The GM Food Issue

Key Facts and Figures: 2019

GM Crops are still...

largely a story of the Americas

95% of all GM food is grown in the Americas – as it has been since GM cropping began 20 years ago.

78% of global GM crop production (including cotton) was in the US, Brazil, Argentina and Canada. (ISAAA 2018)

In the five Asian countries growing GM crops, just 4% is crops for direct human consumption. Non-food crops (cotton) account for 96% of acreage. (ISAAA 2017)

4 commodity crops

Four commodity crops – soy, maize, canola and cotton - account for around 99% of GM acreage. (ISAAA 2018) GM animal feed crops alfalfa and sugar beet account for less than 1% of all production while cultivation of other GM crops (squash, papaya, apple and eggplant) ranges from small to miniscule (ISAAA 2017).

2 traits

Since 1996, two traits dominate commercial GM agriculture - **herbicide and insect resistance - or a combination of the two (so-called stacked traits)**. These account for virtually 100% GM crops grown. (ISAAA 2018)

Other traits promised have proved difficult to deliver and most have yet to materialise. The first GM drought resistant crop on the market – a Monsanto maize - **performs no better than conventional corn** bred to cope with dry conditions. (USDA 2011)

4 **countries** grow 78% of all GM crops

crops account for 99% of all GM acreage

Markets call the tune

No GM crops grown in NZ

It is widely agreed that the GMOs currently available are **not relevant to New Zealand conditions**.

The primary reason that no GM crops are grown in NZ, however, is **consumer resistance to GM foods**.

Markets avoid direct human foods

GM crops for direct human consumption - including wheat, potatoes, tomatoes and flaxseed - have foundered in the market. Most GM crops produced today end up as **animal feed, biofuel feedstock**, or in highly processed **food ingredients that do not need to be labeled**.

GM Free position dominates Europe

17 EU countries - more than 2/3 of Europe's arable land - have prohibited GM crops and some leading GM seed companies have closed down their European operations. (Nelson 2015; Michail 2015) GM cropping in the EU 28 is tiny, with just one GM crop (an insect-resistant corn) grown on 121,000 ha last year, less than 0.1% of global GM acreage. Spain accounts for around 95%, with Portugal growing the rest (5,733 ha). (ISAAA 2018) Czech Republic and Slovakia abandonned GM maize production "due to difficulty in marketing their biotech maize to feed millers who demand non-biotech maize." (ISAAA 2017)

Consumers still reject GM foods

Opposition to GM food is not confined to wealthy markets – it's global. A survey of 18 countries found that a majority of consumers do not want GMOs in food. Even when promised benefits, on average 57% of respondents disagreed with the statement that: "I don't mind GMOs in food if it helps farmers produce more and/or keeps prices down"; only 18% agreed. (Greendex 2014)

GM foods remain highly controversial in the EU. US government dispatches report "consumer attitudes to GE products are most negative" across the single market and that "many producers have changed the composition of their products to avoid losses in sales". (USDA 2017)

Even in the US – the home of GM food production - demand for non-GM food products is booming. Consumers overwhelmingly want labelling for GM content and the ability to choose GM Free products. The Non-GM Project now certifies a whopping $26 billion in food products for the North American market per annum.

Increased labelling for GM animal feed

The trend is for **increased labelling of products for GM feed**. **France** and **Germany** have introduced GM free labelling schemes for animal products and major supermarket chains in **Italy**, **Switzerland** and **the UK**

either prohibit GM animal feed in their own brands or provide clear choice. Major international companies such as Danone, Lidl and Asda have also pledged to move to GM free feed products.

NZ meat exporters leveraging off GM Free status include: Harmony NZ, First Light Foods, NZ Natural Lamb Company, Ovation, Wakanui Beef, Lean Meats, Duncan New Zealand Venison and PAMU. Fonterra, Atkins Ranch and NZ Jerky are among those to gain Non-GMO Project certification to meet consumer demand in the US market.

"Grass-fed" – by definition non-GM – provides a huge opportunity for New Zealand meat and dairy exporters.

GMO development in NZ: the grasses

Lack of industry support for GM crop trials

After more than three decades of public investment, domestic R+D has **yet to produce a commercial product**.

Two field trials are underway in New Zealand: AgResearch's GM livestock and Scion's GM pine trees.

GM vegetable and fruit are unlikely to be grown here for the foreseeable future due to consumer resistance in key markets and because **Horticulture New Zealand** has **generally been cautious regarding GM horticulture crops**. (HortNZ 2009)

GM Grasses at least a decade off

GM grasses are running **decades behind schedule** due to technical difficulties and pastoral industry worries. After 15 years of R+D, work on a GM drought resistant line has been put on ice indefinitely in favour of advanced non-GM methods (RNZ 2015). One strain – AgResearch's "high-metabolisable energy grass" is being field trialled in the US but it will be **at least a decade** before they are available to farmers. (NZ Parliament 2019)

Fears of market backlash is the primary reason that the GM grasses are being trialled in the US, rather than in New Zealand. Fonterra is concerned that even field trials could negatively impact on market perceptions and that they could not be properly contained. (Fonterra 2012; Farmers Weekly 2016)

GM grasses an all-or-nothing proposal

Government and industry agree that there is no way to contain GM grasses. As such, release (and some types of field trialling) of GM grasses is **an irreversible decision** that could ultimately affect all pastoral production – through market perceptions as well as in the supply chain.

And GM 2.0 (gene editing)?

New GM is still on the lab bench

Just two new GMOs are on the market, and their production volumes are tiny. Most new GM work is in the lab. In New Zealand, Scion is working in the lab on sterile pine trees using gene edting techniques. Results of this initial research are not expected until 2020 at the earliest. The lead scientist said that "because the project can be carried out inside, any risks are easier to contain than with trees planted outside." (Scion 2017)

Europe – the most influential jurisdiction for GMOs – has ruled

Europe's highest court – **the European Court of Justice** - has ruled that gene editing is GM under EU laws and that the techniques should be regulated to manage biosafety risks. That decision, which is binding on European member states, will have a huge influence on the commercial prospects of new GM in the near term.

New genetic engineering will not be "invisible"

New genetic engineering techniques – like gene editing - **raise significant economic risks due to uncertainty about consumer acceptance** and their regulatory status in export markets (Sustainability Council 2016).

Powerful gatekeepers have deemed the new techniques to be GM, separate to the courts, and products containing new GMOs will not qualify for certification. They include:

- the Non-GMO Project, which certifies $26 billion US in products for North America (Non GMO Project 2017)
- The German Retail Association for Non-GM Food, (5.6 billion euros of certified products (VLOG 2016).

Recognising the risks for New Zealand export economy of being out in front, the current and previous Governments determined the best position is to continue to regulate new GM techniques. (NZ Govt 2015, Hansard 2019)

References

AgResearch. 2011. Statement of Corporate Intent 2011-2016
Farmers Weekly. 2017. Five-year trials to begin in the US April/May. January 30
Fonterra. 2012. The Future of Genetic Modification in New Zealand. *Radio New Zealand,* December 9
Greendex 2014: Consumer Choice and the Environment, A Focus on Food and Behaviour Change, National Geographic.
Horticulture New Zealand. 2009. Genetic Engineering Policy
ISAAA. 2018. *Global Status of Commercialised Biotech/GM Crops: 2018.* Brief 54.
ISAAA. 2017. *Global Status of Commercialised Biotech/GM Crops: 2017.* Brief 53.
Michail N. 2015. Three more countriesto opt of GMO. *Food Navigaor.* October 7.
Nelsen A. 2015. Half of Europe opts out of new GM crop scheme. *The Guardian,* October 1.
NZ Government. 2015. EPA to consult on GMO regulations. Media statement, October 30
Non-GMO Project. 2017. Non-GMO Project Standard, Version 14.2
NZ Parliament. 2019. *2017/18 Annual review of AgResearch Limited.*
NZ Parliament, 2019. Hansard, 25 July.Oral questions
RNZ. 2015. New pasture research to boost livestock farming. *Rural News,* July 15.
Scion. 2017. Finding an acceptable way to sterilize trees. *New Zealand Logger*
Straight Furrow. 2012. GM issue raises range of views. Sandra Finnie. August 13
Straight Furrow. 2012b. Dilemma over GM pasture research. Sandra Finnie. August 13
Sustainability Council. 2016. *5 Reasons New Zealand Should Not Deregulate New Genetic Engineering Techniques*
USDA. 2017. EU-28. Agricultural Biotechnology Annual. GAIN Report SP1743
USDA. 2011. *Monsanto Petition (07-CR-191U) for Determination of Non-regulated Status of Event MON 87460*
VLOG. 2016. VLOG Demands Strict Regulation of New Gene Technologies. http://www.ohnegentechnik.org

5 Reasons

New Zealand Should Not Deregulate New Genetic Engineering Techniques

SUSTAINABILITY
COUNCIL of NEW ZEALAND

August 2016

The Issue

Developers want the Government to relax New Zealand's laws on genetic modification (GM) to allow a new generation of genetic engineering techniques to escape regulation.[1]

They hope that by avoiding labelling and mandatory safety testing they can sidestep the market rejection that has beleaguered first generation GM techniques.

This audacious bid to evade public scrutiny comes as two-thirds of Europe's arable land has been effectively deemed GM Free and amid an exponential growth in US demand for food products certified as non-GM.

Were New Zealand to deregulate any of the new generation GM techniques now, it would put the country at the bleeding edge of the new GM frontier and generate serious exposures for the nation's food exporters.

Second generation GM presents new and complex territory for governments around the world. The techniques are still in the early stages of development and none of New Zealand's key trading partners has concluded how to handle regulation of this new generation of breeding methods.

Recognising these risks, the Government has judged that deregulating new GM at this time is not in the country's best interests. The Environment Minister stated:

> New Zealand is an exporter of billions of dollars of food products and we receive a premium for our natural brand and high quality standards. […] we do not want New Zealand getting ahead of market perceptions of these new biotechnologies.[2]

The Government confirmed this position following public consultation, warning that an export-focused nation must be "mindful of market perceptions".[3]

This briefing outlines five reasons why New Zealand should not agree to developer demands to deregulate new GM breeding techniques.

1 Protecting Exports

NZ should not be out in front on new GM

Deregulating new GM techniques now would put the country's food export economy out of step with key trading partners

Food production accounts for around 60% of New Zealand's export income[4], and helps underpin the nation's economy. New Zealand is a standards-taker in the global marketplace and one issue that markets tend to have very clear standards on is GM foods. These face unrelenting consumer resistance and are subject to strict regulatory requirements in key markets. More stringent still are the standards set by major retailers and food processors that New Zealand exporters directly supply. Such standards have seen GMOs effectively excluded from supply chains serving high-end food markets.[5]

There is considerable uncertainty over how new generation techniques will fare in the marketplace. Key trading partners have yet to decide how to handle their regulation (with the exception of a few isolated products, principally in North America), while decisions in Europe look set to go to the European Court of Justice and could take years to resolve. Some expert panels have considered whether certain new techniques are GM, but there has been no public debate and no country has yet reviewed its GM laws to deliberately include or exclude new techniques from coverage.

As GM remains a politically sensitive issue in many parts of the world, it could be years before markets and consumers provide reliable signals to food exporters on use of the new techniques.

If New Zealand were to deregulate new techniques ahead of other jurisdictions, and new foods produced using them were to enter the export supply chain, they would likely be classed as "unapproved GMOs". The trade response would be punishing. Key export markets have zero tolerance for unapproved GMOs and typically reject entire shipments if these are detected in even trace quantities.[6]

>> Preserving the regulatory status quo protects New Zealand exporters.

Unapproved GMOs A Costly Business

Trade incidents involving GMOs not approved in the country of import have routinely cost US producers around $1 billion a throw.[7] The most recent event - where a variety of GM maize not approved by Beijing was detected in shipments to China - is the most costly yet, with estimates that it could set the US economy back as much as $3 billion through export rejections.[8]

This is the scenario that New Zealand food exporters could face if a new GM product entered the local supply chain before being deregulated or approved elsewhere. All it would take is for Brussels or Beijing to decide the product is GM and the losses could be serious. The impacts food exporters could face include:

- Immediate financial losses from rejection of contaminated product.
- Lengthy and costly programmes to eliminate unapproved GMOs from the supply chains. (It took eight years for the US rice industry to come clean from GM rice;[9] and is six years and still counting for the Canadian flax industry.[10])
- The loss (potentially long term) of supply contracts, particularly in highly competitive markets where other suppliers can guarantee GM free produce.[11]
- Costly litigation as actors in the supply chain seek to recoup losses. (The most recent US-China event has spawned nearly 300 lawsuits against the developer, Syngenta, including grain merchants Archer Daniels Midland and Cargill.[1213])

New GM Courts Controversy

Status in EU to Be Decided at ECJ

Europe is key as the position it takes on the new GM techniques is likely to influence decisions in other countries. The European Commission has yet to issue an opinion on the legal status of the new techniques and so provide guidance to interpret existing EU law. Meanwhile, developer hopes that one of the new techniques would duck the regulatory definition of a GMO in Europe have hit the skids in Germany.

