROSTAT)

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

In 2022, the EU imported about 800,000 MT of Distiller's Dried Grains with Solubles (DDGS) and Corn Gluten Feed and Meal (CGFM; see **Graph 5**).[10] The share of GE products of total imports is estimated at 80 percent. The United States is the main supplier of DDGS and CGFM to the EU. The volume of imports varies from year to year depending on prices and on the pace of EU approvals of new GE corn varieties.

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

Graph 5. EU Imports of DDGs and CGFM (by Calendar Year)



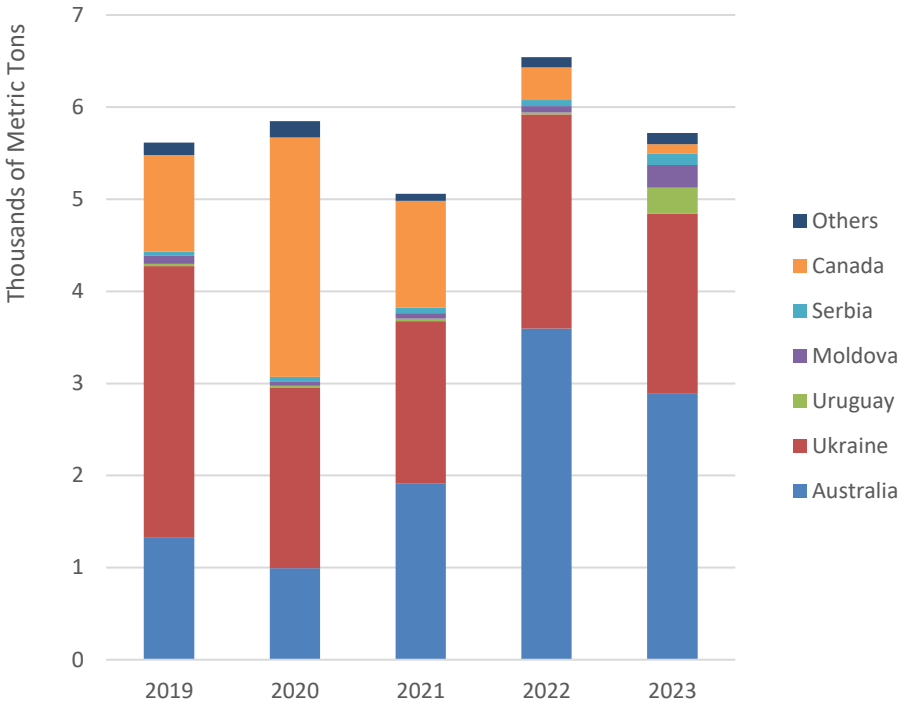
Source: Trade Data Monitor (EUROSTAT)

- **The EU imports between 5 to 7 million MT of rapeseed products every year.**

In the last five years, the EU imported on average 5.7 million MT of rapeseed and around 600,000 MT of rapeseed meal per year (see **Graphs 6 and 7**). The share of GE products of total imports is estimated at less than 25 percent. The three major suppliers of rapeseed to the EU (Australia, Ukraine, and Canada) grow GE rapeseed (see **Table 3** above). Russia is the main rapeseed meal supplier to the EU; however, Russia does not grow GE rapeseed.

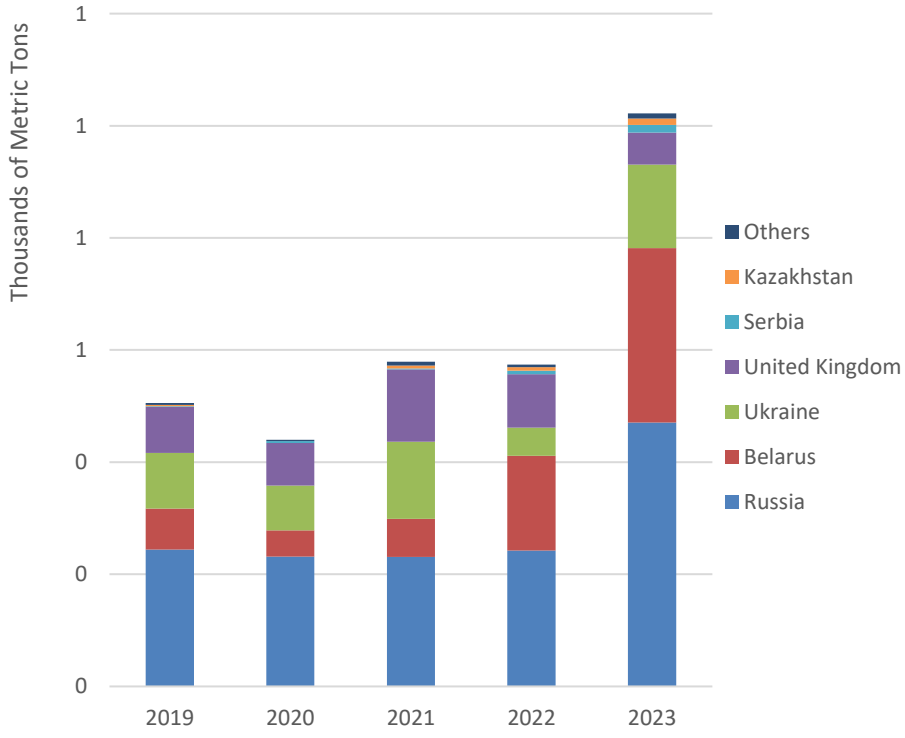
Although the EU is the world's largest producer of rapeseed, local demand exceeds domestic supply and large quantities of rapeseed are imported for crushing. Rapeseed meal is used for animal feed in the livestock sector.

Graph 6. EU Imports of Rapeseed (by Calendar Year)



Source: Trade Data Monitor (EUROSTAT)

Graph 7. EU Imports of Rapeseed Meal (by Calendar Year)



Source: Trade Data Monitor (EUROSTAT)

e) FOOD AID

The EU provides food aid in the form of food products, money, vouchers, equipment, seeds, or veterinary services. The Commission's Humanitarian Aid and Civil Protection department responsible for food aid. 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, which does not include GE products.

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 have been banned for import and processing.
- Bulgaria has a ban on sales of foods containing GE products in schools.

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

In both cases, the European Food Safety Authority (EFSA) must conclude during the risk assessment phase of the authorization process that the product in question is as safe as a comparable conventional variety. Once EFSA issues a positive opinion, a political decision is taken by the MS on whether 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 in the "GMO" 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 "GMOs."

The responsible government ministries in the MS 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 organisms (based on 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 unauthorized GE organisms that might arrive or might be present in the EU.
- **Self-tasking activities:** On its own initiative, the panel identifies scientific issues related to the risk assessment of GE organisms that require further attention. For instance, the panel has produced a scientific report on the use of animal feeding trials in the risk assessment of GE organisms.

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 4.7 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. This is due in part to the strong emotional and ideological stance on biotechnology taken by EU consumers and anti-biotech groups pressuring European Parliament representatives. Therefore, 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. Argentina, Brazil, Canada, and the United States 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) Marketing, a) Public/Private Opinions.

On December 1, 2019, the European Commission, led by Ursula von der Leyen, began its first mandate with the European Green Deal as its cornerstone initiative. This ambitious framework sought to implement transformative changes across EU policies, notably through the Biodiversity[11]and Farm to Fork[12] strategies. These strategies were designed to achieve ambitious environmental goals, including reductions in pesticide use and a shift towards more sustainable farming practices.
However, by 2024, many of the policies outlined in these strategies had been significantly diluted, postponed, paused, or canceled due to a combination of economic pressures, geopolitical challenges, and opposition from key stakeholders, including certain Member States and industry groups.

As von der Leyen embarks on a second mandate, political discourse is intensifying around how the EU can balance its environmental ambitions with fostering a competitive edge for European farmers. This debate is particularly relevant for plant biotechnologies, as a restrictive regulatory framework risks hindering innovation and leaving EU agriculture lagging behind global counterparts that are rapidly adopting advanced technologies.

- **EFSA's Transparency Initiative**

Regulation (EU) 2019/1381 of June 20, 2019 on the transparency and sustainability of the EU risk assessment in the food chain is an amendment to the General Food Law and entered into force on March 27, 2021. The regulation's goal is to ensure more transparency, increase the independence of studies, and strengthen the governance of EFSA as well as developing comprehensive risk communication. The regulation has an influence on eight sectoral legislative acts across the agri-food industry, including the

[11] Please read more on the EU Biodiversity Strategy here: https://www.fas.usda.gov/data/european-union-eu-member-states-adopt-their-position-biodiversity-strategy.
[12] Please read more on the EU Farm to Fork Strategy here: https://www.fas.usda.gov/data/european-union-eu-member-states-adopt-official-position-farm-fork-strategy.

"GMO" Directive 2001/18/EC and Regulation (EC) No 1829/2003. On March 9, 2021, the Commission published the following new guidance document: COMMISSION NOTICE on the submission of notifications under Articles 13 and 17 of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms.

Most stakeholders welcome greater transparency and additional resources for EFSA to conduct their reviews but applicants have shared a few concerns. Most of these surround the timing of disclosure of scientific information and studies from the EFSA review, and the manner that this information is made accessible, such as through a web portal requiring registration for access or an open access database accessible globally. The legislation calls for EFSA to pro-actively disclose non-confidential data associated with EFSA applications as soon as EFSA has considered an application valid or admissible. This disclosure happens at a very early stage of the risk assessment process and the industry has concerns that this could lead to false interpretations of scientific data by non-scientists and therefore politicize EFSA's outcome before EFSA's assessment is complete.

The legislation also calls for EFSA to advance a risk communication strategy to better enhance public understanding of risk analysis and management, which may help depoliticize authorizations of GE products. For more information, please see the GAIN report on its implementation and the Commission's website.

- **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. 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.

On January 31, 2020 the Rapporteur for the EP's Committee of Legal Affairs (EP JURI) Jozsef Szajer (European People's Party, Hungary) submitted a draft report proposing 11 amendments to the Comitology Proposal from 2014. The amendments are mostly aimed to inform the EP and the public of the risk management process, as well as the rationale for specific votes taken by the MS. Five other EP Committees adopted opinions on the file, which will feed into the final report of the JURI Committee. These Committees are: The Committee on International Trade (INTA), the Committee on Agriculture and Rural Development (AGRI), the Committee on Industry, Research and Energy (ITRE), the Committee on Environment, Health and Food Safety (ENVI), and the Committee on Constitutional Affairs (AFCO). A European Parliament Plenary vote took place on December 16, 2020. The work in

the Council is still at a standstill. Industry stakeholders and Post analysis anticipate the majority of MS will not take up reform as a legislative priority.

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 (the "opt-out" Directive).

- 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 process preferring instead to apply for food and feed approvals only.

- **Authorization for placing biotech events on the market for food or feed use**[13]

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

- An application[14] 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.

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

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

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

- EFSA 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 provided to the PAFF after March 1, 2011, are subject to the procedural rules outlined in the Lisbon Treaty. Under these rules, in the case of no qualified majority in favor of the draft decision, the Commission may either submit an amended draft to the Committee or submit the original draft to the Appeal Committee (comprised of officials from the MS). If the Appeal Committee has neither adopted the draft decision nor opposed it by qualified majority within two months from the date of referral, it *may* be adopted by the EC. The post-Lisbon procedural rules give more discretion to the Commission. Previously, the Commission was obliged to adopt the draft decision. Under the new rules, the Commission has the option to adopt or not.

Authorizations granted are valid throughout the EU for a period of ten years. They are renewable for ten-year periods on application to the EC by the authorization holder and at the latest one year before the expiration date of the authorization. This application for renewal of authorization must include, among other items, any new information which has become available regarding the evaluation of safety and risks to the consumer or the environment since the previous decision. Where no decision is taken on the renewal before the authorization's expiration date, the period of authorization is automatically extended until a decision is taken.

For the list of approved products, see Part B) Policy, b) Approvals.

- **Authorization for cultivation of biotech events**[15]

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.[16]

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

[16] 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.

- Using the information exchange system that has been set up by the EC, the competent authorities of the MS send to the Commission, within 30 days of receipt, a summary of each notification received.
- The Commission must forward these summaries to the other MS within 30 days following their receipt.
- Those MS may present observations through the Commission or directly within 30 days.
- The national competent authority has 45 days to evaluate the other MS comments. If, as is typically the case, these comments are not in line with the national competent authority's scientific opinion, the case is brought to EFSA which has three months from receipt of the documentation to give its opinion.
- The Commission then presents a draft decision reflecting EFSA's opinion to the Regulatory Committee for vote.
- As is the case for placing biotech events on the market for food and feed use, draft decisions that have been put to the Regulatory Committee after March 1, 2011, are subject to the procedural rules outlined in the Lisbon Treaty and similar to for the placing on the market of biotech events for food and feed use as explained in the previous sections above.