Earlier this year, the German Federal Agency for Consumer Protection and Food Safety stated that a herbicide resistant oilseed rape produced using a technique called oligonucleotide-directed mutagenesis (ODM) is not a GMO and can be released in Germany without having to go through the GM regulatory approval process.

However, the German Federal Agency for Nature Conservation subsequently released a legal opinion that comes to a very different conclusion: ODM is a GM technique under European law.[14] Consumers and environmental groups are also contesting the decision, with the support of one of the country's foremost legal academics. This question now looks set to go all the way to the European Court of Justice.

2 Transparency & Trust

Ducking regulation is not the answer

GMO developers will not escape consumer demands for transparency and accountability

GM developers and proponents, including some in New Zealand, blame regulation for the fact that first generation GM foods have predominantly ended up as animal feed and unlabelled food ingredients.

That assessment is misplaced and suggests the industry has yet to come to terms with the causes of widespread resistance to GM crops.

"Every time we get together with companies [...] the question is posed: How else can we circumvent these regulations?"
Nature Biotech 2012

The sustained difficulties GMO developers face in getting GMOs accepted in food products are largely due to the industry being out of step with – and, in cases, hostile to - the wider community from whom it must gain its license to operate. As such, the GM food "crisis" is not regulatory in origin, but largely societal – quite simply a failure to win hearts and minds.[15]

Surveys and public opinion polling have repeatedly shown that labeling of GM food ingredients is a bottom line for consumers – even for the minority that is more accepting of the technology.

A big struggle everyone here has is how to do you talk about your product without calling it a genetically modified organism
Wired Magazine 2015

Repeating history – by attempting to avoid regulation and labelling – could have the opposite effect to the one developers seek. Indeed, deregulation of new GM techniques would likely trigger a new cycle of marketplace rejection as there would be no legal requirement to label new GM products. Retailers would then be tasked by consumers with identifying the GM content and labelling for it so they can continue to exercise choice.

>> If there is one lesson to be learnt from the history of GM food technologies, it is that developer resistance to regulation and transparency breeds mistrust. And once that trust is lost, it is difficult to recover.

3 R&D Proceeds as Usual

Without Jeopardising Exports

Continuing to regulate new GM techniques allows R+D that explores their potential to continue

R+D activities using new GM techniques will likely be laboratory-based for some time in New Zealand and approvals to research the new techniques in containment will be readily granted, as is the case with current GMOs.[16]

In the competitive global marketplace, successful agricultural innovation is not about giving developers a free rein: it must satisfy a wide range of criteria. Where use of GM in the food chain is concerned, transparency and traceability are entry-level requirements.

If the Government were to deregulate new GM techniques, developers would no longer have a duty to:

- Demonstrate that a release of a new GMO would deliver a net benefit to New Zealand, rather than just the GMO promoter; or
- Be accountable to affected parties by having to declare proposals in advance, and reduce the potential for contamination of productions lines that must remain GM Free to meet market demand.

"The strategic choices to be made around these issues should not only be focused on short-term financial impacts, but how to best enhance New Zealand's brand as a sustainable, innovative and premium producer."

KPMG 2015

Preserving the status quo means applications for research that are approved by the EPA can proceed, subject to controls that protect New Zealand food producers.

Decisions that focus on R+D needs without considering wider economic implications put Brand NZ and export earnings at risk.

>> **New Zealand's innovation strategy must encompass broader objectives of enhancing the national brand, premium positioning in the global marketplace and sustainability.**

4 Biosafety

Too early to exempt New GM

New GM techniques are at a very early stage of development. Assessments of their safety are equally preliminary

Developers want the Government to deregulate at least some new GM methods now so they can invest in techniques with the easiest path to market. Yet it is simply too early to conclude that the new techniques will generally produce food crops that are safe and do not require independent risk assessment.

Deregulating new GM techniques would mean no mandatory risk assessment is required before new GM foods are grown in the fields and enter the food chain. It would amount to a declaration that the techniques are "safe by design".

Comprehensive reviews undertaken for the Austrian and Swiss governments have concluded that new GM techniques broadly require the same safety testing, labelling and other controls as first generation GMOs. This is because:

- There is insufficient safety data to show risk assessment is not required.
- Some of the biological processes and mechanisms the new techniques seek to harness are still poorly understood.
- While some of the new techniques are more targeted than first generation GM, the literature to date has identified a wide range of unintended and unexpected effects from applying these methods. [17]

Moreover, new GM is still an unknown quantity: the techniques are still evolving and expanding in scope:

- Some of the techniques can be used to bring about far greater genetic change than standard descriptions describe (for example, repeated application of the technique to a cell;[18]) and
- The techniques are likely to be used in combination with one another.[19] (See next page)

This means new GM techniques could impact a great deal more tomorrow than is expected today.

"This power [of CRISPR] is so easily accessible by labs — you don't need a very expensive piece of equipment and people don't need to get many years of training to do this. […] We should think carefully about how we are going to use that power."
Nature, 2015

>> Mandatory risk assessment is required to assess the biosafety of new GM techniques, which is not yet properly understood.

CRISPR/Cas: Genome Editing on Steroids

Although heralded just four years ago, a new technique known as CRISPR/Cas is attracting significant commercial interest. The method uses genes from bacteria which cut up invading viruses, accompanied by RNA guides that help target these scissors to cut DNA at specific sites. Reportedly easy to apply, cheap and flexible, CRISPR-Cas – says one researcher,- "lets you target anything you want to anywhere you want[20].

Despite the excitement, it is well recognised that the technique is prone to unexpected errors.[21]Further, recent disclosures of what this supposedly 'discrete' system can achieve have triggered considerable concern about its safety and ethical acceptability.

What is unique about the CRISPR/Cas9-based gene drives proposal is that wild alleles would be rendered unable to compete, Darwinian selection would be turned on its head and **decisions made by researchers could become permanently written into the genomes of entire wild populations.** *The Scientist, 2014*

First, there is the prospect of "supercharged GMOs"[22] which came to light when Harvard University scientists revealed that they want to put CRISPR/Cas to work to achieve **permanent alteration or deliberate eradication** of wild species. Simply put, the technique can be paired with so-called 'gene drives' to speed up the rate at which mutations are inherited and spread through a wild population.[23] This could either drive permanent genetic change through an entire population or eliminate the population altogether.

Eradication of mosquitoes to prevent the spread of malaria is one of the first applications Harvard scientists have mooted. While the public health objective is clear, this would mean using a method that is fraught with risk and far-reaching consequences given that there is no reliable 'off-switch', or at least not one considered reliable.

US National Academy of Sciences review noted that "gene drives are designed to spread a genotype through a population, making confinement and containment much more difficult (or even irrelevant) and the environmental changes introduced by release potentially irreversible." The Academy identified a myriad of risks and concerns around gene drives and concluded that "there is insufficient evidence available at this time to support the release of gene-drive modified organisms into the environment"[24]

Further controversy around CRISPR/Cas erupted when scientists announced they had applied the technique to human embryos, leading to widespread concern and a call by a group of largely US-based scientists for a moratorium on its use.[25] Scientific researchers warned that using the technique on human embryos "could have unpredictable effects on future generations".[26] As Nature reports, the "breakneck pace leaves little time for addressing the ethical and safety concerns such experiments can raise".[2728]

"People just don't have the time to characterize some of the very basic parameters of the system. There is a mentality that as long as it works, we don't have to understand how or why it works."
University of California Researcher, *Nature* 2015

"Regulators and the wider world need to keep pace with the rapid development of CRISPR technology," warned an editorial in the influential journal, *Nature,* "and there is little time to waste."[29]

5 Market Opportunities

Rising demand for certified Non-GM products

New Zealand exporters benefit from the country's current GM Free status and the assurances the GM regulatory regime provides. The value of this position looks set to increase as market opportunities for non-GM products continue to grow

Prominent New Zealand food exporters already recognise a clear value from the country's reputation as a GM Free food producer. **Horticulture New Zealand's view is that** "New Zealand's current position of no commercial production of genetically engineered crops compliments our clean green image"[30] while **Zespri** believes that "the market for premium kiwifruit is enhanced by the association with 'clean, green, GMO-free New Zealand'"[31]. The **seed production** industry similarly sees the country's GM Free status as "increasingly attractive for international companies wishing to ensure GM Free seed lots".[32] Other sectors such as **maize** production[33], **bioactives**, **oilseed** such as rape[34] and flax and **dietary supplements** also leverage off the GM Free status.[35]

Now, significant opportunities are opening up for the pastoral sector, as overseas demand for **non-GM fed animal products** grows. In the US, formerly a haven market for GM foods, consumer demand for non-GM products (including products from animals not reared on GM feed) is particularly strong and fast-growing.

At a New York food show last June, New Zealand was promoted as "creat[ing] and nurtur[ing] only the best of the best: Non-GMO, grass-fed, hormone-free meat and dairy products".[36] Large chains such as Whole Foods Markets and the Safeway group are committing to meet this demand[37] and New Zealand companies that have achieved strict Non-GM certification are now stocked by high-end retailers such as Whole Foods.[38]

Being a follower rather than a leader in this case is protective of trade because New Zealand will continue to be a GM Free producer in the view of trading partners.

Ministry for the Environment, 2016

Significant market opportunities also lie beyond the US**.** NZTE identifies Germany as a potential growth market for New Zealand exporters due to the rising popularity of Non-GM animal products. NZTE notes that this "creates new opportunities, as New Zealand lamb, beef, or venison could potentially be marketed (implicitly or explicitly) as GM Free." [39]

>> **Once the country's commercially valuable GM Free status is forfeited, it would be very difficult to regain.**

Conclusion

There is no case for deregulating new genetic engineering techniques at this stage, given that it will be some time before New Zealand's key trading partners and the market place come to a position.

The Government has been right to not rush decisions that are highly complex, and dependent on decisions yet to be revealed by regulators, consumers and major retail chains.

Giving new GMOs free access to the food supply chain now, as some developers propose, could put an end to New Zealand's valued GM Free food producer status.

Maintaining the status quo allows developers and researchers to explore possibilities for using the new techniques, but under conditions that protect New Zealand food exporters from market rejection if new GMOs were to enter the supply chain ahead of market approval overseas.

[1] NZ Bio, Letter to Minister for the Environment, 29 October 2014.
[2] Minister for the Environment. 2015. EPA to consult on GMO regulations. Government media statement, October 30.
[3] Minister for the Environment. 2016. GMO regulations clarified. Government media statement, April 5.
[4] Statistics New Zealand. 2014. *Global New Zealand – International trade, investment, and travel profile: Year ended June 2014*. Wellington: Ministry of Foreign Affairs and Trade, and Statistics New Zealand.
[5] See for example USDA. 2014. EU-28. Agricultural Biotechnology Annual. GAIN Report Number FR9169, p. 39.
[6] See Sustainability Council. 2014. *Busted at the Border. GMOs and the High Cost of Running Ahead of Market Approval.* New Zealand could also become a testing ground for new GM cultivars as overseas developers capitalise on the lack of regulation.. This would increase the chances that the New Zealand supply chain would become contaminated and that food exports would be rejected.
[7] The Starlink maize and Liberty Link rice contamination incidents (in 2000 and 2006 respectively) are estimated to have cost the US industry US$1 billion each. Macilwain C. 2005. US launches probe into sales of unapproved corn. *Nature* and Shumaker L. 2007. U.S. GMO rice caused $1.2 bln in damages – Greenpeace. *Reuters*, November 5.
[8] National Feed Grain Association. 2014. "NGFA Estimates Up to $2.9 Billion Loss to U.S. Corn, Soy in Aftermath of Trade Disruption with China Over Detection of Unapproved Syngenta Agrisure Viptera™ MIR 162 Corn." April 24.
[9] USA Rice Federation. 2014. USDA Says "LibertyLink© is Out of the U.S. Rice Supply", April 1.
[10] Flax Council of Canada. 2015. Stewardship Program Update. March 23.
[11] Canadian flaxseed exports to Europe have never recovered after an unapproved (experimental) GM flax was discovered in consignments. At the time, Europe accounted for 70% of Canadian exports and recent industry reports confirm that while a small share of the European market has been recovered, other countries have moved now supply Europeans.
[12] Syngenta Viptera Lawsuit Center. Also see: Cottingham J. 2015. Arkansas farmers say Syngenta tainted grain supply to promote GMO. *Arkansas Business,* February 23. Wyant S. 2015. "Who is to blame when unapproved biotech traits enter international markets?" *High Plains Journal,* March 9.
[13] See the Sustainability Council briefing, *Busted at the Border.*
[14] Spranger T M 2015. Legal Analysis of the applicability of Directive 2001/18/EC on genome editing technologies. Commissioned by the Federal Agency for Nature Conservation.
[15] See Sustainability Council. 2012. Citizens Arrest. Accounting for the Arrested Development of GM Foods.
[16] A line of GM grasses are reportedly at field trial stage, bur progress has been suspended due.to a lack of support for outdoor trials. Fonterra. 2012. Statement provided to Radio New Zealand, December 9.
[17] Austrian Agency for Health and Food Safety (AGES). 2012. *Cisgenesis. A report on the practical consequences of the application of novel techniques in plant breeding;* (AGES). 2013. *New plant breeding techniques. RNA-dependent methylation, Reverse breeding, Grafting.* Reports for the Austrian Federal Ministry of Health. Eckerstorfer M, Miklau M and H Gaugitsch. 2014. *New Plant Breeding Techniques and Risks Associated with their Application.* Report by the Austrian Environment Agency (AEA) for the Swiss Federal Ethics Committee on Non-Human Biotechnology; and Vogel B. 2012. *Neue Pflanzenzuchtverfahren. Grundlagen für die Klärung offener Fragen bei der rechtlichen Regulierung neuer Pflanzenzuchtverfahren.* Report for the Swiss Federal Environment Agency.
[18] COGEM. 2010. *The status of oligonucleotides within the context of site-directed mutagenesis*. Report for the Dutch Minister for Housing, Spatial Planning and the Environment.
[19] See, for example, Vogel B. 2012, *as cited above.*
[20] Baker M. 2014. Gene editing at CRISPR speed. *Nature Biotechnology* 32(4): 309-312
[21] Lin Y, Cradick T K et al. 2014. CRISPR/Cas9 systems have off-target activity with insertions or deletions between target DNA and guide RNA sequences. *Nucleic Acids Research. doi: 10.1093/nar/gku402*
[22] Connor S. 2015. 'Gene drive': Scientists sound alarm over supercharged GM organisms which could spread in the wild and cause environmental disasters. *The Independent,* August 2.
[23] Ledford H. 2015. CRISPR, The Disruptor. *Nature.* Vol 522, p. 22.
[24] National Academies of Science. 2016. *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values*. Washington, DC: The National Academies Press. doi: 10.17226/23405
[25] Ahuja A. 2015. Geneticists' quest for crisper prose in the book of life. *Financial Times,* June 28.
[26] Cyranoski D and S Reardon. 2015. Chinese scientists genetically modify human embryos. *Nature,* April 22.
[27] Ledford H. 2015. CRISPR, The Disruptor. *Nature.* Vol 522, p. 21.
[28] Prywes N. 2014. Opinion: On the Irreversibility of Gene Drives. *The Scientist*, September 16.
[29] Anon. 2015. Driving Test. *Nature* (524): 5.
[30] Horticulture New Zealand. 2009. Genetic Engineering Policy.
[31] Dunahay T. 2010. *Is the Grass Always Greener? Issues Affecting the Adoption of Genetically Modified Pasture Grasses in New Zealand.* Ian Axford (New Zealand) Fellowships.
[32] Hampton J G, Rolston M P, Pyke N B and W Green. 2012. Ensuring the long term viability of the New Zealand seed industry. *Agronomy New Zealand* 42: 135.
[33] Tipa R. 2014. GM could put niche maize at risk. *New Zealand Farmer,* October 6 2014
[34] http://www.pureoilnz.co.nz/products/
[35] NZTE. 2015. Dietary Supplements. New Zealand on the world stage. Presentation by Fiona Murray, February 26; NZTE. Profiles of Our Natural Product Companies; NZTE. 2013. Bioactives Buyers Guide.
[36] NZTE. 2015. Get a 'Taste of New Zealand' Summer Fancy Food Show New York 2015. Media Release, June 26.
[37] NZTE. 2014. Sustainability Market Intelligence in North America – November 14 - GMO
[38] NZTE. 2015. Food and Beverage Product Guide USA.
[39] NZTE. 2014. Sustainability Market Intelligence in Germany - March 14.

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Report Highlights:

The European Union's (EU) complex and lengthy policy framework for biotechnology creates a challenging environment for research and limits access to innovative tools for EU farmers. As such, the EU imports large amounts of genetically engineered (GE) feed and produces very few of its own GE crops. Public acceptance of GE crops is low, and in July 2018, the European Court of Justice issued its judgment that organisms created through innovative biotechnologies should be regulated as GE organisms in the EU. The new Commission's flagship Green Deal also aims at drastically reducing the use of plant protection products and incorporating sustainability criteria into the agricultural biotechnology approval process. This could further limit access to these tools for EU farmers. In addition, upon specific requests of some Member States, the Council of the EU asked the European Commission to submit a study on new genomic techniques and if necessary, an associated legislative proposal by April 2021.

Executive Summary

The European Union (EU) imports large amounts of genetically engineered (GE) feed to sustain its livestock sector. The United States is the main supplier of soybeans to the EU, most of which are GE. In spite of efforts on 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 one percent of the EU's total corn area (102 thousand hectares of GE corn in Spain and Portugal). 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 more than two decades, European consumers have been exposed to consistent fear mongering from anti-biotech groups. As a result, consumer attitudes toward GE products are mostly negative. The EU's food industry and retailers adapt their product offerings to meet consumer perceptions. There are increasingly more initiatives to differentiate non-GE food products at the retail level by using voluntary GE-free labels. Several major supermarkets promote themselves as carrying only non-GE products.

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 2020, only one GE crop for import was fully authorized. The Commission has eight GE products awaiting final authorization to address in 2021.

In September 2019, the European Union adopted a Regulation amending the General Food Law Regulation, with the intention to increase: the transparency of the risk analysis processes; the reliability, objectivity, and independence of studies used in this process; and the governance and resources of EFSA – the agency responsible for executing the risk assessment process. The Regulation will enter into force in March 2021 and the Commission is currently preparing for the Regulation's implementation.

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.

On July 25, 2018, the European Court of Justice (ECJ) ruled that organisms produced with newer mutagenesis methods (i.e., genome editing) are subject to the regulatory obligations of the Directive for genetically modified organisms (GMOs). These newer mutagenesis methods will be subject to the same risk assessment and review requirements, labeling, and monitoring obligations, as well as traceability laws, currently applied to genetically engineered products. In November 2019, the Council of the EU requested that the EC submit a study on the status of new genomic techniques in the EU by April 30, 2021, as well as a legislative proposal (if appropriate) on how to regulate these "new breeding techniques" (NBTs), or other measures required as a follow up to the study. The proposal must be accompanied by an impact assessment.

The court also found that EU Member States have the authority to regulate organisms produced by conventional mutagenesis (chemical and radiation) that are exempt from the "GMO" Directive, as long as the actions follow the overarching obligations of EU law, particularly the free movement of goods. In May 2020, France notified the EC 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. If France determines additional measures are needed to implement the ECJ decision, U.S. agricultural exports for products developed using NBTs could be negatively impacted.

Finally, on May 20, 2020, the Commission announced both the Farm to Fork (F2F) Strategy and the EU Biodiversity Strategy for 2030 as roadmaps for enhancing food and agricultural sustainability by 2030 under the EU Green Deal.[1] The Strategies mark the beginning of a multi-step legislative development process that aims to fundamentally change the way EU agriculture operates and food is produced for, and provided to, EU consumers. On page 10 of the F2F Strategy, the Commission specifically notes:

> *New innovative techniques, including **biotechnology** and the development of bio-based products, **may play a role in increasing sustainability**, provided they are safe for consumers and the environment while bringing benefits for society as a whole. […] Farmers need to have access to a range of quality seeds for plant varieties adapted to the pressures of climate change.*

In the coming year, the Commission's study on new genomic techniques will likely play a role in determining potentially how agricultural biotechnology will support the goals of the F2F Strategy and what sort of sustainability criteria may be incorporated into the approval process for GE crops.

[1] See GAIN report on announcement: https://www.fas.usda.gov/data/european-union-green-deal-strategies-eu-agri-food-sector-present-politically-ambitious-policy

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
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 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) and the United Kingdom (UK), unless otherwise stated.

Table of Contents

CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

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

Several major **private developers** including BASF, Bayer, KWS, and Limagrain are European. However, the private sector's interest in developing varieties of GE plants suitable for cultivation in the European Union (EU) has waned. Repeated vandalism of test plots by activists, together with the uncertainty and delays of the EU approval process, makes genetic engineering an unattractive investment. EU companies have thus concentrated their efforts on non-European markets, and most of their research sites in plant biotechnology are now outside Europe. Several major private European developers have moved their research and development operations to the United States (Bayer in 2004, BASF in 2012, and KWS opened its new research center in the United States in 2015). Research and development of innovative biotechnologies is in danger of undergoing the same fate. In February 2020, HZPC, the largest Dutch seed potato producer, announced it will move some of its research and field trials to Canada in 2021 given stringent EU rules for NBTs.

Public institutions and universities conduct basic research and limited product development.

- Public research is unlikely to lead to the commercialization of **GE plants** in the EU within the coming years, because little emphasis is placed on product development, which is the end of the research pipeline, and most public institutions are unable to afford the high costs of the EU regulatory approval system. An international consortium including several EU research institutions and the United States Department of Agriculture's Agricultural Research Service (USDA ARS) developed a GE plum tree called HoneySweet that is resistant to the plum pox virus. While many field trials have been successfully completed already, it is expected to take several years before the EU MS gain final approval for the possible commercialization of this tree.
- As for **innovative biotechnologies**, several EU countries including Belgium, Germany, Hungary, Italy, the Netherlands, Poland, Spain and Sweden, and the United Kingdom are using these techniques to develop new plant varieties. For example, in Belgium, a research consortium is developing cisgenic late blight resistant Bintje potatoes. In the Netherlands, Wageningen University conducts research on cis-genic potatoes and apples. However, these plants are unlikely to

be commercialized in the EU in the coming years due to the uncertain regulatory environment, including the July 2018 judgment of the Court of Justice of the European Union. For additional information, please see Part B) Policy e) Innovative Biotechnologies.

The EU has several **public-private partnerships (PPPs)** in plant biotechnology. Most of them focus on industrial rather than agricultural applications. For instance, the Bio-Based Industries PPP that came into force in 2014 aims to develop new bio-refining technologies to transform biomass into bio-based products, materials, and fuels. It plans to invest €3.7 billion ($4.2 billion, 25 percent of which is publicly funded) in research and innovation efforts between 2014 and 2020 with the purpose of replacing at least 30 percent of oil-based chemicals and materials with bio-based and biodegradable ones by 2030. Biotechnology is one of the fields of research covered by this PPP.

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

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

b) COMMERCIAL PRODUCTION

- **Only two MS cultivate Bt corn in 2020.**

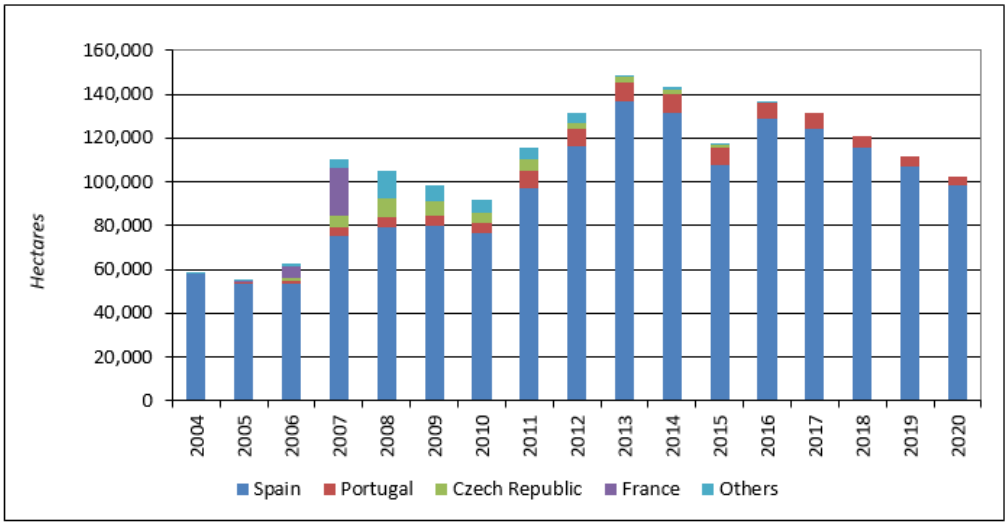
The only GE plant approved for cultivation in the EU is MON810 corn. It is a Bacillus thuringiensis (Bt) corn resistant to the European corn borer (a pest).

Graph 1 and Table 1 below demonstrate that area planted in Bt corn in the EU decreased by 8.5 percent to 102 thousand hectares in 2020. **Spain** represents 96 percent of the total area and **Portugal** the remaining 4 percent. MON810 is grown in areas where the corn borer is present and harmful to production.

Bt corn produced in the EU is used locally as animal feed. Spain and Portugal's feed grain elevators do not keep separate production lines for GE and non-GE corn as practically all marketed feed contains GE soybean as a source of protein, and consequently it is default labeled as "contains GE products." The corn processing industry uses GE-free corn for production that is intended to enter the food chain, in many cases sourced through identity preserved programs. Better prices paid by the food corn processing industry is leading some farmers to opt for conventional corn varieties.

Since 2017, the **Czech Republic** and **Slovakia** stopped cultivating Bt corn (Romania in 2016). Although the Czech government has a science-based approach to biotechnology, farmers stopped growing GE corn due to the difficulties marketing GE products. Domestic production of GE corn in the Czech Republic was used for biogas production and on-farm cattle feeding. In both the Czech Republic and Slovakia, retail buyers push for GE-free products and for products from animals that were not fed GE feed.