For the list of approved products, see Part B) Policy, 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 (the opt-out Directive). More information about this Directive is available in Part A) Production and Trade, b) Commercial Production.

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

See Part A) Production and Trade, f) Trade Barriers.

vi. Timeline followed for approvals

New GE crops are entering the global marketplace 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.

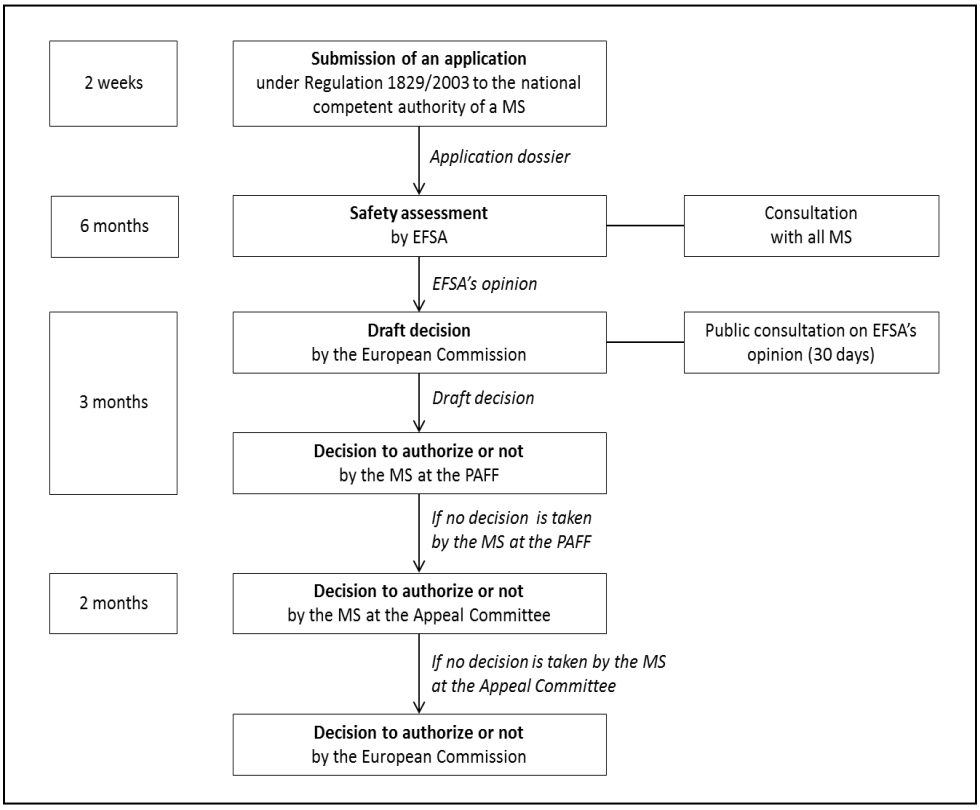
This represents a problem for commodity trading companies, as it limits their sourcing options and increases the risk in their operations with those countries where not-yet approved events are grown. Shipments of agricultural commodities destined for the EU have been rejected when traces of such events 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, the average approval time for a new product from submission to approval over the past five years (2020–2024) is 5.2 years, which is longer than in other regions. In comparison, the approval process takes about two years in Canada, Brazil, and the United States, and approximately three years in South Korea. The main bottleneck in the EU’s lengthy approval process remains with EFSA. Despite over 25 years of globally recognized safe use of genetically engineered (GE) products and EFSA's extensive experience in regulating them, the average time for EFSA to deliver opinions on six new products risk-assessed in 2024 was approximately 2.9 years. The duration of these assessments depends significantly on the product's complexity: less complex products are typically evaluated more quickly, averaging around 2 years, while products that involve unconventional data packages, such as innovative products or those that do not meet typical regulatory requirements, can take 5 to 6 years. This disparity underscores the challenges faced by developers in introducing new and innovative products to the market.

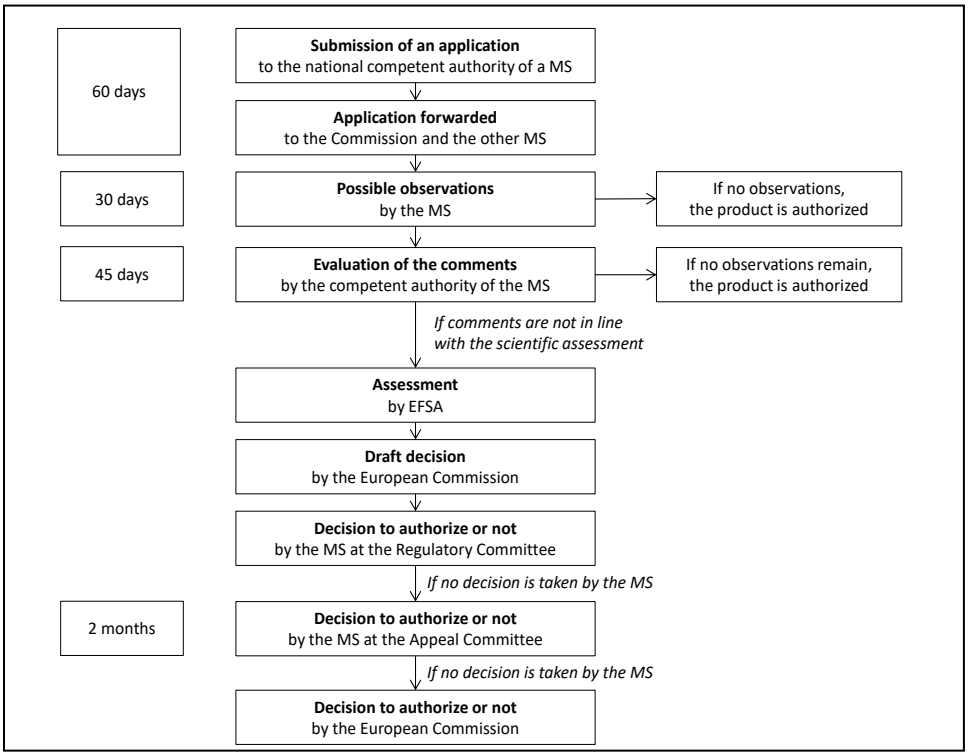
The very first step of applying for approval of GE products in the EU usually takes longer than six months. Applicants submit their GE dossier to EFSA and then wait between a few weeks and about two years – exceptionally up to four years – for EFSA to review the application and perform a “completeness check.” Upon successfully passing EFSA’s “completeness check,” the six-month clock begins. EFSA working groups then review the dossier to undertake environmental, human and animal-health safety assessments; at any time, the working groups 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.

Chart 1. EU Approval Process for Food and Feed



Source: USDA/FAS

Chart 2. EU Approval Process for Cultivation



Source: USDA/FAS

Over time, more biotech applications have been submitted each year 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[17]) 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.

Following this case, the EU more closely approached their timeline. This increased scrutiny and pressure from stakeholders have likely contributed to a greater focus on efficiency and adherence to statutory deadlines within the GMO authorization process. However, the complexity of the regulatory framework, coupled with public concerns and political considerations, are still leading to delays and significant uncertainties in decision-making, which can discourage innovation and hinder the development of new biotechnological solutions. More details can be read at the end of section b) Approvals.

b) APPROVALS/AUTHORIZATIONS

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

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 several varieties of corn, cotton, soybean, rapeseed, sugar beet, and microorganisms. An authorization decision is valid for 10 years, and if an application is active with EFSA, the authorization continues until there is a new authorization.

In 2023, the Commission approved 13 products, while in 2024, 9 products received authorization:

- 2 products approved in February
- 3 products approved in July
- 4 products approved in October

The EC approves GE events after they have completed the EU's comprehensive "GMO" authorization procedure. Products produced from authorized GE events are subject to the EU's strict labeling and traceability rules. Despite the challenges of the EU's long and complex approval process for biotech products, these authorizations are a positive sign that the Commission is still following EU regulation.

a) [17] The agricultural biotechnology **portfolio** was taken out of EuropaBio, and it now lies with CropLife Europe.

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

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 most countries); this policy slows the pace of approvals for corn and may start to slow the approval process for soybeans as stacked soybeans become more common.

d) FIELD TESTING

Any entity intending to introduce GE crops into the environment through field trials for experimental purposes must first receive authorization from the relevant national authority in the MS where the release or field trial is planned. Field trials are permitted in eleven MS[18] and the United Kingdom (UK). The primary challenges for conducting field trials include recurrent disruptions by activists, a cumbersome authorization process, and unappealing investment prospects for seed companies.

> Within the EU, **experimental** field trials for GE crops are referred to as the "deliberate release into the environment of plants GMOs for any other purposes than placing on the market (experimental releases)." Field trials are not considered "confined release," and they are not associated with the "GMO" authorization process of placing products on the market.

The European Commission's Joint Research Center (JRC) maintains a list of the notifications of these field trials submitted to EU countries' Competent Authorities under Part B of Directive 2001/18/EC both for GE plants and for GE organisms other than plants. Some public institutions that conduct laboratory research enter into partnerships with private companies to carry out field trials in other countries. The number of field trials actually conducted may be lower than the number of notifications. A report on the management of field trials can be found here.

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

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

e) INNOVATIVE BIOTECHNOLOGIES [19]

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 30 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 genetic engineering. In addition, most of these techniques have the 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 MS have 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 Court of Justice of the European Union (ECJ) judged that organisms created through many newer genome editing techniques are to be regulated as "GMOs" according to the EU legislation. 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.

Following the ECJ's ruling, the EC requested the Joint Research Centre (JRC) of the European Commission and the European Network of GMO Laboratories (ENGL) to publish a report on the "detection of food and feed plant products obtained by new mutagenesis techniques." As expected, the report found that "several issues with regard to the detection, identification and quantification of genome edited products cannot be solved at the present time." For example, it is impossible to prove that a single nucleotide mutation did not occur naturally or via traditional mutagenesis.

On November 8, 2019, the Council adopted without debate a decision requesting that the European Commission submit, by April 30, 2021, a study on the status of new genomic techniques in the EU, as well as a proposal or other measures required as a follow-up to the study. The proposal must be accompanied by an impact assessment. Supplementary statements from some MS have been made public: Cyprus, Hungary, Latvia, Luxemburg, Poland, and Slovenia stated that the current level of protection should be maintained; the Netherlands and Spain stated that the study needs to "address the adequacy, efficiency and consistency" of the current legal framework; the Netherlands underlined the urgency of the steps to be undertaken; and Sweden added that the study should include cost estimates.

The Commission collected input from MS and stakeholders via questionnaires to assist in the study. The stakeholders are listed here: https://ec.europa.eu/food/plant/gmo/modern_biotech/stakeholder-consultation_en. European stakeholder associations in favor of exempting innovative biotechnologies from the EU's "GMO Directive" also provided ample input.

[19] "Genetic Engineering" means transgenesis. "Innovative biotechnologies" is a synonym of New Breeding Techniques (NBTs), New Genomic Techniques (NGTs), or genome editing and excludes transgenesis.

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

On April 29, 2021, the European Commission published its report titled, "Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16."[20] While the Court of Justice ruling stated that products of genome editing fall under the "GMO Directive" the Commission's study concluded that this Directive is not "fit for purpose" for these newer biotechnology products and a targeted policy action was needed. The study says that genome editing can contribute to the objectives of the European Green Deal's F2F and Biodiversity Strategies.

On September 24, 2021, the European Commission published its policy initiative or roadmap to develop "legislation for plants produced by certain new genomic techniques (NGTs)". This initiative will propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. The policy roadmap is based on the findings of the Commission's study. The publication of the roadmap is the first step in the legislative process with the final proposal scheduled to be published in quarter two of 2023.

The roadmap began with a 4-week feedback period, which ended on October 22, 2021, and collected over 70,000 responses. Then, on April 29, 2022, the Commission launched a public consultation period to seek additional views from stakeholders on this policy initiative. The public consultation was accessible for 12 weeks and closed on July 22, 2022, collecting views from the public and stakeholders to support the preparation of an impact assessment for the initiative. The consultation received about 2,300 comments covering topics like Risk Assessment for NGTs and other important aspects related to sustainability, traceability, and labeling of products of these newer techniques.

An important contribution to the debate is the EFSA study[21] on the applicability of its current "GMO" hazard assessment guidelines to regulate plant products created with some types of genome editing. EFSA published its opinion on November 24, 2020. In its findings, EFSA determined that not all of its guidelines apply to certain products derived by genome editing, particularly those that do not contain DNA from another species. The opinion is at least a partial recognition, by the EU's flagship food safety authority, that certain genome-edited products are fundamentally different from those produced by transgene-introducing techniques. Per the EFSA executive abstract, the "GMO" Panel did not identify new hazards specifically linked to the genomic modification produced via SDN-1, SDN-2 or ODM [i.e., genome-editing techniques that do not result in a product with DNA from another species].

Following the ECJ's decision mentioned above, **France** notified the European Commission of its intention to delist in-vitro random mutagenesis with chemical or physical agents to comply with the French Council of State's February 2020 ruling. However, this ruling is not in line with the most recent European Commission's decision, and should France go ahead with its Council's advice, there would be a risk of European sanctions as this may not be compliant with the single market, as FAS/Paris reported.

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[20] See GAIN.
[21] EFSA opinion: https://www.efsa.europa.eu/en/efsajournal/pub/6299?

After a request for clarification from the French State Council, the First Advocate General of the Court of Justice of the European Union Maciej Szpunar ruled on October 27, 2022, that random mutagenesis applied in vitro must be excluded from the scope of EU law concerning deliberate release into the environment of GMOs.

On October 20, 2022 the European Food Safety Authority (EFSA) published a statement on risk assessment criteria for plants produced by targeted mutagenesis, cisgenesis, and intragenesis. The statement follows a request for technical guidance by the European Commission in the preparation for its legislation for plants produced by certain new genomic techniques. Recognizing that some plants produced with new genomic techniques may have only small changes that might also occur in nature or through conventional breeding while others may contain multiple and extensive modifications that may be similar to those in plants produced by established techniques of genetic modification, EFSA seems to suggest a mandatory case-by-case GMO-like risk assessment process. The step by step proposed scenario would need to evaluate and characterize the genetic modification introduced in the recipient plant. In case no alteration of the host plant's gene has happened, a history of safe use (HOSU) criterion is suggested.

On July 5, 2023, the European Commission officially adopted its new proposal to regulate plants obtained by certain new genomic techniques (NGTs) such as genome editing and the food and feed produced from them. The Commission's proposal was presented as part of the 'Sustainable use of key natural resources' package, designed to strengthen the resilience of EU food systems and farming and thus contributing to the goals of the European Green Deal's Farm to Fork Strategy.

The scope of the proposal are plants produced by NGTs (targeted mutagenesis and cisgenesis, including intragenesis), products containing or consisting of these plants and food and feed containing, consisting or produced from these plants. The proposal sets specific new requirements for NGTs plants but specifies that they will still fall under the overarching legal framework of the current GMOs Directive Regulation (EC) No 1829/2003 and Directive 2001/18/EC.

The general objectives of the proposal are to:

- Maintain a high level of protection of human and animal health and of the environment, in accordance with the precautionary principle.
- Enable the development and placing on the market of plants and plant products contributing to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies.
- Ensure the effective functioning of the internal market in NGT plants and products and food and feed containing, consisting or produced from NGT plants, and enhance the competitiveness of the Union agri-food sector at the Union and global levels, including a level-playing field for operators.

Specifically, the proposal has the goal to release and place on the market a wide range of NGT plants and the food and feed they produce that are as safe as their conventional counterparts without

unnecessary regulatory burden, and to encourage a large number of developers to bring new traits to market that can contribute to a more sustainable agri-food system.

The Commission proposes two categories of NGT plants:

- **Category 1** – NGT plants that **could** also occur naturally or be produced by conventional breeding techniques.

- **Category 2** - NGTs plants that **could not** occur naturally or be produced by conventional breeding techniques.

Particularly, to define the two categories and establish a verification procedure for competent authorities, the proposal sets out criteria on the type and extent of genetic modifications that can be observed in nature or in organisms obtained with conventional breeding techniques, including thresholds for both size and number of genetic modifications.

Category 1 NGT plants will be treated like conventional plants and therefore exempted from the requirements of the GMO legislation. This means that for these plants no risk assessment has to be made and they can be labelled in the same way as conventional plants. The proposal indicates that the Commission will also establish a public database listing the status of category 1 NGT plants.

Category 2 NGT plants will be treated like GMOs following the authorization procedure required in the GMO framework. GMO labelling will be required. The proposal indicates an intent to offer regulatory incentives for Category 2 plants that have a sustainability benefit, though notably it excludes herbicide tolerance traits from these incentives.

NGTs plant reproductive materials (PRM) for both categories will be subject to labelling requirements and will not be allowed in organic farming. The possibility for Member States to restrict or prohibit cultivation in their territory of "GMOs" pursuant to Directive 2001/18 will not apply to NGT plants. The publication of the proposal initiates the beginning of a lengthy legislative process. The adopted act was open for feedback for a period of 8 weeks (07 July 2023 - 05 November 2023). All feedback received was summarized by the European Commission and presented to the European Parliament (EP) and Council which, as co-legislators, will have to assess the proposal. Amendments to the legislative proposal need to be done separately by the Parliament and Council; however, negotiations will eventually occur to find institutional agreement before the proposals are adopted as official EU law.

In the EP, independent committees, ENVI and AGRI, conducted thorough analyses, hearings, and stakeholder consultations. ENVI, serving as the lead, assessed the proposal's impacts on environmental sustainability, consumer safety, and ethical considerations, while AGRI focused on implications for farmers, rural communities, and the agricultural sector. On February 7, 2024, with 307 votes out of 611 members present, the EP voted in favor of the Commission's proposal while introducing a series of concerning amendments, including requiring labeling across all NGT products and a potential ban on patentability. A ban on patentability was not part of the EC proposal, but the EC expressed an intention

to assess the impact of patenting plants and report on the findings by 2026. This vote solidifies the Parliament's position, and the process now awaits the Council's response before trilogue negotiations can unfold, which will also take time.

The Agriculture and Fisheries (AGRIFISH) committee within the Council of the EU, with technical support from the Working Party on Genetic Resources and Innovation in Agriculture, is responsible for reaching a Council position on the proposal. The Spanish Council Presidency (July – December 2023) aimed to achieve consensus during their term but failed to do so.

At the start of the Belgian Presidency of the Council of the EU in January 2024, Agricultural Minister Clarinval prioritized advancing the NGT proposal as Chair of AGRIFISH. The Presidency built its strategy on member states' positions from the December 2023 AGRIFISH meeting under Spain's leadership. Key demands from member states included stricter risk assessments, the ability to restrict cultivation of plants with complex DNA modifications, and enhanced labeling and traceability requirements. A ban on patenting NGT crops emerged as a contentious issue, with Poland leading a blocking minority advocating for the ban, while other states opposed it.

To secure consensus, the Belgian Presidency proposed banning patenting for Category 1 plants, seeking to align with Poland's demands while maintaining broader member state support. Despite this effort, achieving a 65 percent qualified majority remained elusive. Discussions stalled as Poland and other countries maintained their opposition, leaving the proposal unresolved at the end of the presidency semester.

Hungary holds the Council Presidency for the second half of 2024, but little progress is expected on the NGT proposal due to the country's longstanding opposition to plant biotechnology. Poland is set to take over the Presidency in January 2025, and while political hurdles will likely persist, there may be attempts to reach a consensus. The focus will then shift to Denmark, which will take on the Presidency in July 2025. Much hope rests on Denmark's leadership to move the proposal forward and kickstart trilogue negotiations.

After its adoption, the proposal would enter into force on the 20th day following the publication in the Official Journal of the European Union. It would apply two years after the entry into force.

Until these discussions make headway, genome-edited plant products will remain regulated under the EU's GMO Directive, despite posing minimal or no risk to human, plant, or animal health. The ongoing regulatory delays also hinder the alignment of global regulations, limiting scientific progress that could support farmers in combating climate change and improving food security.

- **Acceptance of NGTs varies across EU countries.**

Official positions of each MSs governments are not always available or unambiguous as the topic is often controversial:

During the past five years, the **Dutch** Government's position towards the application of NGTs has been roughly in line with the content of the current European Commission (EC) proposal. Dutch support for NGTs is based on their role as an important propagation tool for the Dutch plant breeding sector and as a vital technology to improve the sustainability of agricultural production systems.

The positions of the **Swedish, Danish, and Finnish** governments towards innovative plant biotechnologies are generally supportive, particularly when such methods are used to safeguard local and regional varieties, maximize resource efficiency, and create crops more resilient to variable and extreme climates.

In **Germany**, reactions from leaders within the ruling coalition to the European Commission's NGT proposal have been mixed, demonstrating a continued lack of consensus within the government. Besides the contentious issue of patent law, a repeated concern voiced by politicians and NGOs opposing the proposal is freedom of consumer choice. Critics argue that consumers would not be able to decide whether to consume genetically modified products if the new law is adopted. Furthermore, they highlight potential conflicts between the proposed regulation and the precautionary principle set out in Article 191 of the Treaty on the Functioning of the European Union (TFEU).

Hungary's government continues to emphasize the importance of maintaining its GE-free status. At the same time, the potential of innovative technologies like NGTs is regarded by key agricultural stakeholders as a means to ensure competitiveness and foster agricultural innovation and sustainability.

At the September 2022 AGRIFISH informal meeting of EU agriculture ministers, former **Czech** Minister of Agriculture Zdenek Nekula stated that the EU plays an important role in global sustainable agriculture and food production. He identified NGTs as an important and affordable tool and emphasized the need to update the current EU legislation.

The **Romanian** Ministry of Agriculture initially supported the European Commission's NGT proposal. However, by October 2023, it had shifted its position, raising concerns about the preservation of local seed varieties, seed patentability, the future of Romanian grain and oilseed exports, as well as issues of traceability and labeling.

Although **Slovakia's** Ministry of Agriculture and Rural Development supports the use of innovative technologies in agriculture, its primary focus remains on precision farming.

Spain is committed to adapting the risk assessment framework for NGTs while maintaining high safety standards and reasonable coexistence rules. Sustainability considerations, it argues, should be approached holistically rather than exclusively based on the type of technology used. During its Presidency of the EU Council in the second half of 2023, Spain prioritized advancing NGT discussions in Council meetings following the release of the EC's NGT proposal on July 5, 2023.

Despite **Italy's** historical opposition to genetically engineered (GE) products, its government, agricultural associations (Coldiretti, Confagricoltura, and CIA), agri-food industry players, and scientists

have shown growing support for NGTs. On June 13, 2023, the Italian government enacted Law No. 68, which included urgent provisions for agricultural genetics, authorizing field trials of innovative biotechnologies for research until December 31, 2024. Following the destruction of an open-field trial of gene-edited rice in June 2024, this authorization was extended to December 31, 2025.
Italian stakeholders, including Minister Francesco Lollobrigida, stress the importance of NGTs in developing productive, climate-resilient, and disease-resistant crops, while accelerating modifications that occur naturally, without introducing foreign DNA. Senator and scientist Elena Cattaneo proposed removing the temporary deadline, arguing that longer-term planning is essential for effective research.

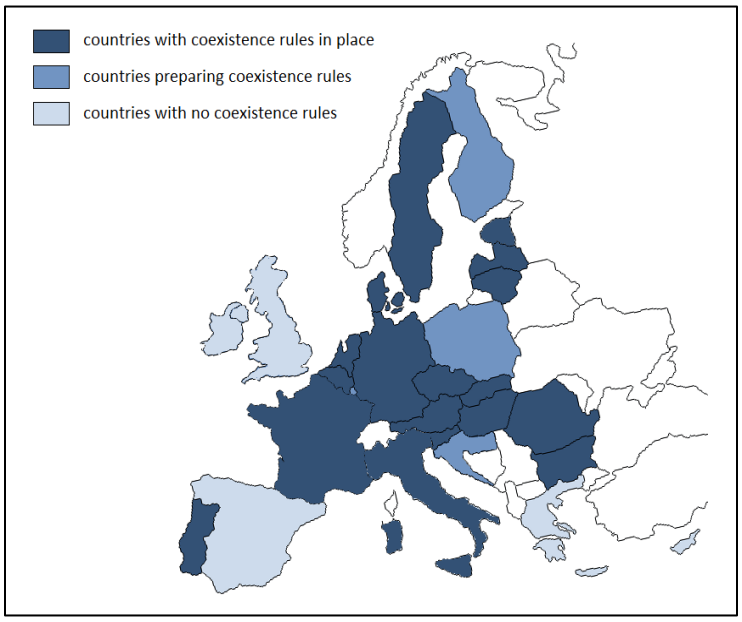
Genome editing remains a sensitive topic in **France**. While public institutions advocate a cautious approach, newly appointed Agriculture Minister Annie Genevard has expressed intentions to support research, training, and stakeholder initiatives in the sector. Her predecessor, Marc Feneau, was more vocal in endorsing NGTs, asserting their potential to drive the agro-ecological transition and address climate challenges. Meanwhile, critics of genome editing continue to label these techniques as "New GMOs" or "hidden GMOs" to undermine public confidence.