Graph 1. Bt Corn Area in the EU



Source: FAS EU offices

Table 1. Bt Corn Area in the EU

in hectares (ha)	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Spain	107,749	129,081	124,197	115,246	107,130	98,152
Portugal	8,017	7,069	7,036	5,733	4,718	4,216
Czech Republic	997	75	0	0	0	0
Romania	2.5	0	0	0	0	0
Slovakia	400	112	0	0	0	0
Total Bt corn area	117,166	136,337	131,233	120,979	111,848	102,368
Total corn area planted in the EU	9,255,560	8,561,930	8,271,640	8,259,470	8,923,970	8,980,000 (estimate)
Share of Bt corn in total corn area	1.27%	1.59%	1.59%	1.46%	1.25%	1.14%

Source: FAS EU offices and Eurostat

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

Since 2015, nineteen EU countries have "opted out" of GE crops cultivation for all or part of their territories under Directive (EU) 2015/412. This regulation, also called the "opt-out" Directive, allows any MS to "opt out" of cultivating an approved GE crop for socio-economic as opposed to scientific reasons. The rationale behind introducing that law was to prevent MS from invoking the safeguard clause by using "spurious science." The cultivation opt-out did not lead to a change on farms as none of the countries that opted out in 2015 cultivated GE crops when the regulation was implemented, nor resulted in a change in MS votes on cultivation files during the authorization process.[2]

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

Table 2. Cultivation Bans in the EU

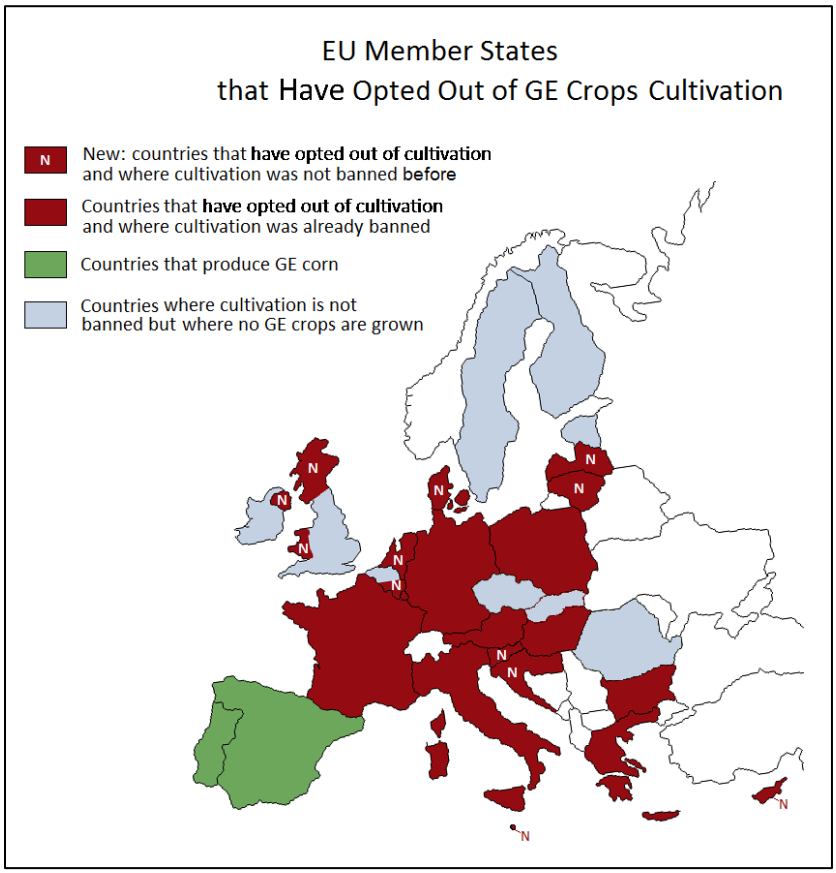
Situation	Countries and regions
N [N = New] Eight countries and four regions where cultivation was not banned before have opted out of GE corn cultivation under the 2015 Directive. This decision did not lead to a change on farms as none of the countries that opted out in 2015 cultivated GE crops for 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 in 2019.	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
**Notes:* • *Before opting out, Croatia did not have a countrywide ban on GE crops being cultivated. However, Croatia's old law on "GMOs" banned the release of GE plants in protected areas and their buffer zones, in areas of organic farming, and in areas that are of importance to ecotourism. The law provided a legal tool for excluding most of the country from planting GE*	

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

plants.

- *Denmark and Luxembourg have only opted out of cultivation for MON810 and three from the seven varieties of corn that were in the pipeline at that time.*
- *The coalition agreement of the new German government, published in spring 2018, states that the ban on the cultivation of GE plants (opt-out) will be regulated nationwide. The legislation has not yet come into force.*
- *Slovakia did not officially opt out, but legislation greatly discourages cultivation of GE crops.*

Map 1. EU MS 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);
- 12 to 25 million MT of corn and corn-processing byproducts (GE and non-GE);
- 3 to 6 million MT of rapeseed and rapeseed meal (GE and non-GE).

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

Trade data does not differentiate between conventional and GE varieties. The graphs presented in this section therefore include both categories. **Table 3** below gives the share of GE crops in total soy, corn, and rapeseed production in the EU's main supplier countries.

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

Soy	
Argentina	100%
Brazil	96%
Canada	95%
Paraguay	99%
Ukraine	estimated at 50 to 65% of exports
United States	94%
Rapeseed / Canola	
Australia	22%
Canada	95%
Russia	0%
Ukraine	estimated at 10 to 12% of exports
Corn	
Brazil	89%
Canada	100%
Russia	0%
Serbia	0%

Ukraine	estimated at <1% of exports
United States	92%
Vietnam	3%

Source: ISAAA Report 54 and FAS/Kyiv (2020)

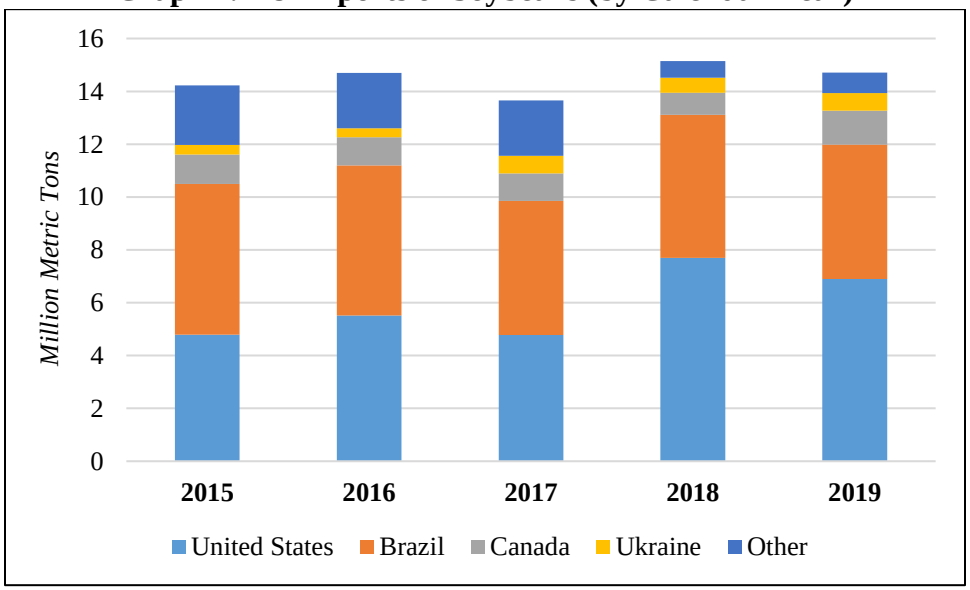
- **The EU imports more than 30 million MT of soybean products every year.**

The EU is protein deficient and does not produce enough to meet animal feed demands. The EU must import more than 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 19 million MT (see **Graphs 2 and 3** below for a breakdown). The EU is currently importing around 77-78 percent of its soybean supply.[3] 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,[4] and Italy) are also the main producers of livestock and poultry.[5]

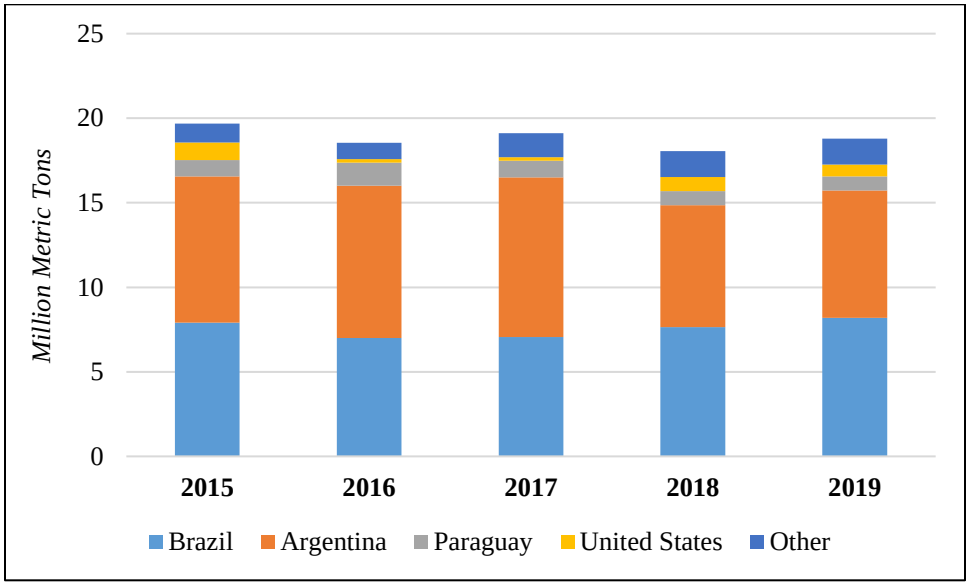
Graph 2. EU Imports of Soybeans (by Calendar Year)



Source: Trade Data Monitor (EuroStat)

[3] See the most recent GAIN update on EU oilseeds.
[4] Belgium, the Netherlands, and Luxembourg
[5] As referenced in last year's report: https://www.fas.usda.gov/data/eu-27-agricultural-biotechnology-annual

Graph 3. EU Imports of Soybean Meal (by Calendar Year)



Source: Trade Data Monitor (EuroStat)

The demand for non-GE soybean meal in the EU is driven by the organic sector, some of the products sold under Geographical Indications, and various GE-free labeling initiatives. Non-GE soybean meal is mainly supplied by domestically grown soybeans and imports from Brazil and India. European non-GE soybean production is expected to increase in the coming years.

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

There has been a long-standing debate in the EU over the dependence on imported soybeans and soybean meal. Overall, the EU's current potential for soy production remains minor relative to total animal feed demand. EU soybean production is estimated at 2.8 million MT for marketing year 2020/21, which is a small percentage of what is needed.[6] In contrast, more than 30 million MT of soybean products are imported every year.

In November 2018, the European Commission released a report on The Development of Plant Proteins in the European Union. However, this report does not discuss how EU restrictions on agricultural biotechnology could adversely affect EU goals such as improved breeding stock and more resilient protein crops adapted to the climatic and environmental conditions of the EU.

Several EU countries subsidize local non-GE protein production:

- Some MS such as France, Germany and Spain have national strategies for protein crops which aim to encourage crop rotation while reducing their dependence on imported protein. These strategies include incentives such as providing coupled supports to farmers or considering protein crops as nitrogen fixing crop (Ecologic Focus Areas) for

[6] See most recent GAIN update on EU oilseeds: https://www.fas.usda.gov/data/european-union-oilseeds-and-products-update

greening compliance under the 2014-2020 Common Agricultural Policy (CAP).

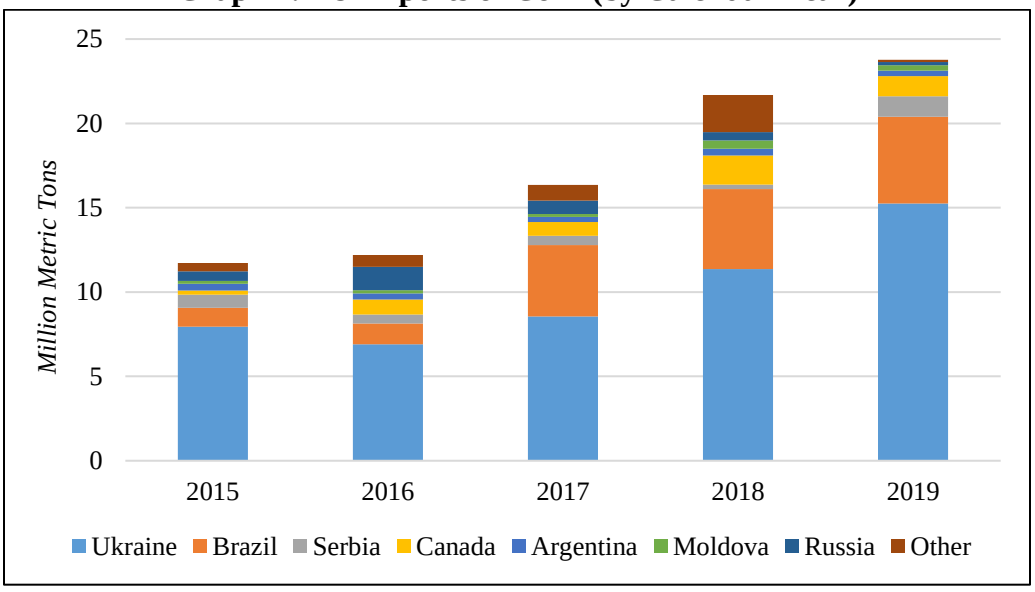
- The Donau Soya Organization, a non-governmental association supported by the Austrian government, promotes the production of non-GE soybeans in the Danube region (Austria, Bosnia Herzegovina, Bulgaria, Croatia, Germany, Hungary, Romania, Serbia, Slovakia, Slovenia, and Switzerland). According to the association, the production potential for soybeans in the Danube region would be 4 million MT.
- Since July 2017, 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.