Austria has strongly criticized the European Commission's adopted regulation on NGTs. Following the September 29, 2024, general elections, this position is unlikely to change as all major Austrian parties support mandatory labeling for all NGT-derived products and stringent approval processes.

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 facilitates the exchange of technical and scientific information to develop crop-specific guidelines for coexistence measures.

Map 2. Coexistence Policies in the European Union



Map 2 shows that most MS have adopted internal coexistence rules. *(Source: FAS EU Offices)*

In Spain, coexistence is managed by adhering to good agricultural practices advocated by the National Association of Seed Breeders. These practices are annually published and distributed by seed distributors along with seeds. The latest version of the recommendations is available in the link (in Spanish). According to the Ministerial Order APA/1083/2018 (Spanish language only), farmers who grow GE corn must establish an isolation distance of 20 meters from the French border. Additional

information can be found in Section a) on Approvals. In some parts of the EU such as Southern Belgium and Hungary, coexistence rules are very restrictive and limit **the cultivation of GE crops.**

The coexistence rules for NGTs plants, as established in the adopted proposal, vary depending on the category. For Category 1, no additional rules would be required. In contrast, Category 2 necessitates adherence to the GMOs directive, with each member state tasked to formulate its specific regulations.

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

g) LABELING AND TRACEABILITY

- **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 labels on food that ingredients are derived from genetic engineering, 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 2.2 (f) of Regulation 1169/2011, such as processing aids (i.e. 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 near 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 (EC) No 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.

The labeling requirements for **NGTs plants** and derived products, as outlined in the adopted proposal by the European Commission, are contingent on the assigned categories. Products falling under NGTs Category 1 would not necessitate labeling. In contrast, those in Category 2 should adhere to the GMO directive. However, it is important to note that plant reproductive material (PRM) for Category 1 would indeed require labeling.

- **Voluntary GE-free Labeling Systems**

There is no EU-harmonized legislation on GE-free labeling. GE-free labels are allowed on a voluntary basis 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.

Austria, the Czech Republic, France, Germany, Hungary, Italy, Poland, and Slovakia have legislation and/or guidelines in place to facilitate GE-free labeling. The **Swedish** government has not implemented GE-free labeling as it believes such labeling can be misleading, as most food products generally do not contain GE ingredients.

In almost all EU countries, there are several private initiatives for GE-free labeling. In the **Czech Republic** and **Slovakia** retail buyers of meat and milk products often require 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 several third countries, including the United States. For more information, please refer to the EC's study.

For more information about GE-free labeling systems in individual country, please see 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[22] on the market is the submission of an application. This application must include a monitoring plan for environmental effects.[23] The duration of the monitoring plan may be different from the proposed period for the consent.
2. Where appropriate, the application must include a proposal for post-market monitoring regarding use as food or feed.[24]

[22] "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.
[23] Directive 2001/18/EC: Article 5 and Annex III for experimental releases, Article 13 and Annex VII for placing on the market

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. Based on these reports, in accordance with the consent and within the framework for the monitoring plan specified in the consent, the competent authority which received the original notification may adapt the monitoring plan after the first monitoring period.[25]
4. The results of the monitoring must be made publicly available.[26]
5. Authorizations are renewable for ten-year periods. Applications for renewal of an authorization must include, among other items, a report on the results of the monitoring.[27]

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

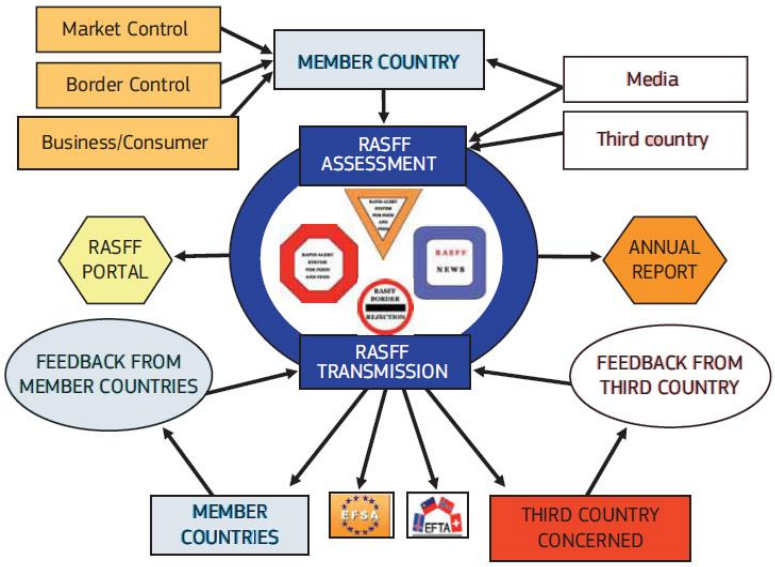
The Rapid Alert System for Food and Feed (RASFF) is used to report possible food safety issues. According to the most recent RASFF annual report available, in 2020, ten shipments were rejected at the EU border due to adventitious presence of GE food or feed.

The general functioning of the RASFF is illustrated in the chart 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 possible risk 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.

A list of recent notifications is available online on RASFF's portal. In 2024, 20 notifications for presence of unauthorized GE food or feed have been issued (to date).

[24] Regulation (EC) No 1829/2003 Articles 5 and 17
[25] Directive 2001/18/EC Article 20
[26] Directive 2001/18/EC Article 20 - Regulation (EC) No 1829/2003 Article 9
[27] Directive 2001/18/EC Article 17 - Regulation (EC) No 1829/2003 Articles 11 and 23

Chart 3. RASFF Information Flow



Source: RASFF 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).

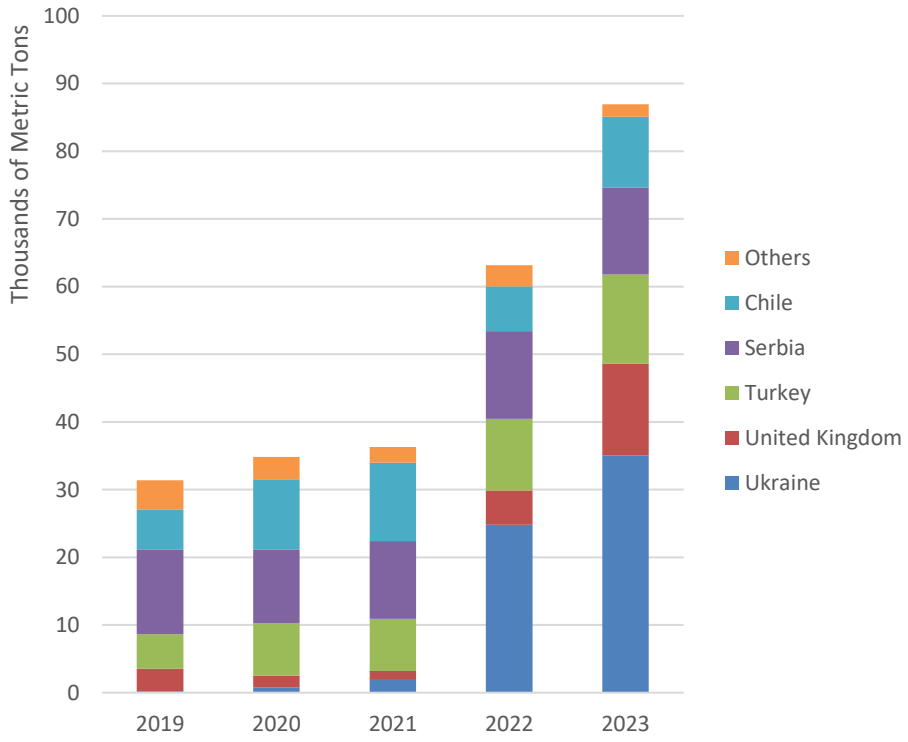
- **Thresholds for adventitious presence in feed, food, and seeds**

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 an 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 graph below for imports of corn seed).

Graph 8. EU Imports of Corn Seed



Source: Trade Data Monitor (EUROSTAT)

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

On November 20, 2017, EFSA published a guidance document on the risk assessment of the presence at low level of genetically modified plant material in imported food and feed under Regulation (EC) No 1829/2003.

j) ADDITIONAL REGULATORY REQUIREMENTS

All farmers that produce GE crops must register their fields with the government.[28] In some countries, this obligation tends to discourage farmers from growing GE crops, since it can be used by activists to locate fields.

In Spain, since 2019, when submitting the CAP payment application form, farmers must declare all the agricultural plots on their holding, and for statistical and control and surveillance purposes, whether they are growing GE corn varieties, including those planning to grow GE corn as a second crop.

In Portugal, farmers who want to grow GE crops must submit a completed notification form to the competent authorities 20 days before planting and communicate any alteration of the planting plan.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

- ### Comparison Between Plant Variety Rights and Patents

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

Table 4. Plant Variety Rights Compared to Patents

	Plant variety rights	Patents
What does the property right cover?	Plant breeders' rights cover **a plant variety**, defined by the expression of the characteristics resulting from a genotype or a combination of genotypes.	Patents cover **a technical invention**. Elements that are patentable include: - plants, if they result from a process which is not exclusively an essentially biological process and 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 as well as plants and animals exclusively obtained by means of an essentially biological process are not patentable.
Conditions to be met	Plant varieties can be granted variety rights if they are new clearly distinguishable from any	Patents can only be granted for inventions that are new, involve an inventive step, and are susceptible of industrial application.[29]

[28] In Spain, total area is calculated based on GE seed sales records, and it is publicly available on the Ministry of Agriculture's website. Since 2019, when submitting the CAP payment application form, farmers must declare all the agricultural plots on their holding, and for statistical purposes, whether they are growing GE corn varieties.

	other variety of common knowledge, sufficiently uniform in their relevant characteristics, and stable (DUS).	
Scope of the protection	One single variety and the varieties that are not clearly distinguishable, the varieties for the production of which the repeated use of the protected variety is needed (hybrids) and the varieties essentially derived from it are protected by an EU plant variety protection title.	All plants with the patented invention are protected within the EU. The protection extends to all biological material in which the patented invention is incorporated provided that the invention expresses its function (see Article 9 of Directive 98/44).
Exemptions	- Research exemption - Breeders' exemption allows free use of a protected variety for further breeding and free commercialization of new varieties (except for essentially derived ones). - Exception for private and non-commercial use - There is a derogation in the Regulation (EC) 2100/94 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.[30]
Duration	The variety is protected for 25 years from the date of grant (30 years for some plants: trees, vines, potatoes, asparagus, flower bulbs, woody ornamentals and woody fruit crops 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	The legal basis for patenting biotechnological

[29] 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.

[30] This point has been controversial in some EU countries. The research exemption and exception of use for private and non-commercial purposes exists also under patent law. Moreover, under the EU Directive 98/44 there is also the same derogation for FSS use as under the EU PVP system. See article 11: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31998L0044&qid=1639429294467

Further to this, indeed in some national laws such as French, German and Dutch law there is also a so-called limited breeder's exemption which allows for the use of the protected biological material for use in breeding and development (not commercialization though).

	available on the CPVO website. They include Regulation (EC) 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.	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.

Euroseeds (the European Seed Association) – while confirming that plant breeder's rights is the best suited intellectual property protection system for plant varieties as such – has always supported the co-existence of all intellectual property rights offering adequate protection for each kind of inventive activities in living matter and results thereof. Euroseeds also supports the exclusion of plant varieties per se, essentially biological processes for the production of plants as well as plants obtained by such processes from patentability. Furthermore, Euroseeds promotes safeguarding free access to all plant genetic material for further breeding, as is the case in the French, German, and Dutch patent laws via a limited breeder's exemption (or 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. However, the EPO's Technical Board of Appeal rejected this decision in December 2018, arguing that the European Patent Convention takes precedence over EPO's implementing rules. A final decision will be taken by the EPO's Enlarged Board of Appeal.[31]

[31] This decision was rendered on May 14, 2020. Here is the final decision of the Enlarged Boar of Appeal of the EPO: https://www.epo.org/law-practice/case-law-appeals/pdf/g190003ex1.pdf

The decision dismissed the views and decision of the Technical Board of Appeal and confirmed the validity of the Rule 28(2) excluding plants and animals exclusively obtained by essentially biological processes from patentability.

On September 19, 2019, the EP adopted a non-binding resolution on "Patentability of plants and essentially biological processes." The resolution called on the EU Commission to do its utmost to convince the EPO not to grant patents to products obtained from essentially biological processes. It also urged the EPO to immediately restore legal clarity on the matter, stressing that none of the 38 states that signed the European Patent Convention allow conventionally bred products to be patented.

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 on trans-boundary movements of GE products 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; and 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.

Euroseeds 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.[32]"

m) INTERNATIONAL TREATIES AND FORUMS

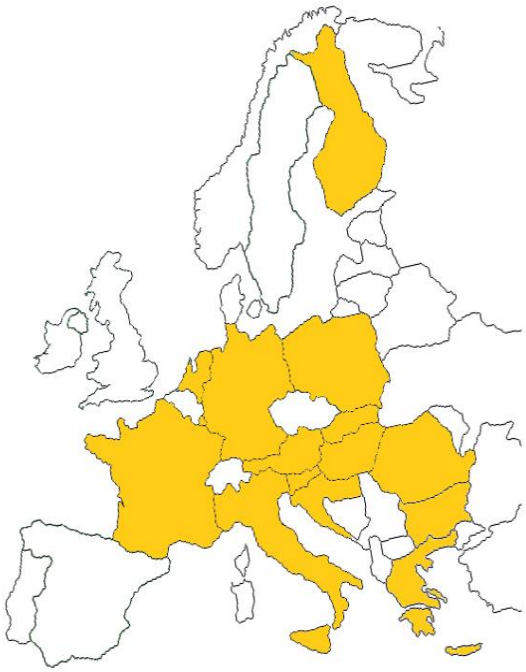
The EU is a member of the Codex Alimentarius alongside its 27 MS (in addition to the United Kingdom). The EC represents the EU in Codex; DG SANTE is the contact point.

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 nor have any of the member states.

n) RELATED ISSUES

- **European Soy Declaration**

Map 3. European Soy Declaration Signatories



Source: FAS EU offices

Since July 2017, fifteen EU MS and five non-EU European countries (Kosovo, Moldova, Macedonia, Montenegro, and Switzerland) 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, Bulgaria, Croatia, Finland, France, Germany, Greece, 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 Donau Soya and Europe Soya.

[32] https://euroseeds.eu/app/uploads/2019/07/15.0562.2-Euroseeds-position-on-commercialised-varieties-1.pdf

- **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 these 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 or their products (e.g. feed). In October 2015, the 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 against agricultural biotechnology since it was first introduced in the 1990s. These groups are generally opposed to globalization. They see more risks than opportunities in agricultural biotechnology 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. They are skeptical of biotechnology specifically indicating that 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 increase public awareness about possible risks. 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 include **scientists** and **professionals in the agricultural sector** such as 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. Following the 2018 ECJ ruling on genome editing, a network of scientists called EU-SAGE (European Sustainable Agriculture Through Genome Editing) was formed to provide information about genome editing and promote the development of European and EU member state policies that enable the use of genome editing for sustainable agriculture and food production. EU-SAGE represents 134 European plant science institutes and societies. Please find more information on their website, www.eu-sage.eu.

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. Most 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 better adapted to their agronomic conditions were made available.
(b) Nineteen MS have implemented a ban on the only GE crop authorized for cultivation. However, many farmers in these countries would grow GE crops if it was permitted.
(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, where location information is collected by competent authorities but only aggregated information at the regional level is publicly released.
(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 supposedly with 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.

The feed industry has also taken actions that aim at using less GE products in some MS, in line with local government's protein strategies and/or to meet consumer demand. This is the case in Austria, Croatia, the Czech Republic, France, Germany, Greece, Hungary, Ireland, the Netherlands, Slovakia, Slovenia, and the United Kingdom, especially in the dairy sector, but this is also true for poultry, eggs, beef, and pork production.

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. Hence, their use in food has become a highly contentious and politicized issue. Moreover, public opinion generally expresses distrust of international companies. Public research exists but is less visible, even though it is considered more credible and neutral than information from private companies. 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 the potential to begin to change consumer perceptions. They are: GE crops that provide nutritional or other benefits to consumers; innovative techniques, such as cisgenesis and genome editing, which are perceived as more "natural" than transgenesis; and GE crops that provide environmental benefits.

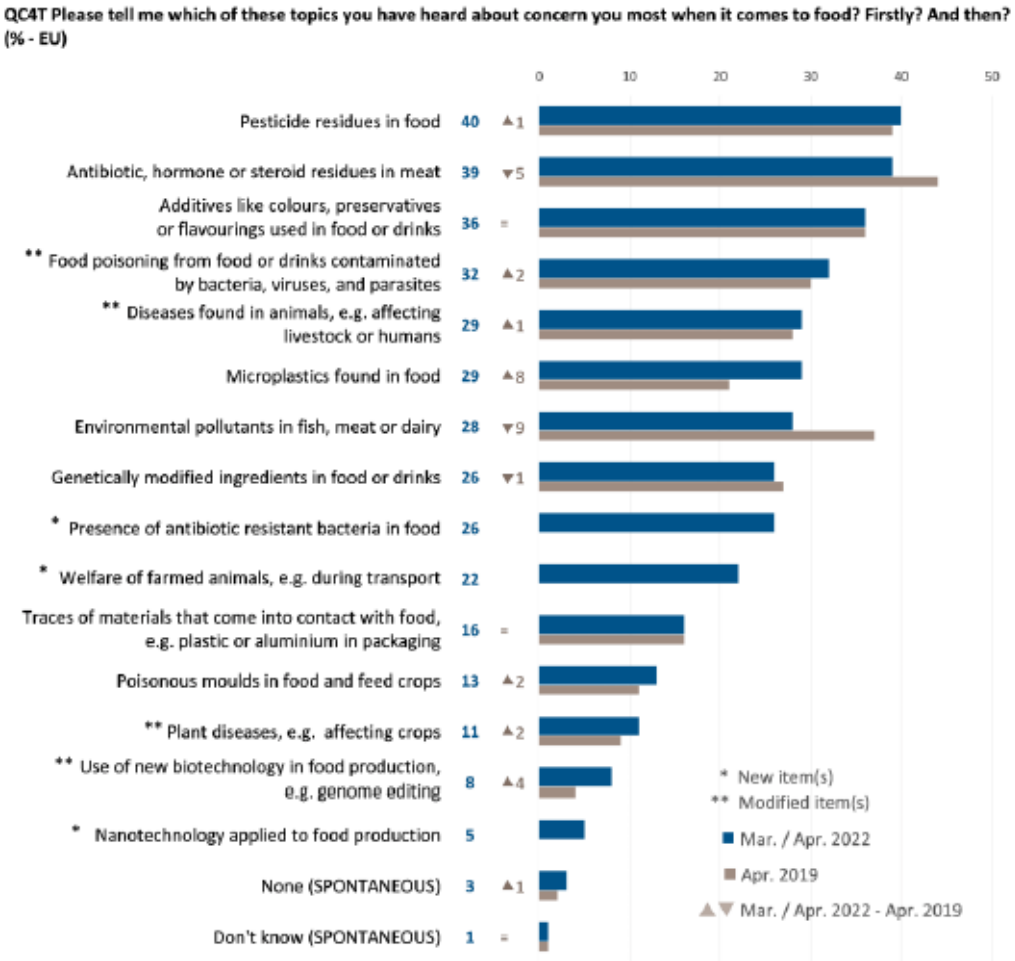
The Eurobarometer survey[33] on food safety released from 2022 shows that the presence of GE ingredients in food is far from being the main concern of EU consumers (see chart and map 4 below). Only 26 percent of EU consumers rank "GE ingredients in food or drinks" as one of their five main concerns, one percent less compared to the same survey in 2019. Only 8 percent of respondents perceive as dangerous the use of new biotechnologies in food production. The chart below reflects media

[33] More recent versions of the Eurobarometer do not include this type of information, so better stick with this version https://europa.eu/eurobarometer/surveys/detail/2241

coverage of the different topics; antibiotic and pesticide residues have received much more media attention than other topics in recent years.

Concern about genetically modified ingredients in food or drinks is the highest in Greece (47 percent) Austria (41 percent) and Bulgaria and Lithuania (both 40 percent). Conversely, those in Sweden (8 percent) Finland (11 percent) and Denmark (12 percent) are the least likely to indicate this. Use of new biotechnology in food production is selected most frequently in Bulgaria (16 percent), Hungary (15 percent) and Greece (12 percent). On the other hand, less than one in twenty select this in Sweden (3 percebt) and Denmark, Estonia, Finland, and Lithuania (all 4 percent) (**Chart 4**).

Chart 4. EU Citizen Concerns About Food



Source: 2022 Eurobarometer on Food Safety in the EU

Table 5. Eurobarometer 2022 on Food Safety Concerns: Concerns about food

		EU27	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE
Pesticide residues in food	Mar/Apr 2022	40	40	32	25	50	43	37	36	69	46	51	43	31	55	34	41	43	43	47	31	32	29	50	29	46	43	40	29
	Δ Apr 2019	▲1	▼4	▲1	▲8	▼1	-	▲4	▲6	▲2	▲1	▼6	▲4	▲6	▼5	▼3	▲4	▼5	-	▼7	▼7	▼7	▲5	▼7	▲4	▼2	▲3	▼6	▼28
Antibiotic, hormone or steroid residues in meat	Mar/Apr 2022	39	32	38	33	50	53	36	24	48	32	28	41	41	40	42	42	33	33	22	36	36	36	35	32	44	44	39	46
	Δ Apr 2019	▼5	▼7	▼5	▲8	▼9	▼8	▲2	▼8	▲4	▼5	▼10	▲1	▼3	▼7	▲1	▼6	▼3	▲1	▲2	▼19	▼13	▼13	▼2	▼3	▼8	-	▼13	▼29
Additives like colours, preservatives or flavourings used in food or drinks	Mar/Apr 2022	36	38	44	46	32	28	58	29	54	32	44	32	33	39	44	54	28	49	39	41	39	41	25	33	38	36	33	19
	Δ Apr 2019	-	▲7	▼5	▲9	▼3	▲1	▲3	▼3	▲10	▼5	▲1	▲1	-	▼2	-	▼2	▲1	▲6	▲18	▼9	▲7	▼4	▲2	▼10	▲3	▲5	▼11	▼21
Food poisoning from food or drinks contaminated by bacteria, viruses, and parasites **	Mar/Apr 2022	32	30	32	20	28	23	19	39	45	41	39	28	32	38	24	28	25	23	26	25	23	28	56	38	31	28	20	15
	Δ Apr 2019	▲2	▲1	▲13	▼9	▼8	▲1	-	▼2	▲22	▲11	▲4	▼12	▲4	▲13	▼5	▲9	▼3	▼1	▲5	-	▼1	▲2	▼6	▲5	▼7	▼2	▼7	▼11
Diseases found in animals, e.g. affecting livestock or humans **	Mar/Apr 2022	29	22	32	23	17	20	18	25	42	43	28	31	36	36	28	20	26	26	25	39	17	22	57	26	20	27	20	20
	Δ Apr 2019	▲1	▲3	▼3	▼22	▲3	▼5	▼6	▼5	▼10	▲14	▲11	▼10	▲8	▼11	▲5	▼10	▲7	▼1	▼20	▲25	▼2	▼15	▲1	▼3	▼11	▼16	▲6	-
Microplastics found in food	Mar/Apr 2022	29	36	11	37	47	40	20	28	12	29	31	23	16	23	24	19	41	20	40	55	37	18	17	14	41	21	40	29
	Δ Apr 2019	▲8	▲13	-	▲22	▲7	▲6	▲7	▲11	▲5	▲3	▲12	▲10	▲1	▲17	▲10	▲12	▲6	▲10	▲24	▲18	▲12	▲11	▲6	▲6	▲17	▲11	▲10	▼8
Environmental pollutants in fish, meat or dairy	Mar/Apr 2022	28	34	23	24	36	29	31	26	29	24	30	17	30	29	30	30	27	20	27	38	25	23	36	24	25	20	36	30
	Δ Apr 2019	▼9	▼5	▼8	▲3	▼9	▼13	▼14	▼2	▼4	▼18	▼17	▼5	▼3	▼6	▼8	▼8	▼6	▼3	▼6	▼9	▼3	▼6	▼5	-	-	▲1	▼15	▼32
Genetically modified ingredients in food or drinks	Mar/Apr 2022	26	22	40	24	12	30	30	24	47	20	21	31	25	34	36	40	19	31	21	17	41	32	17	23	38	36	11	8
	Δ Apr 2019	▼1	▲6	▼2	▲6	▼2	-	▲7	▼1	▲5	▲3	▼7	▼1	▲1	▲3	▼5	▼5	▼6	▼1	▲9	▼4	▲4	▼7	▲2	▲1	▲2	▲11	▼2	▼13
Presence of antibiotic resistant bacteria in food *	Mar/Apr 2022	26	22	21	16	33	35	8	22	21	23	23	23	25	22	20	22	28	15	10	27	25	20	34	24	27	24	24	38
Welfare of farmed animals, e.g. during transport *	Mar/Apr 2022	22	26	4	16	27	34	7	20	10	23	33	9	11	12	7	6	34	8	8	43	33	7	15	9	10	10	25	26
Traces of materials that come into contact with food, e.g. plastic or aluminium in packaging	Mar/Apr 2022	16	18	12	19	15	14	15	19	14	13	15	11	18	23	15	8	18	16	27	16	21	20	15	15	20	12	13	6
	Δ Apr 2019	-	▲1	▼1	▲6	▼6	▼3	▼6	▲2	▲1	▼2	▼2	▼2	▼2	▲12	▼1	▼1	▲1	▲2	▲2	▼3	-	▲7	▼3	-	▲3	▲3	▼3	▼8
Poisonous moulds in food and feed crops	Mar/Apr 2022	13	9	16	23	18	16	12	15	8	10	6	22	13	14	14	15	10	17	9	7	16	17	19	17	20	32	8	8
	Δ Apr 2019	▲2	-	▲1	▲1	▲5	▲3	▼3	▲2	▲1	▲5	▲2	▲2	▼3	▲9	▲1	▲1	▲6	▲1	▲1	▲1	▼1	▲1	-	▲6	▲5	▲9	▼3	▼4
Plant diseases, e.g. affecting crops **	Mar/Apr 2022	11	8	19	12	8	4	10	15	24	14	6	11	16	20	11	6	6	16	11	10	10	13	14	10	9	21	12	7
	Δ Apr 2019	▲2	▲1	▲5	▲2	▲3	-	▲5	-	▼3	▲3	▼1	▼1	▲10	▼2	▲6	▼5	-	▲4	-	▲3	▲1	▼1	▲2	▼3	▼4	▲1	▲8	▲1
Use of new biotechnology in food production, e.g. genome editing **	Mar/Apr 2022	8	7	16	8	4	7	4	10	12	8	5	11	8	7	6	4	9	15	6	6	10	9	5	8	10	10	4	3
	Δ Apr 2019	▲4	▲4	▲10	▲3	-	▲4	▼2	▲7	▲5	▲3	▲2	▲3	▲4	▲2	▲3	-	▲1	▲9	▲2	▲2	▲3	▲4	▲4	▲4	▲7	▲7	▼7	▼4
Nanotechnology applied to food production *	Mar/Apr 2022	5	4	8	5	2	8	2	5	7	4	4	5	6	9	3	3	5	9	3	4	9	5	2	7	5	7	1	1
None (SPONTANEOUS)	Mar/Apr 2022	3	3	2	4	4	3	9	4	1	3	3	2	1	3	3	4	1	2	2	2	5	3	2	5	1	2	8	1
	Δ Apr 2019	▲1	▼1	▼1	▼1	-	▲1	▲3	▲2	-	▲2	▲1	▲1	-	▲2	▼1	▲1	-	▲1	▲1	▼5	▼1	▲2	▲1	▲2	▼2	▲1	▼1	▼1
Don't know (SPONTANEOUS)	Mar/Apr 2022	1	1	1	2	1	1	5	1	0	1	3	1	1	1	2	2	1	1	2	1	2	2	1	2	0	2	4	1
	Δ Apr 2019	-	▲1	▼1	-	▼1	-	▲3	▲1	-	▼1	▲1	▲1	-	▲1	-	▲2	▲1	▲1	▲1	▲1	▲1	▼2	-	▲2	▼1	▲1	▲4	-