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

- **The EU imports 12 to 25 million MT of corn per year.**

Over the past five years, corn imports averaged 17 million MT. The EU currently imports about 20-25 percent of its corn supply. It is estimated that just over 20 percent of total corn imports are GE. The largest importers of corn (Spain, Benelux,[7] Italy and Portugal) have large livestock and poultry sectors, but are limited in their domestic grain production.[8] In the past five years, Ukraine has been the EU's major supplier of corn; it accounted for 64 percent in 2019. GE crop production is not officially allowed in Ukraine.

Graph 4. EU Imports of Corn (by Calendar Year)

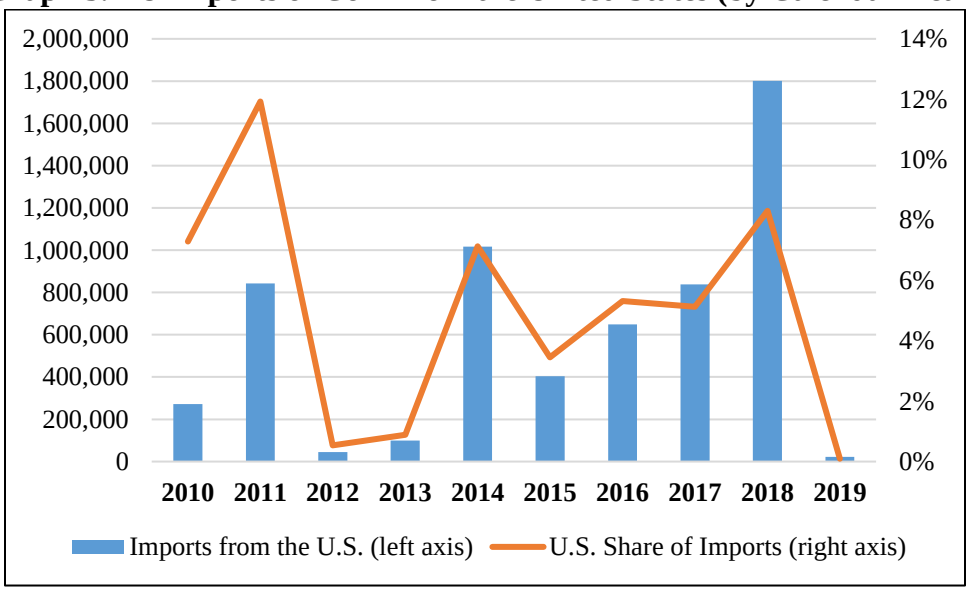


Source: Trade Data Monitor (EuroStat)

[7] Belgium, the Netherlands, and Luxembourg
[8] Additional information on EU's grain market can be found in the EU-28 Grain and Feed GAIN Annual Report 2020.

Over the past 10 years, on average, the United States represented five percent of total EU imports of corn (see **Graph 5**). The beginning of GE corn plantings in the United States in 1998 resulted in a drastic decline in U.S. exports to the EU. This is due to the lag of 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[9] in one variety. These varieties are referred to as stacks. Imported U.S. corn is primarily used for animal feed and bioethanol production; Spain is by far the main importer of U.S. corn in the EU. Imports increased in 2011, 2014, and 2018; however, they sank to nearly 0 percent of market share in 2019 due to additional duties imposed by the EU on U.S. sourced corn in June 2018 in retaliation to the United States' tariffs on steel and aluminum products.

Graph 5. EU Imports of Corn from the United States (by Calendar Year)



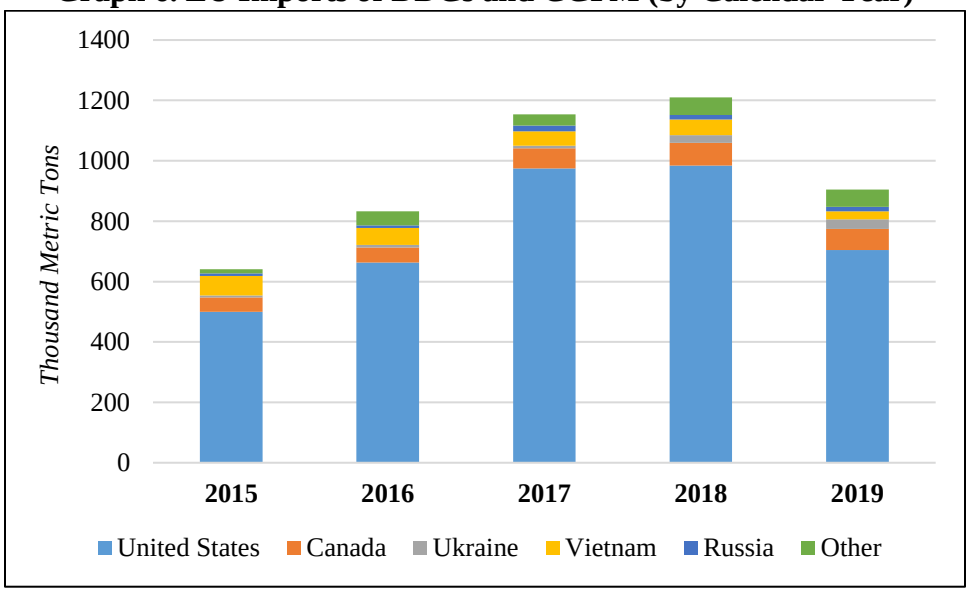
Source: Trade Data Monitor (EuroStat), in metric tons

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

In 2019, the EU imported 905 thousand MT of Distiller's Dried Grains with Solubles (DDGS) and Corn Gluten Feed and Meal (CGFM; see **Graph 6**).[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, with an average market share of 80 percent over the past five years. The volume of imports varies from year to year depending on prices and on the pace of EU approvals of new GE corn varieties.

[9] A transgenic event is the DNA sequence incorporated into the target genome.
[10] DDGS are a corn by-product of the distillation process; CGFM is a corn by-product of wet milling.

Graph 6. EU Imports of DDGs and CGFM (by Calendar Year)



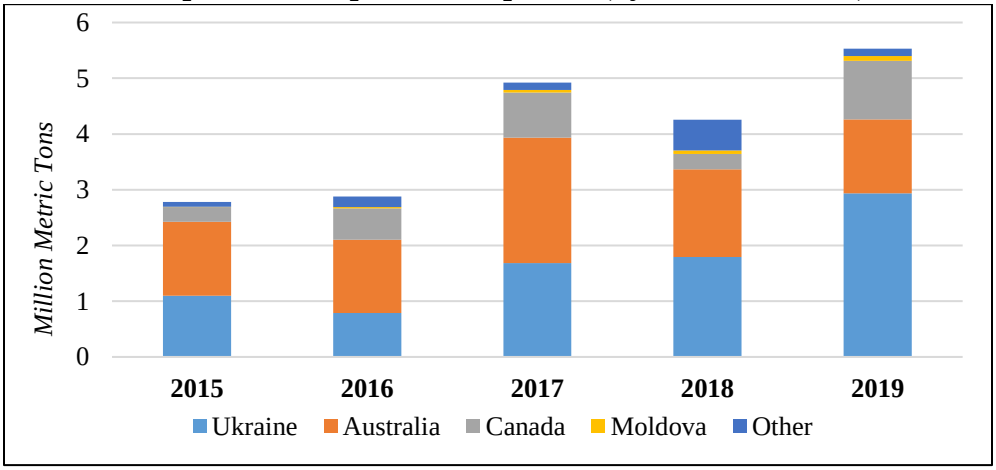
Source: Trade Data Monitor (EuroStat)

- **The EU imports 3 to 6 million MT of rapeseed products every year.**

In the last five years, the EU imported on average 4 million MT of rapeseed and 361 thousand MT of rapeseed meal per year (see **Graphs 7 and 8**). The share of GE products of total imports is estimated at less than 25 percent. The three major suppliers of rapeseed to the EU (Ukraine, Australia, 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.

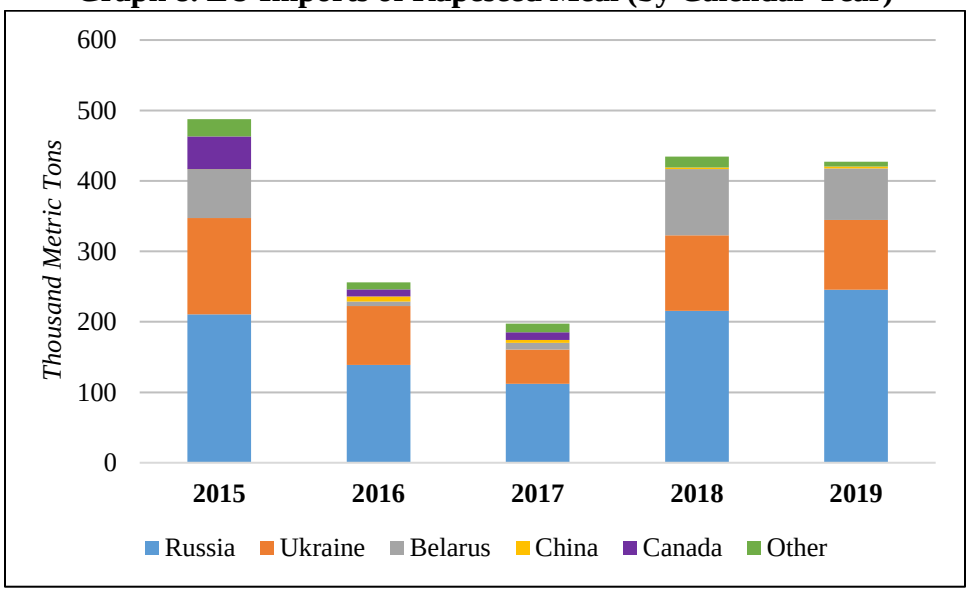
Although the EU is the world's largest producer of rapeseed, local demand exceeds domestic supply and large quantities of rapeseed are imported for crushing. Rapeseed meal is used for animal feed in the livestock sector.

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



Source: Trade Data Monitor (EuroStat)

Graph 8. 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 are 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 six years overall for EFSA's opinion on a biotech product.

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

The EU has had a somewhat conflicted relationship with agricultural biotechnology since it was introduced over 30 years ago. The European Commission (EC) continues to pursue inconsistent and unpredictable approaches regulating the technology. This is due in part to the strong emotional and ideological stance on biotechnology taken by EU consumers and anti-biotech groups pressuring the EP 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 1st, 2019 the new European Commission led by Ursula Von der Leyen came into office. To secure the support of environmental political groups and address the environmental concerns many EU citizens have, the Commission's first act was to develop the EU *Green Deal*.

It consists of two strategies, the Biodiversity Strategy[11] and the Farm to Fork Strategy[12] – both aiming to drastically restrict the use of pesticides and other farm inputs. The Commission has stated that in light of the Green Deal, it would add sustainability criteria to the GE authorization process and is currently investigating how to go about these criteria.

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; applicants prefer 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.

[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
[13] Regulation (EC) No 1829/2003 of the European Parliament and of the Council
[14] The application must include:
- Name and address of the applicant.
- Designation of the food, and its specification, including the transformation event(s) used.

- EFSA informs other MS and the EC of the application without delay and makes it available. EFSA also makes the summary of the application dossier available to the public via the internet.

- EFSA is obliged to respect a limit of six months from the time it receives a valid application to when it gives its opinion. This six-month limit is extended whenever EFSA or a national competent authority through EFSA requests supplementary information from the applicant.

- EFSA forwards its opinion on the application to the EC, the MS, and the applicant. The opinion is made available for public comment within 30 days of publication.

- Within three months from receiving the opinion from EFSA, the EC presents the PAFF with a draft decision reflecting EFSA's opinion. PAFF votes on the draft decision.

- Draft decisions that have been put to the PAFF after March 1, 2011, are subject to the procedural 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.

- 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.

- **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]

- 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

[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.

information about this Directive is available in Part A) Production and Trade, b) Commercial Production.

- **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 but at the time of writing, no results are known.

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. During the 2020 WTO Biotech Consult, the European Commission expressed that they do not expect the proposal to move forward due to MS reluctance, but is not planning to withdraw the Comitology Reform Proposal.

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.