Source: 2022 Eurobarometer on Food Safety in the EU

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, because 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 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 of genetic engineering varies greatly across EU countries**

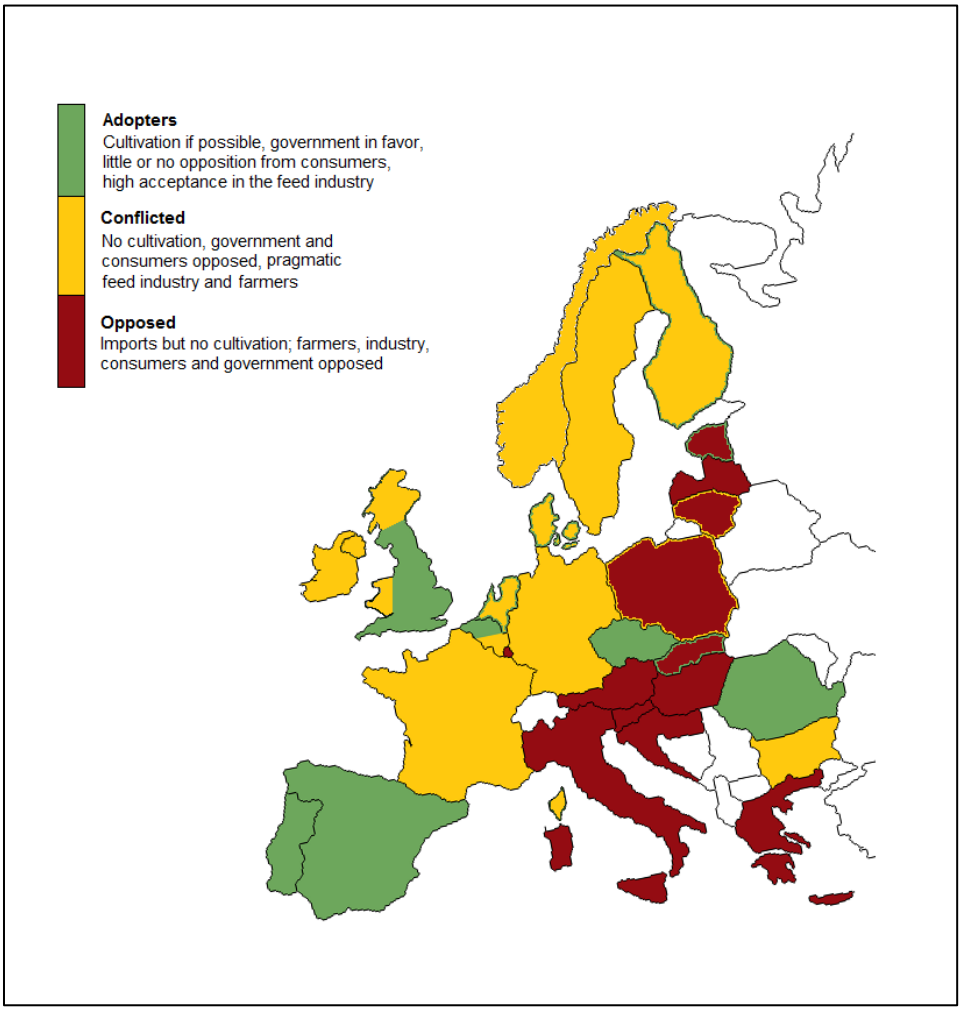
There are three major categories of MS depending on their acceptance of agricultural applications of genetic engineering, as illustrated in Map 6 below.

- 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 were more suitable for their conditions or if they were approved for cultivation in the EU and/or have a significant dependency on imported feedstuffs (**the Czech Republic, Flanders in Northern Belgium, and England in the United Kingdom**). Portugal, since April 2022, has changed its GE events import approval sense of vote from abstention to in favor. The global crisis triggered by Russia's invasion of Ukraine may lead to a more pragmatic approach towards biotech. The United Kingdom's departure from the EU (Brexit) has further reduced 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, and Ireland** are under the influence of the other countries of this group, especially France and Poland. **Sweden** is conflicted and has a voluntary GE feed ban since 2011. As for **Northern Ireland, Scotland, and Wales**, they have been in the conflicted group since 2016 following their decision to opt out of GE crop cultivation. In **Denmark, Finland,** and **the Netherlands** farm unions' views on genetic engineering have become conflicted. Farmers in **Romania** still support the use of GE crops, but elsewhere in society, views differ. The public acceptance of genetic engineering in **Germany** is currently challenging to gauge accurately. Recent polling results indicate that "only" 58 percent of society opposes the deregulation of GE crops, showing a decrease from older polling results where opposition ranged between 65-80 percent. Moreover, approximately 17 percent of respondents express uncertainty regarding their stance on deregulation. In the face of pressing issues like climate change, public opinion seems to be evolving, presenting a more nuanced landscape. In line with this, public debate has shifted towards questions around transparency and labelling of potential NGT products. However, a considerable amount of uncertainty remains prevalent in society.

- In the "**opposed**" MS, most stakeholders and policy makers reject the technology. Most of these countries are in Central and South Europe (**Austria, Croatia, Cyprus, Greece, Hungary, Italy, Malta, and Slovenia**). **Latvia and Luxembourg** oppose GE technology. 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 political changes. **Lithuania** and **Estonia**'s governments, farming sectors, and consumer bases are currently opposed to genetic engineering.

Map 5. Acceptance of GE Crops by Member State – 2021



Source: FAS EU offices

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

When considering **scientists, professionals in the agriculture and food sectors, the general public, and anti-biotech activists** 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 ECJ judgment on genome editing. They warn that it could put an end to a promising field of research in the EU.
- **Most 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 ECJ decision. Some small farmers' organizations and food companies are close to anti-biotech groups, but they only represent a small share of the EU agriculture and food sector. As for organic farmers, the political spectrum of their movement ranges from dogmatic individuals or groups who believe that only natural

occurrences in nature is beneficial and moral, to the market-oriented groups who use organic farming to maximize economic gains. The dogmatic groups reject everything they perceive as "unnatural;" they reject modern techniques and tend to use varieties created through ancient techniques. For the market-oriented organic farmers, being "GMO free" is a marketing strategy; they may accept to use some seeds produced through innovative biotechnologies if they brought environmental benefits and had a clearly positive image among consumers.

- The priority of **food industry and retailers** is to adapt their product offerings to consumer perceptions. However currently **there is low awareness of agricultural applications of innovative biotechnologies among the general public** (see 2022 Eurobarometer survey in **Table 5** above).

- **Anti-biotech groups are opposed to innovative biotechnologies.** They are actively campaigning against these technologies in France, Germany, Greece, Ireland, Italy, Slovakia, and the United Kingdom.

- **The European Commission** has publicly acknowledged, through its 2021 study on "new genomic techniques" and the legislative proposal adopted in 2023, that these advanced products have the potential to contribute to the objectives outlined in the European Green Deal, particularly within the Farm to Fork and Biodiversity Strategies.

- On November 29, 2021, the European Commission held an **online event calling for "New genomic techniques** – the way forward for safe and sustainable innovation in the agri-food sector." The event focused on the overall benefits of genome editing, how these products can deliver on sustainability goals, how to ensure safety with proportionate risk assessment, concerns around traceability and labeling, and ideas to engage and empower consumers. **Speakers from the Commission, DG SANTE, DG AGRI, EFSA, the Parliament, and Member States were represented.**

- **Studies**

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

Table 5. Studies on GE Plants and Product Perception in the EU

Report	Comment
2022 Eurobarometer Survey on Food Safety in the EU	Eurobarometer survey about European's risk perceptions when it comes to food safety topics commissioned by EFSA (2022)
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[34]

PART D – PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

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

Most of these countries focus their efforts on developing GE animals for **medical and pharmaceutical research purposes**:

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

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

- To improve animal breeding (e.g., high yielding sheep, welfare traits, dairy cattle and swine genomics, disease resistant poultry);
- To study the immunization of livestock animals;
- To study the molecular processes of reproduction in farm animals; and
- 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, pigs, goats, sheep, cattle, 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 Institute of Genetics and Biotechnology of the Hungarian University of Agriculture and Life Sciences is the most active agricultural research facility in animal

[34] Animal genetic engineering and genome editing result in the modification of an animal's DNA to introduce new traits and change one of more characteristics 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.

biotechnology. Its precision breeding and model animal genetics research groups aim to create GE model animals (mouse, rabbit) and to provide a technological basis for precision developments. In addition to the CRISPR / Cas9 system, they are using transposon-based transgenesis and traditional gene delivery methods as well. While the development of genetic, genomic and biotechnology approaches directly support agricultural purposes, these groups also represent a special segment of research providing high value animal models for non-food purposes. For example, recent projects involve rabbit models of heart and cardiovascular diseases and a mouse model of autism.