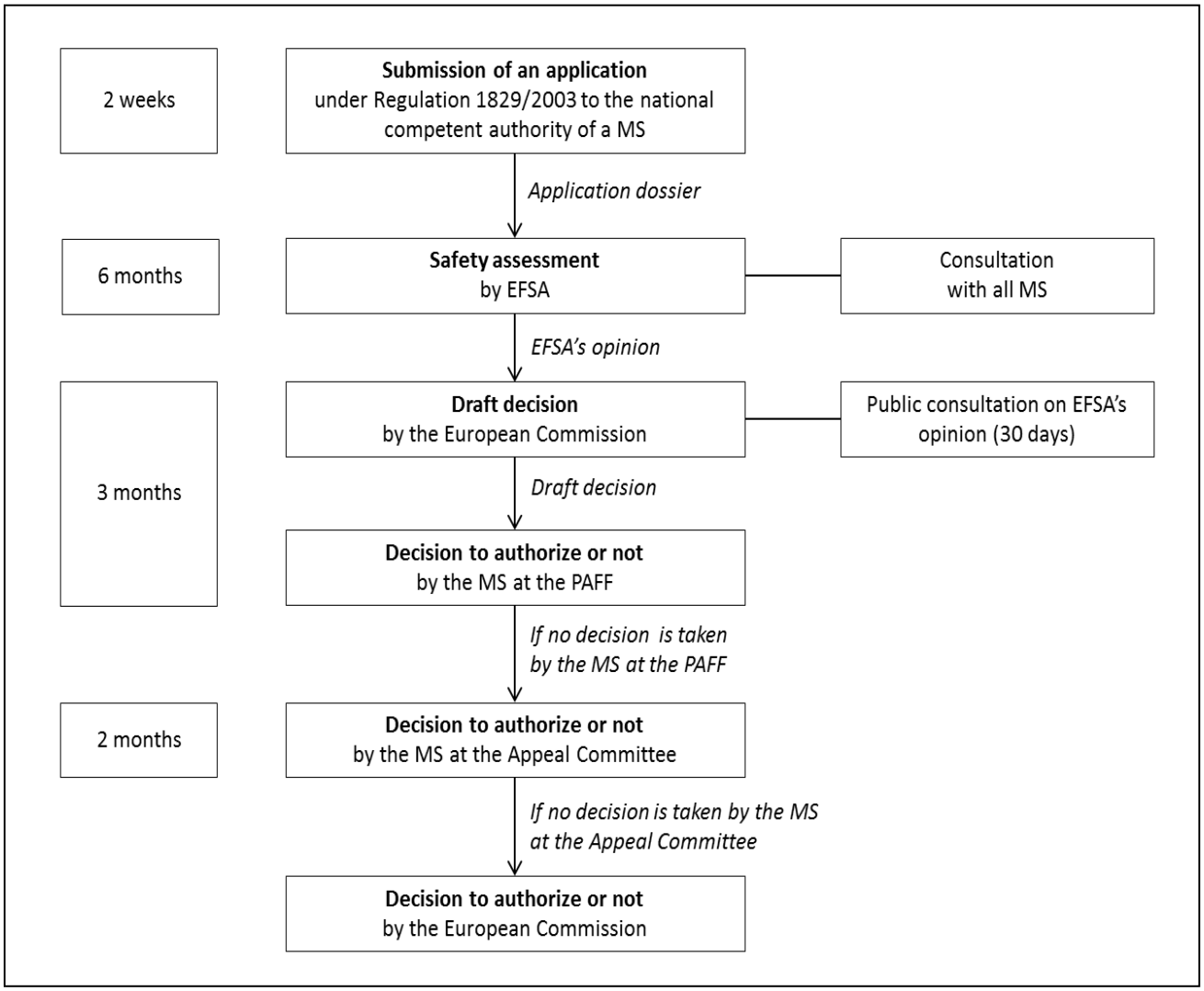
This represents a problem for commodity trading companies, as it limits their sourcing options and increases the risk in their operations with those countries where not-yet approved events are grown. Shipments of agricultural commodities destined for the EU have been rejected when traces of such events 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 GE events are taking more than six years for approval. In contrast, the average approval process takes about two years in Canada, Brazil and the United States and three years in Korea. The main bottleneck of the EU's lengthy approval process lies with EFSA. Despite 25 years of history of safe use of GE products globally, and EFSA's extensive institutional record of regulating GE products, it took the organization an average of 4.7 years to deliver its safety assessments for the events approved in 2018, and 4.9 years for the events approved in 2019. Only one event was approved in 2020. It took EFSA about half the 2019 average to process this event.

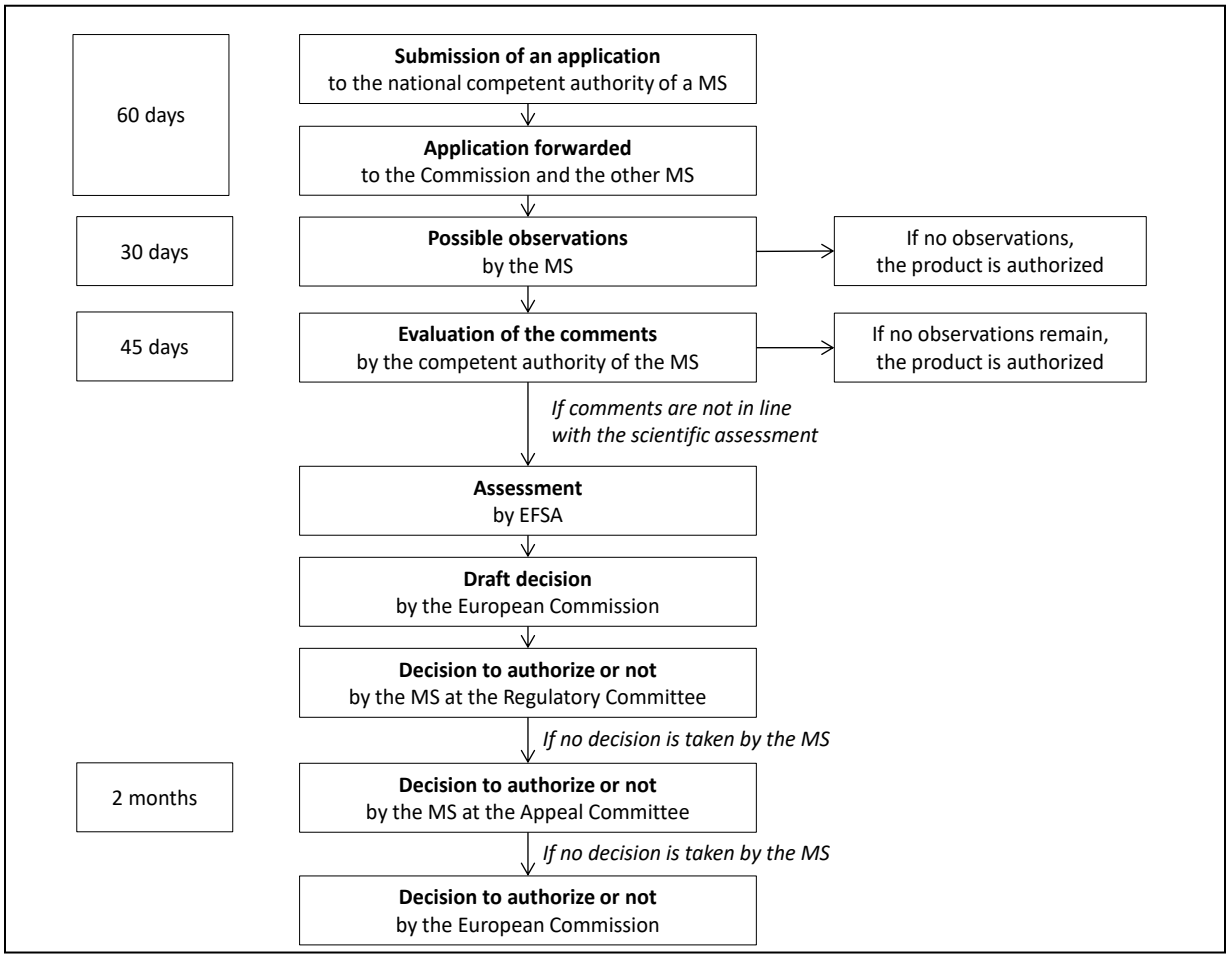
The very first step of applying for approval of GE products in the EU usually takes longer than six months. Applicants submit their GE dossier to EFSA and then wait between a few months and about two years – exceptionally up to four years – for EFSA to review the application and perform a "completeness 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

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

After that, the EU was getting closer to their timeline. However, due to the pandemic in 2020, there was an exceptional backlog building up, as the new Commission first focused on its signature Green Deal and then had to adapt to COVID-19 restrictions. Committees were slow to organize virtual meetings. Voting had to be done through written procedure, adding weeks. More details can be read at the end of section b) Approvals.

b) APPROVALS

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

MON810 Bt corn is the only GE plant authorized for cultivation. At the time of this report, GE products authorized for food or feed use in the EU include 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.

So far, only one GE event has been authorized in 2020. On September 28, the European Commission (EC) approved Bayer's herbicide tolerant soybean MON 87708 x MON 89788 x A5547-127[17]. The EC last authorized a GE crop in November 2019. Since the EU wants to decrease its use of pesticides, and glyphosate in particular (according to the European Green Deal[18]), this authorization is a positive sign that the new Commission is still following EU regulation. As of this writing, the EC has processed all GE product import applications on its bench; however, eight applications are pending final authorization.

Due to the COVID-19 outbreak and the suspension of PAFF meetings (Standing Committee on Plants, Animals, Food and Feed), the MS have around 20 EFSA approved GE crops waiting in the authorization pipeline, including the eight that are at their final stage. At the time of writing, the PAFF organized three times: September 15, October 7, and December 16, but due to COVID-19 restrictions, the MS were forced to use teleconferencing. As a consequence, voting was conducted via written procedure, leaving MS about two weeks to cast their vote.

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 labelling and traceability rules.

c) STACKED EVENT APPROVALS

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

The EU approves a stacked product separately from the singles it has already reviewed (unlike

[17]Bayer's XtendFlex® soybean, more information in this GAIN report: https://www.fas.usda.gov/data/european-union-european-commission-approves-import-ge-soybean

[18] Updates on the EU Green Deal are published regularly by FAS/Brussels through the GAIN system. See for example: https://www.fas.usda.gov/data/european-union-eu-green-deal-september-2020-update

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[19] and the United Kingdom (UK). However, only six MS and the UK conducted open-field testing in 2020: Belgium, the Czech Republic, the Netherlands, Romania, Spain, and Sweden. The main disincentives for field trials include: Repeated destruction by activists, a burdensome authorization process, and the unattractive investment 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. Spain leads the number of accumulated notifications of experimental field trials. In the last few years (2015 to 2020), the countries with the largest number of notifications were Spain (125 notifications), Germany (98 notifications), the Netherlands (87 notifications), and Sweden (28 notifications). Belgium had 20 notifications, and the United Kingdom and Hungary were tied with 17 notifications during this period. 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.

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

e) INNOVATIVE BIOTECHNOLOGIES [20]

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. That ruling has significant potential negative consequences for EU innovation and EU agriculture. This judgment also has potential to create trade disruptions in the future.

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.

During the EU Agriculture and Fisheries Council meeting of May 14, 2019, the Netherlands "invited the new Commission to add a review of the EU's "GMO" legislation to its working program."[21] The request for a common EU approach and a review of the current legislation was supported by twelve MS. On September 6, 2019, building on the May 14, 2019 Council meeting, the Finnish presidency of the Council of the EU asked the European Commission to submit a study and a proposal on the status of mutagenesis and to conduct an impact study of possible decisions on this subject.[22] 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.

[20] "Genetic Engineering" means transgenesis. "Innovative biotechnologies" is a synonym of New Breeding Techniques (NBTs) and excludes transgenesis.
[21] See the Outcome of the Council Meeting.
[22] See the Draft Council Decision.

Supplementary statements from some MS have been made public: Cyprus, Hungary, Latvia, Luxemburg, Poland and Slovenia state that the current level of protection should be maintained; the Netherlands and Spain state that the study needs to "address the adequacy, efficiency and consistency" of the current legal framework; the Netherlands underlines the urgency of the steps to be undertaken; Sweden adds that the study should include cost estimates.

The Commission has 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" have also provided ample input.

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

Another important contribution is the EFSA study[23] 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].

For more background on this subject, please see the 2019 Agricultural Biotechnology Annual report for the EU.

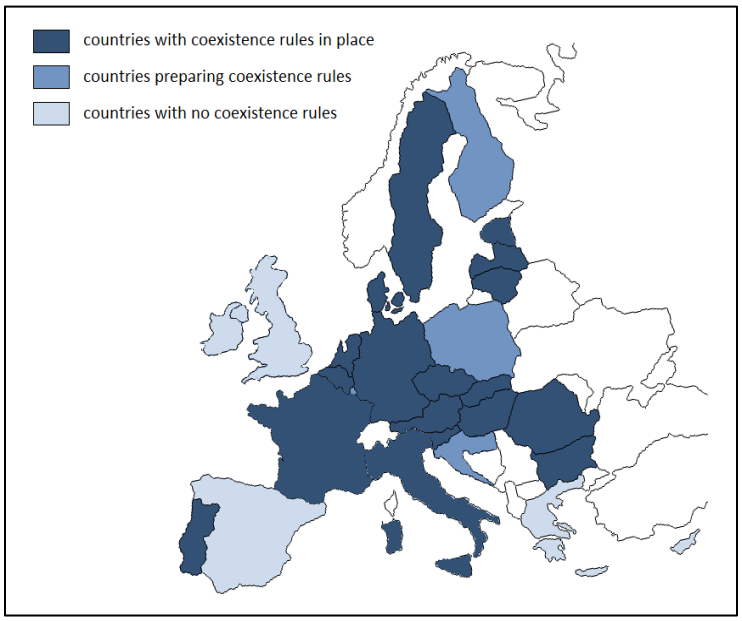
Following the ECJ's decision that since the EU has not developed legislation on mutagenesis, the MS can, the French government now wants to ban herbicide-tolerant conventional mutagenesis crops. This may however not be compliant with the single market, as FAS/Paris reports.[24]

f) COEXISTENCE

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

[23] EFSA opinion: https://www.efsa.europa.eu/en/efsajournal/pub/6299?
[24] Please find more information in FAS/Paris' GAIN report on the subject: https://www.fas.usda.gov/data/france-french-implementation-european-court-justice-ruling-jeopardizes-exports-rapeseed-france

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 at the farm level is managed by following the good agricultural practices defined by the National Association of Seed Breeders and in 2017. This decree was enacted to avoid possible cross-border effects of genetic engineering into neighboring MS. In some parts of the EU such as Southern Belgium and Hungary, coexistence rules are very restrictive and limit **the cultivation of GE crops.**

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

g) LABELING

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

EU **Regulations** (EC) No 1829/2003 **and** (EC) No 1830/2003 **require food and feed produced from or containing GE ingredients to be labeled as such**. These regulations apply to products originating in the EU and imported from third countries. Bulk shipments and raw materials must be labeled, as well as packaged food and feed.

In practice, consumers rarely find 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 6.4 of Directive 2000/13/EC, 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 1829/2003 require all business operators involved to transmit and retain information on GE products in order to identify both the supplier and the buyer of the product. Operators must provide their customers with the following information, in writing:

- an indication that the product – or certain ingredients – contains, consists of, or is obtained from GMOs;

- information on the unique identifier(s) for these GMOs;
- in the case of products consisting of or containing mixtures of GMOs to be used only as food or feed or for processing, this information may be replaced by a declaration of use by the operator. It has to be accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture

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

- **Voluntary GE-free Labeling Systems**

There is no EU-harmonized legislation on GE-free labeling. GE-free labels are allowed on a voluntary basis 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[25] on the market is the submission of an application. This application must include a monitoring plan for environmental

[25] "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.

effects.[26] 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.[27]
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.[28]
4. The results of the monitoring must be made publicly available.[29]
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.[30]

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

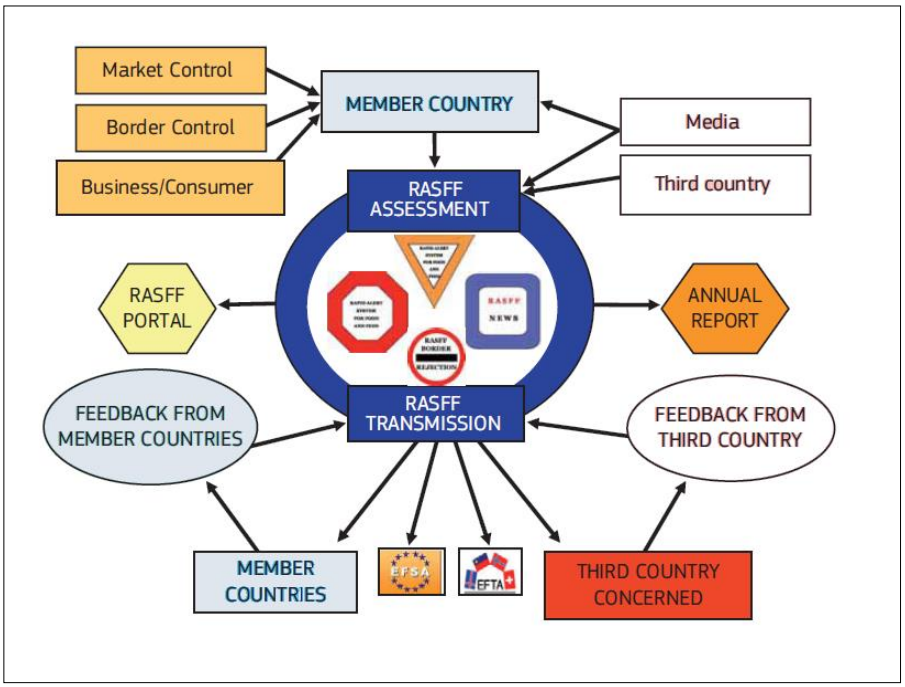
The Rapid Alert System for Food and Feed (RASFF) is used to report possible food safety issues. According to the most recent RASFF annual report available, in 2019, nine shipments were rejected at the EU border due to adventitious presence of GE food or feed. There was also one "information for attention" and three "information for follow-up." These notifications do not mean that there was an actual risk but that there was uncertainty due to the presence of GE products that have not been approved in the EU (they may have been approved in another country).

The general functioning of the RASFF is illustrated in the graph below. Whenever a member of the RASFF network (the EC, EFSA, a MS, Norway, Liechtenstein, or Iceland) has any information relating to the existence of a 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.

[26] Directive 2001/18/EC: Article 5 and Annex III for experimental releases, Article 13 and Annex VII for placing on the market
[27] Regulation (EC) No 1829/2003 Articles 5 and 17
[28] Directive 2001/18/EC Article 20
[29] Directive 2001/18/EC Article 20 - Regulation (EC) No 1829/2003 Article 9
[30] 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).

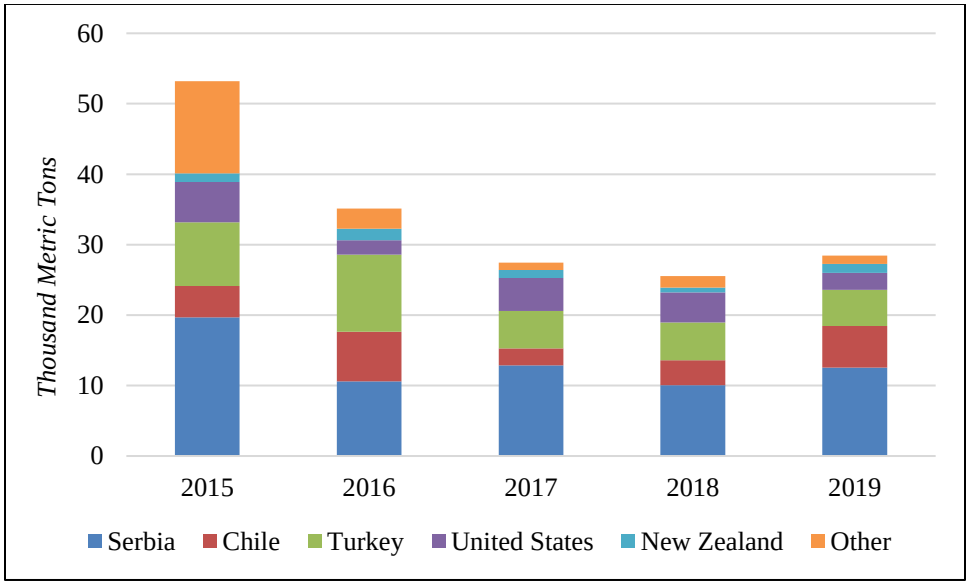
- **Thresholds for adventitious presence in feed, food and seeds**

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 chart below about imports of corn seed).

Graph 9. EU Imports of Corn Seed



Source: Trade Data Monitor (EuroStat)

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

On November 20, 2017, EFSA published a new 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

In almost all MS, with the notable exception of Spain, farmers that produce GE crops must register their fields with the government.[31] In some countries, this obligation tends to discourage farmers from growing GE crops, since it can be used by activists to locate fields.

k) INTELLECTUAL PROPERTY RIGHTS (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 its whole genome or by a gene complex.	Patents cover **a technical invention**. Elements that are patentable include: - plants, if the plant grouping is not a variety, if the invention can be used to make more than a particular plant variety, and as long as no individual plant varieties are mentioned in the claim; - biological material (e.g., a gene sequence) isolated from its natural environment or technically produced, even if it previously occurred in nature; - microbiological processes and their products; - technical processes. Plant varieties and essentially biological processes for the production of plants and animals are not patentable.
Conditions to be met	Plant varieties can be granted variety rights if they are clearly distinguishable from any other variety, sufficiently uniform in their relevant characteristics, and stable.	Patents can only be granted for inventions that are new, involve an inventive step, and are susceptible of industrial application.[32]
Scope of the	One single variety and the	All plants with the patented invention are

[31] 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.
[32] 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.

protection	varieties essentially derived from it are protected within the EU.	protected within the EU.
Exemptions	- Breeders' exemption allows free use of a protected variety for further breeding and free commercialization of new varieties (except for essentially derived ones). - There is an option for producers to use farm-saved seed under certain conditions.	At EU level, according to the European Patent Office, a plant is protected for all its uses.[33]
Duration	The variety is protected for 25 years from the date of issue (30 years for some plants: trees, vines, potatoes, legumes, etc.).	The invention is protected for 20 years from the application date.
Responsible office	The Community Plant Variety Office (CPVO) is responsible for the management of the plant variety rights system.	The European Patent Office (EPO) examines European patent applications.
Legal basis	All the legislations in place are available on the CPVO website. They include Regulation (EC) No 2100/94 on plant variety rights. The UPOV website gives the text of the UPOV Convention (International Convention for the Protection of New Varieties of Plants) and the legislation of MS that has been notified in accordance with it.	The legal basis for patenting biotechnological inventions in the EU include: - the European Patent Convention (EPC), an international treaty ratified by all MS that provides the legal framework for the granting of patents by the EPO; - the case law of the EPO boards of appeal, that rules on how to interpret the law; - Directive 98/44/EC on the legal protection of biotechnological inventions, that has been implemented into the EPC since 1999 and shall be used as a supplementary means of interpretation; - national laws that implement EPC and Directive 98/44/EC (in place in all MS since 2007, see USDA FAS country reports).

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.

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

The European Seed Association (Euroseeds) supports the co-existence of patents and plant variety rights. Euroseeds also supports the exclusion of plant varieties and essentially biological processes from patentability. Furthermore, Euroseeds promotes safeguarding free access to all plant genetic material for further breeding, as is the case in the French and German patent laws via an extended research exemption.

In July 2017, the European Patent Office (EPO) amended the Implementing Regulations to the European Patent Convention, establishing that European patents shall not be granted for plants or animals exclusively obtained by means of "essentially biological processes." "Essentially biological processes" means naturally occurring processes such as the crossing of whole genomes and the subsequent selection of plants or animals. 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.

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 regulates trans-boundary movements of GE products and transposes the Cartagena Protocol on Biosafety into EU law. Procedures for the trans-boundary movement of LMOs include: notification to importing parties; information to the Biosafety Clearing House; requirements on identification and accompanying documentation.

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

- **Nagoya Protocol on Access to Genetic Resources**

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

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

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."

m) INTERNATIONAL TREATIES/FORUMS

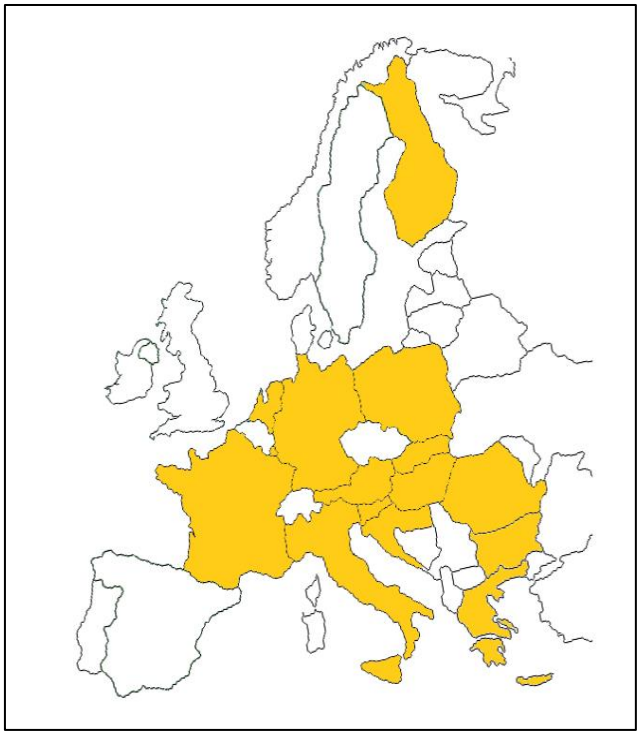
The EU is a member of the Codex Alimentarius alongside its 27 MS (in addition to the United Kingdom). The EC represents the EU in Codex; DG SANTE is the contact point.

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.

- **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.

- **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. 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 will have an influence on eight sectoral legislative acts across the agri-food industry, including the "GMO" Directive 2001/18/EC and Regulation (EC) No 1829/2003.

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 will be made accessible, such as through a web portal requiring registration for access or an open access database accessible globally. Although full details are not yet available, 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 will be 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. Together with EFSA, the Commission will develop an implementing act with details about its "general plan for risk communication."