- In **Spain**, research involving animal biotechnology is permitted, provided prior notice is given through the same procedures and institutions as those for plant biotechnology. According to the public log managed by the Spanish Ministry for the Ecological Transition, confined research on GE animals from 1998 to 2023 has been conducted on hogs, rodents, flies, and zebrafish. Most notifications pertain to basic scientific research for pharmaceutical purposes, primarily carried out by public institutions. Institutions like the National Center for Biotechnology (CNB) and the National Center for Animal Research (CISA–INIA) lead Spanish research on animal genome editing. Since 2013, basic research using CRISPR-Cas9 in mice has been ongoing. In 2023, CISA–INIA reported research involving transgenic mice to study susceptibility to various Transmissible Spongiform Encephalopathy (TSE) isolates and prion protein expression.
  In 2024, media reported that researchers from the Animal Reproduction Department at INIA-CSIC generated Spain's first genetically modified lamb, named Teodoro. The lamb carries a mutation in a fertility-related gene and serves as a model for studying reproductive failures in farm animals and human fertility. The researchers emphasized the importance of GE animal models for understanding biological processes, including reproduction. As for cloning, as of 2024, the Spanish company Ovoclone Laboratory offers cloning services for pets, particularly horses, as well as cats and dogs.
- In **Belgium**, there are no GE or cloned animals under development. However, some basic research with GE animals is occurring mostly for medical and pharmaceutical research purposes. Various research centers are active on innovative biotechnologies and extensive biomedical research programs use both plant and animal-based models in the development of new diagnostic tools and disease treatment solutions in both human and veterinary medicine.
- In 2020, a team of Czech scientists from the Institute of Molecular Genetics of the Academy of Sciences of the **Czech Republic** and the Biopharm Company announced that they had developed a chicken resistant to avian leukosis virus, through precise CRISPR/Cas9 editing of the NHE1 gene. For detailed information please refer to a 2022 article in the Proceedings of the National Academy of Sciences of the United States.

And some examples from the United Kingdom:

- 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 this breakthrough 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 is focused on using genome editing to enhance resistance to infectious disease in livestock and on producing a chicken that cannot transmit avian flu.

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.

In 2019, 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. On May 1, 2020, Oxitec announced that it received U.S. EPA approval for pilot projects in the United States. Oxitec's carefully developed field tests will be conducted over a two-year period in Monroe County, Florida, and in Harris County, Texas. On August 19, 2020, Oxitec announced the final approval of an agreement to carry out a demonstration project of Oxitec's safe, non-biting *Aedes aegypti* just-add-water technology in the Florida Keys. For more information: https://www.oxitec.com/en/news/oxitecs-friendly-mosquito-technology-receives-us-epa-approval-for-pilot-projects-in-us

Previously, Cryozootech, a French company produced cloned horses, but the company has ceased its operations.

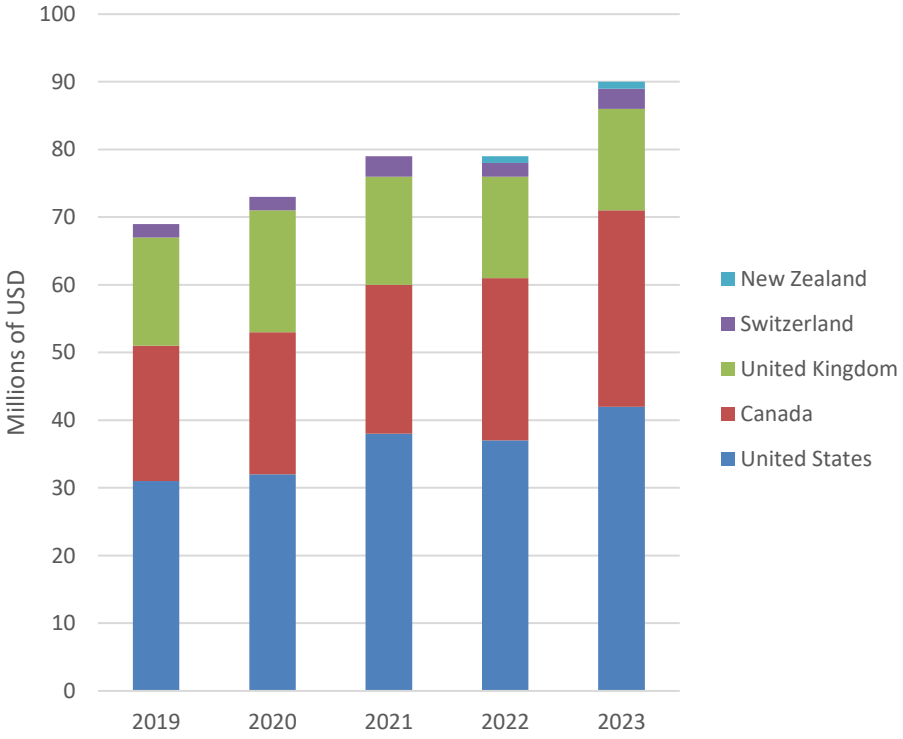
c) EXPORTS

There are no overall EU exports. However, the United Kingdom (UK) exports GE mosquito eggs for development and subsequent release in non-EU countries such as Brazil. Oxitec's technology will be deployed across the City of Indaiatuba, State of São Paulo, Brazil for the 2020 – 2021 mosquito season in collaboration with its dengue control program. For additional details, please see Oxitec's Press Releases.

d) IMPORTS

The EU has 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, followed by Canada (almost 30 percent).

Graph 9. EU Imports of Bovine Semen



Source: EUROSTAT

e) TRADE BARRIERS

The main barriers to using animal biotechnology to improve animal breeding are the public and political opposition to it.

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 (DG SANTE);

- 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 the provisions took effect starting January 1, 2018. This Regulation 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 EP'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 were 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.

In 2020, the Commission also examined all proposals that are currently awaiting decision by the EP and the Council and proposed to withdraw and repeal 34 of them, including the proposal on the cloning of animals of the bovine, porcine, ovine, caprine, and equine species kept and reproduced for farming purposes and the proposal on the placing on the market of food from animal clones.

b) APPROVALS/AUTHORIZATIONS

No GM animals, or food or feed from GM animals, have been authorized for placement on the market in the EU, nor have any applications been made by industry for approval.

c) INNOVATIVE BIOTECHNOLOGIES[35]

The Union of European Academies for Applied Sciences of Agriculture, Food and Nature (UEAA) reported that in June 2019 the Veterinary Academy of France (a member of UEAA) unanimously voted to support a position paper on Genome Editing in domestic animals. The Academy recommended that research projects making use of modern genome engineering technologies be encouraged at all levels and adequately funded. However, to date it has not led to an increase in the projects related to production agriculture, but some research related to animal health and disease mitigation has continued.

The UEAA also recommended that the EU legislation adapted to the case of genetically modified domestic animals should rapidly be introduced in order to establish a regulatory framework which is a function of the type of genetic modification and takes account of the rapid evolution of the technology in this field, so as to foster innovation. This legislation should consider that most research aimed at producing animals whose genomes have undergone targeted modifications is of interest only to the extent that they actually confer appreciable economic, health, animal welfare, or environmental benefits.

Another recommendation by the UEAA includes providing projects relating to the production or importation of domestic animals whose genomes have been modified by editing certain segments of DNA. The recommendation is also that they should be examined on a case-by-case basis by the competent authorities and subject to a scientifically sound basis, also considering an analysis of the degree of acceptability by society.

The European Commission's study on NGTs published in April 2021 covered the use of new genomic techniques in plants, animals, and microorganisms across various sectors. However, less information is generally available on the use of these techniques in animals compared to plants, prompting the need for relevant data generation. Therefore, EFSA has been mandated by the European Commission to provide an opinion on new developments in biotechnology applied to animals, including synthetic biology and new genomic techniques.

[35] "Innovative biotechnologies" is a synonym of New Genomic Techniques (NGTs). It excludes transgenesis.

The Commission aims to map and understand the safety and risk assessment aspects of new biotechnological developments in animals, including synthetic biology applications. The scope is limited to agri-food uses. The terms of reference outline a two-step process:

1. Knowledge gathering on known cases of animals and their products obtained through new biotechnological developments since 2001. This involves identifying animals, detailing techniques used, and collecting data for risk assessment.
2. EFSA's opinion on potential novel hazards/risks from new biotechnological developments applied to current and near-market animals. The opinion will assess the adequacy of existing risk assessment guidelines, covering molecular characterization, food/feed safety, welfare, and environmental impact.

The first delivery, published on September 27, 2023, presented a comprehensive report on the applications of new genomic techniques (NGTs) in farm animals and related agri/food/feed products. The report covers both commercial and pre-commercial stages, incorporating a literature review of 195 publications detailing the development of live gene-edited animals. According to the studies, several applications have received authorization or "non-GMO" status in various countries, including instances in Japan, Argentina, Brazil, and the United States.

A second delivery after 1.5 years will be a draft opinion, subject to public consultations, with the final opinion expected by June 30, 2025. The mandate also integrates a prior request for EFSA's opinion on genetically modified organisms developed through synthetic biology.

d) 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.”

e) ADDITIONAL REGULATORY REQUIREMENTS

Nothing additional to provide.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

The legislative framework on patents for animals produced through biotechnology is the same as for GE plants (see Part B) Policy, 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.[36]

g) INTERNATIONAL TREATIES AND FORUMS

The EU is member of the Codex Alimentarius along with its 27 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 (WOAH) has no specific guidelines on GE animals, but it has guidelines on the production of animal clones. The EC is actively involved in the work of the WOAH and organizes input from the MS.

Twenty-one[37] out of the current 27 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) Policy, l) Cartagena Protocol).

h) RELATED ISSUES

Nothing additional to provide.

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 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

[36] Source: European Patent Office
[37] Non-OECD EU MS include Bulgaria, Croatia, Cyprus, Lithuania, Malta, and Romania.

biotechnology. 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 were higher, it may increase the acceptance of the technologies. However, a significant share of the population would still reject it as being “unnatural.” Several organizations are actively campaigning against the technologies in the EU, including animal welfare activists, local food groups, and biodiversity activists.

Medical applications are the most accepted use for animal biotechnology. 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.

b) MARKET ACCEPTANCE/STUDIES

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

A 2010 European survey on biotechnology included animal cloning. It found that “cloning animals for food products is even less popular than GM food with 18 percent of Europeans in support.”

CHAPTER 3 – MICROBIAL BIOTECHNOLOGY

PART G – PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

It is difficult to obtain information about the development and production practices of GE microorganisms. However, both genetic engineering and genome editing of microorganisms is widely used in laboratories all over the EU. The use of fermentation to produce food enzymes and food additives holds numerous advantages over the chemical production of these components and is likely to gain even more importance in the future. The genetic engineering of microorganisms is key to this success.

In microbial biotechnology, a new sector known as cellular agriculture is emerging. In the **Netherlands**, research institutions and companies focused on dairy and meat alternatives have collaborated in the Cellular Agriculture Netherlands Foundation (CANS). The Dutch Government is investing (Dutch language) €60 million in cellular agriculture through the National Growth Fund. This substantial funding is designated for research, commercialization, and the education of qualified personnel in the field.

In **Germany**, developments in microbial biotechnology are aligned with the increasing demand for sustainable solutions in the food sector. A growing start-up scene is concentrating on precision fermentation and industrial cell technology for alternative protein production, as well as the cultivation of agricultural products in bioreactors.

Denmark is a global leader in microbial biotechnology, with a strong emphasis on research and development in this sector. The country is the world's largest exporter of enzymes (HS code 350790), achieving an export value of $1.4 billion in 2023. Among non-EU markets, the United States stands out as the largest destination, with exports valued at $183 million. Novozymes, Denmark's leading enzyme producer, specializes in creating enzyme and microbial technologies for industries such as agriculture, food production, and bioenergy (notably biofuels). The company reported an estimated annual turnover of $2.25 billion in 2023. In January 2024, Novozymes merged with Chr. Hansen, the country's second-largest enzyme producer, forming a new entity named Novonesis. The combined company is projected to generate an annual turnover of approximately $4 billion, solidifying Denmark's position as a key player in the global biotechnology market.

b) EXPORTS

The EU exports products that contain microbial biotech-derived food ingredients to the United States or other countries. In the EU, if the final products are thoroughly purified to make sure all traces of GE microorganisms are absent, no "GMO" labeling is required.

c) IMPORTS

The EU imports microbial biotech-derived food ingredients or processed products without distinction to similar food produced without GE microorganisms. In consequence, no quantitative data is available. Some EU countries have found traces of GE microorganisms during import controls, leading to RASFF notifications and sanctions under the EU's "GMO" legislation; however, DNA is allowable under EFSA guidelines.

d) TRADE BARRIERS

The GE microorganism and its modified genetic material have to be absent in the end product for it not to be considered by the EU as a "GMO." If this condition is not met, the product has to be labeled as containing "GMO" and the GE microorganism has to be approved under the EU's "GMO" Directive.

PART H – POLICY

a) REGULATORY FRAMEWORK

i. Responsible government ministries and their role in the regulation of GE plants

Please see Part B) Policy a) Regulatory Framework.

ii. How the regulation of microbial biotech and/or derived food ingredients differs from those of GE plants or animals

GE microbes and their products fall under the scope of two GE Directives, Directive 2009/41/EC on contained use of "genetically modified microorganisms" and Directive 2001/18/EC, which covers the deliberate release into the environment of genetically modified organisms.

The "Contained Use" Directive (Directive 2009/41/EC) defines "contained use" as "any activity in which microorganisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment." In order to qualify under this Directive, two criteria are of importance. Firstly, the GE microbe – the production organism – must be absent in the final product. The second criterion is absence of recombinant DNA (rDNA), used to genetically alter the organism.

If these criteria are not met, the product of the GE microbe falls under the scope of Directive 2001/18/EC on the deliberate release into the environment of "genetically modified organisms" – as do GE plants and animals. Such a product of microbial biotechnology has to comply with Regulation (EC) No 1829/2003 that covers the market access requirements and authorization procedure for genetically modified food and feed as well as with Regulation (EC) No 1830/2003 concerning the traceability and

labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. Please see Part B) Policy for more information.

In many cases, industry prefers to apply for authorization of highly purified products of microbial biotechnology under the "Contained Use" Directive (Directive 2009/41/EC). This way the product does not have to be labeled as "GMO." A U.S. food company submitted an application under the "Deliberate Release" Directive for a GE microorganism producing a flavoring that gives their vegetarian burgers a meaty taste. Their soy leghemoglobin producing GE microorganism is currently undergoing the EU's "GMO" approval process. The company has reported that they feel confident that the EU public will not be deterred by the "GMO" label on its products.

iii. Additional product registrations or approval requirements for microbial biotech and/or derived food ingredients prior to their use

As discussed below, products created using GE microbes may be further regulated according to their use. Irrespective of whether or not the production process involves genetic engineering, a suite of horizontal EU Regulations exists for food enzymes, food additives, food flavorings, and novel foods. Additional information about these regulations can be found in the USDA/FAS annual EU Food and Agricultural Import Regulations and Standards Report.

- **Food ingredients**

The EU maintains a positive list of authorized food additives and food flavorings called Union Lists. They are available in the annex of Regulation (EC) 1333/2008 and Regulation (EC) 1334/2008 respectively. The Commission referenced a Union List of food enzymes in Regulation (EC) 1332/2008, but has not yet published it. Based on all applications submitted before the deadline of March 15, 2015, the Commission compiled a Register.[38] The Union List of food enzymes will be adopted once EFSA has issued an opinion on each food enzyme included in the Register. In the meantime, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes continue to apply. Of the MS, only Denmark and France have specific food enzyme legislation. Please consult the appropriate GAIN report for those countries for more, specific information on their legislation.

To add a product to the Union Lists, the "Common Authorization Procedure" described in Regulation (EC) 1331/2008 must be followed for all three categories, each with its own application process. Its implementation is described in Commission Regulation (EU) 234/2011. The Commission website offers guidance for applicants on a dedicated webpage.[39]

- **Novel foods**

[38] https://ec.europa.eu/food/system/files/2020-06/fs_food-improvement-agents_enzymes_register.pdf
[39] https://ec.europa.eu/food/safety/food_improvement_agents/common_auth_proc_guid_en

Microbial biotech-derived products used in food may be subject to the EU's Regulation (EC) 2015/2283 on novel foods.[40] The EU term 'novel food' refers to any food that was not used for human consumption to a significant degree within the Union before May 15, 1997, irrespective of the dates of accession of MS to the Union, and that falls under at least one of ten categories of food mentioned in Article 3 of the 'novel foods' legislation. The Regulation states that the novel foods Regulation (Regulation (EC) 2015/2283) does not apply to "food enzymes falling within the scope of Regulation (EC) 1332/2008, food additives falling within the scope of Regulation (EC) 1333/2008 and food flavorings falling within the scope of Regulation (EC) 1334/2008." However, manufacturers must be aware that their microbial biotech-derived product could be considered a 'novel food' if the way it is produced is completely new. European industry group Food Supplements Europe offers useful guidance on their website in the form of a decision tree. EFSA receives all applications for assessment and is open to questions about the authorization requirements for any product.

iv. Pending legislations or regulations that have the potential to affect U.S. exports

The latest regulatory development stems from the July 2018 Court of Justice of the European Union (ECJ) case concerning applications of mutagenesis in plants developed through newer GE techniques.[41] The ruling has implications for GE microbes as the EU's main "GMO" legislation concerns organisms more broadly. The judgment stated that organisms from new mutagenesis techniques fall within the scope of the EU GMO Directive 2001/18/EC.[42]

The 2023 European Commission's adopted proposal on new genomic techniques (NGTs) is tailored to specifically regulate these techniques applied to plants. Concurrently, microorganisms currently fall under the existing GMO legislation. Recognizing the rapid advancements in the science of NGTs applied to microorganisms, in 2022 the Commission has engaged EFSA to generate a scientific opinion on new developments in biotechnology applied to microorganisms. This pivotal step marks the commencement of the preliminary stages toward a potential new proposal.

EFSA finalized and published its findings in June 2024, evaluating NGT applications in both viable microorganisms designed for environmental release or use in food and feed and non-viable products intended for similar purposes. The assessment concluded that NGT-modified microorganisms do not present unique risks compared to those altered through traditional methods, such as conventional mutagenesis or established genomic techniques (EGTs). EFSA also noted the superior precision and predictability of NGTs, which reduce the risk of unintended genetic modifications.

Despite these assurances, EFSA found existing regulatory guidelines only partially effective for evaluating NGT microorganisms. It recommended updating the framework to better reflect the unique aspects of these advancements. The analysis emphasized the importance of basing risk assessments on the nature of the genetic modifications rather than the technology used to achieve them, advocating for a harmonized approach to regulating products derived from conventional mutagenesis, EGTs, and NGTs.

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[40] See GAIN report New EU Novel Food Regulation Applicable as of January 1 2018
[41] See GAIN report EU Court Extends GMO Directive to New Plant Breeding Techniques (2018)
[42] See the ECJ press release and ruling: https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf.

This underscores the urgent need to align regulatory tools with the rapid pace of innovation in biotechnology.

b) APPROVALS/AUTHORIZATIONS

For products of microbial technology that fall under the EU's "Deliberate Release" Directive, please see Part B) Policy, b) Approvals. Other products of microbial technology – predominantly food ingredients – are not differentiated from their conventionally produced counterparts in previously mentioned Union lists (see above).

c) LABELING AND TRACEABILITY

For products of microbial technology that fall under the EU's "Deliberate Release" Directive, Regulation (EC) No 1830/2003 concerning the traceability and labelling of "GMOs" and the traceability of food and feed products produced from GE events applies. Please see Part B) Policy, g) Labeling for details. If the microbial biotechnology products are thoroughly purified where all traces of GE microorganisms are absent and the EU's "Contained Use" Directive applies, no "GMO" labeling is required.

d) MONITORING AND TESTING

The MS test for evidence of genetic engineering in imports of processed products. Please see the MS reports listed in Annex 2. Positive tests are submitted into the RASFF. Actions following a positive test can be destruction or transport out of the EU. Please see Part B) Policy, h) Monitoring and Testing for more information.

e) ADDITIONAL REGULATORY REQUIREMENTS

Not applicable.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

Directive 98/44/EC protection of biotechnological inventions applies to GE microbes and is implemented in all MS. Please see Part B) Policy, k) Intellectual Property Rights (IPR) and the MS Reports in Annex 2 for more information.

g) RELATED ISSUES

Another challenge facing the sector is the removal of recombinant DNA from the contained use Directive. Detection methods have become increasingly sensitive. Microbial biotech-derived ingredients are generally added to food in small quantities. Now even the smallest amount of recombinant genetic material left in the end product can be detected, which some Member States perceive as non-compliant. Therefore, the sector is calling for a detection threshold.

PART I – MARKETING

a) PUBLIC/PRIVATE OPINIONS

There is no public awareness on microbial biotechnology in the EU. As noted in the first portion of this report, European consumers would prefer for their food to not be GE. Since GE microorganisms in the EU are generally contained and absent in the final consumption product, the European public may not be as averse to the use of this technology.

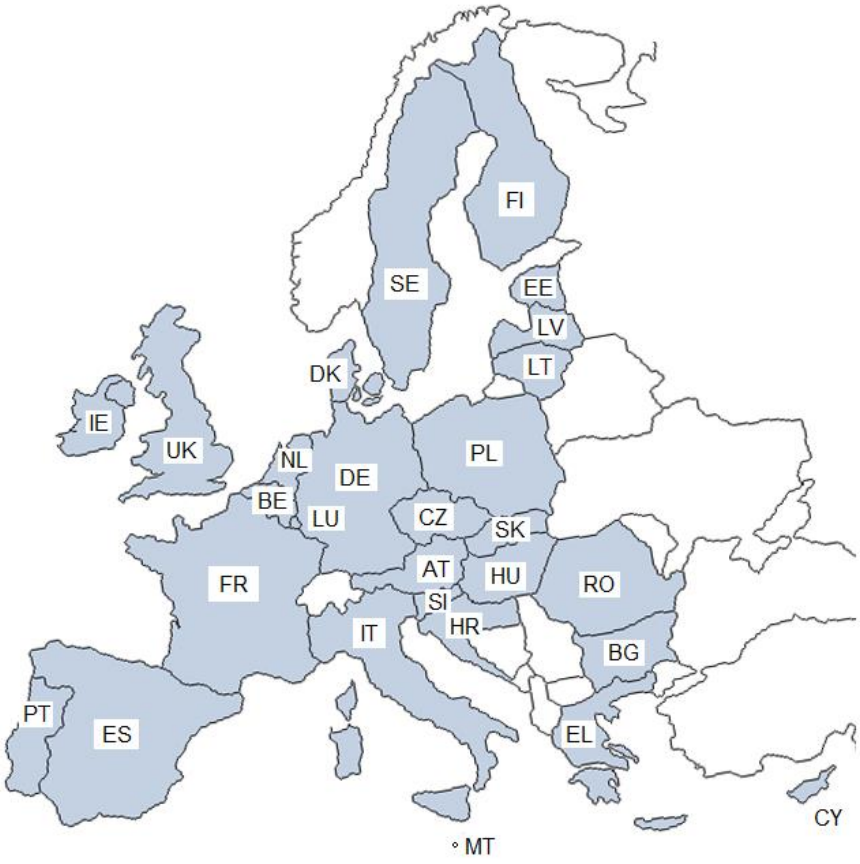
Passing the Green Deal and stimulating the circular economy, the EU has signaled a clear commitment to become more environmentally-friendly.[43] Consumer demand for animal substitutes and dairy-free products and the need for new food packaging material are on the rise. GE microbes are able to produce new and complex molecules through fermentation. Compared to chemical processes, fermentation uses less inputs and produces less waste. Together with the falling cost of the technology, this could provide momentum for microbial biotechnology.

b) MARKET ACCEPTANCE/STUDIES

There are no market acceptance studies available.

[43] See GAIN report Green Deal Strategies for the EU Agri-Food Sector Present a Politically Ambitious Policy Roadmap.

ANNEX 1 – 27 MS OF THE EUROPEAN UNION + UK



AT	Austria	IE	Ireland
BE	Belgium	IT	Italy
BG	Bulgaria	LT	Lithuania
CY	Cyprus	LU	Luxembourg
CZ	Czech Republic	LV	Latvia
DE	Germany	MT	Malta
DK	Denmark	NL	The Netherlands
EE	Estonia	PL	Poland
EL	Greece	PT	Portugal
ES	Spain	RO	Romania
FI	Finland	SE	Sweden
FR	France	SI	Slovenia
HR	Croatia	SK	Slovakia
HU	Hungary	UK	United Kingdom[44]

[44] The UK left the EU on January 31, 2020 (Brexit).

ANNEX 2 – RELATED REPORTS

USDA/FAS writes comprehensive reports about individual EU MS. The latest versions of the Agricultural Biotechnology Annual reports are available for those countries listed below:

Austria
Belgium
Bulgaria
Croatia
Czech Republic
France (2023)
Germany
Hungary
Italy
The Netherlands
Poland
Romania
Spain

USDA/FAS also writes a variety of reports about recent developments in biotechnology. View these reports by selecting the “Biotechnology” category under the search option of the GAIN website or through the FAS website.

Attachments:

No Attachments