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 economic growth and globalization. They see more risks than opportunities in technical progress and campaign for a broad application of the precautionary principle. Some of them defend an ideal science that would focus solely on understanding phenomena, and not on developing useful

and profitable applications; others reject or strongly criticize science and progress, in line with philosophers such as Hans Jonas and Bruno Latour. They are skeptical of new technologies, in general, and for biotechnology specifically 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 heighten public fears. These groups are a minority. However, they are passionate about their cause and very active in the media. The extent to which they are accepted varies across countries, but they have highly developed communication skills. The effectiveness of their campaigns, amplified by the media, has had a strong effect on public opinion. The fact that most of the GE plants cultivated in the world today are insect- or herbicide-resistant plants that bring direct benefits to farmers rather than consumers has made it easier for anti-biotech groups propaganda to be well-received by the public. These groups have played an important part in the adoption of regulations that have restricted the adoption of biotechnology in the EU, directly through lobbying and indirectly through their impact on public opinion. Their actions have made biotechnology a sensitive political issue; it is now difficult for elected officials to remain neutral on biotechnology, forcing them to take a public position for or against and suffer the political consequences.

Stakeholders that defend the use of GE plants at EU level 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 131 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, some 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.
(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.

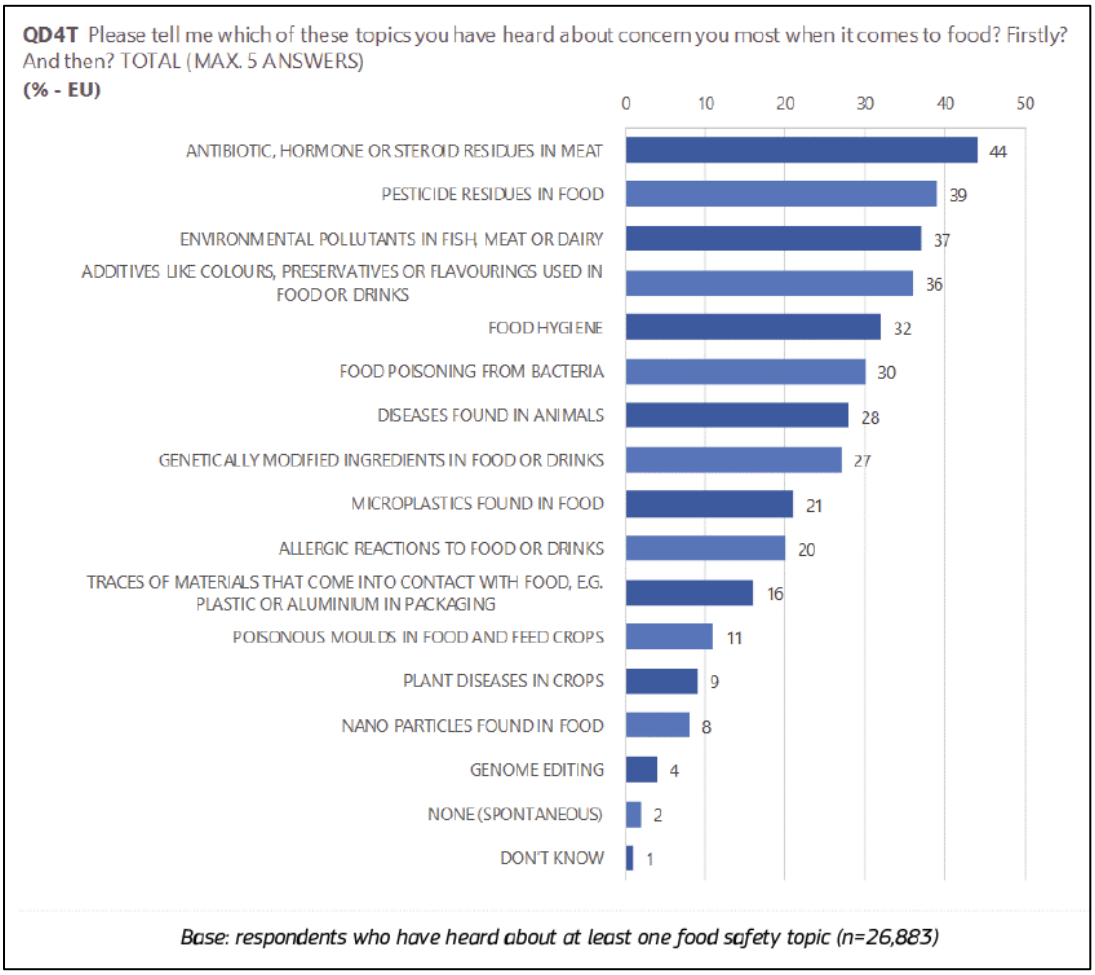
European importers and **feed manufacturers** have repeatedly criticized the EU policy (length of the authorization process, absence of commercially viable LLP policy), arguing that it could result in shortages, price increases for feed, and a loss of competitiveness for the breeding sector, which would 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.

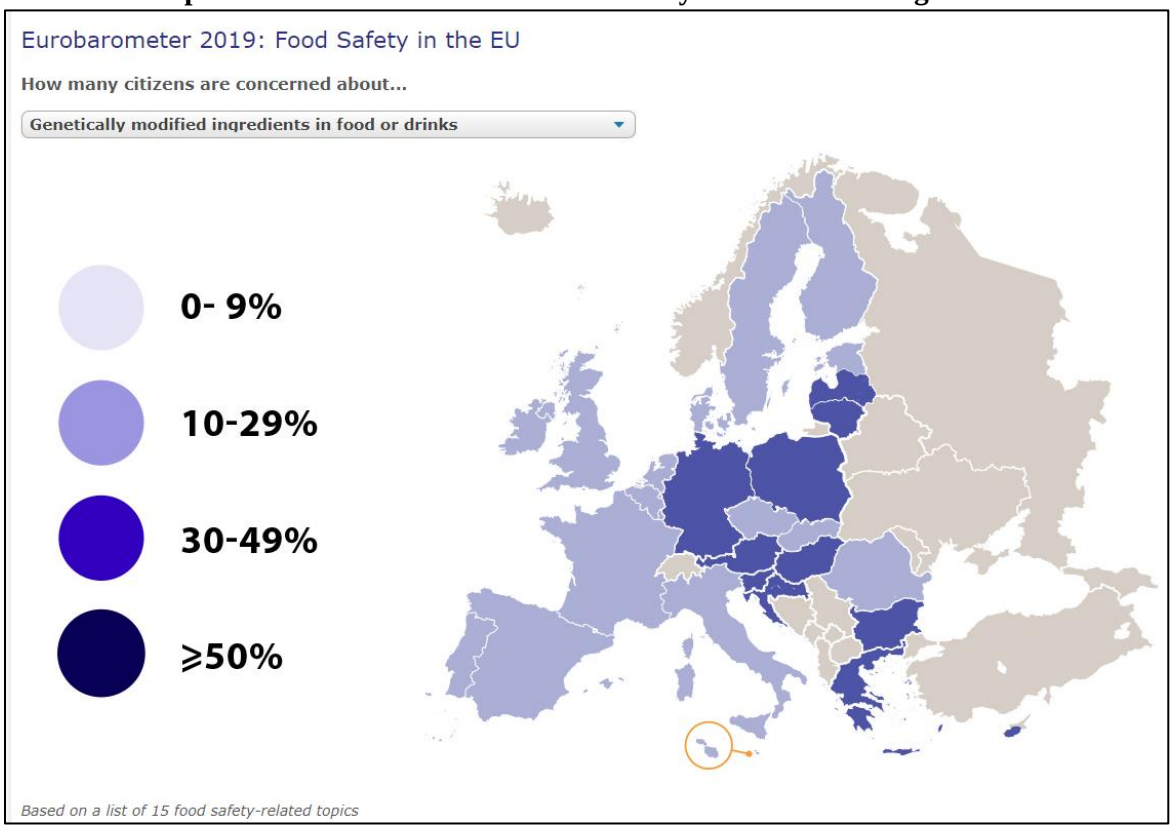
New Eurobarometer survey on food safety released in 2019 shows that the presence of GE ingredients in food is far from being the main concern of EU consumers (see chart and map 5 below). Only 27 percent of EU consumers rank "GE ingredients in food or drinks" as one of their five main concerns when it comes to food. The chart below reflects media coverage of the different topics; antibiotic and pesticide residues have received much more media attention than other topics in recent years.

Chart 4. EU Citizen Concerns About Food



Source: 2019 Eurobarometer on Food Safety in the EU

Map 4. Eurobarometer 2019 on Food Safety Concerns: GE Ingredients



Source: 2019 Eurobarometer on Food Safety in the EU

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

The EU's **food industry** adapts their product offerings to meet consumer perceptions. The EU has approved over 50 GE plants for food use. However, 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 and Spain there are increasing examples of GE-labeled imported food products that achieve sales success.

Most food **retailers**, especially major supermarkets, promote themselves as carrying only non-GE products. There are several initiatives in EU MS to differentiate themselves at the retail level by using voluntary GE-free labels. For instance, in the Czech Republic and Slovakia retail buyers of meat and milk products are requiring farmers' guarantee that their livestock is not fed with GE crops. Some retailers also fear actions by activist organizations that would likely target any retailer offering GE-labeled products, which means an unacceptable brand risk that hinders the introduction of GE-labeled food.

b) MARKET ACCEPTANCE/STUDIES

- **Acceptance of genetic engineering varies greatly across EU countries.**

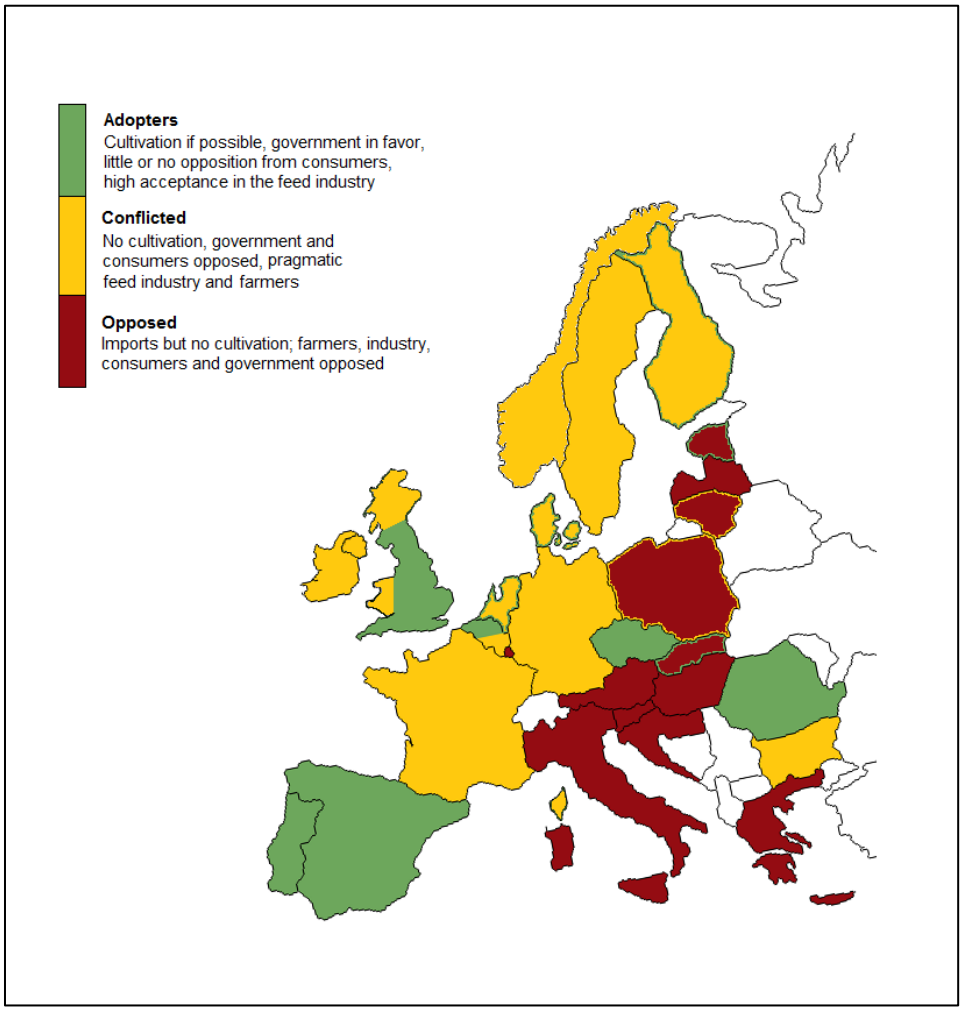
There are three major categories of MS depending on their acceptance of agricultural applications of genetic engineering, as illustrated in Map 6 below.

- 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 more suitable for their conditions 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 is one of the two EU countries that grow biotech crops but unlike the Spanish government, the Portuguese government is conflicted. The **United Kingdom**'s departure from the EU (Brexit) has further reduced the size of this pro-innovation group of countries. Farmers in **Romania** still support the use of GE crops, but elsewhere in society, views differ.

- 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. Within this group, Germany has become increasingly vocal against agricultural biotechnology. In **Denmark, Finland,** and **the Netherlands** farm unions' views on genetic engineering have become conflicted.

- 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 government, farming sector and consumer base are currently opposed to genetic engineering.

Map 5. Acceptance of GE Crops by Member State – 2020



Source: FAS EU offices

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

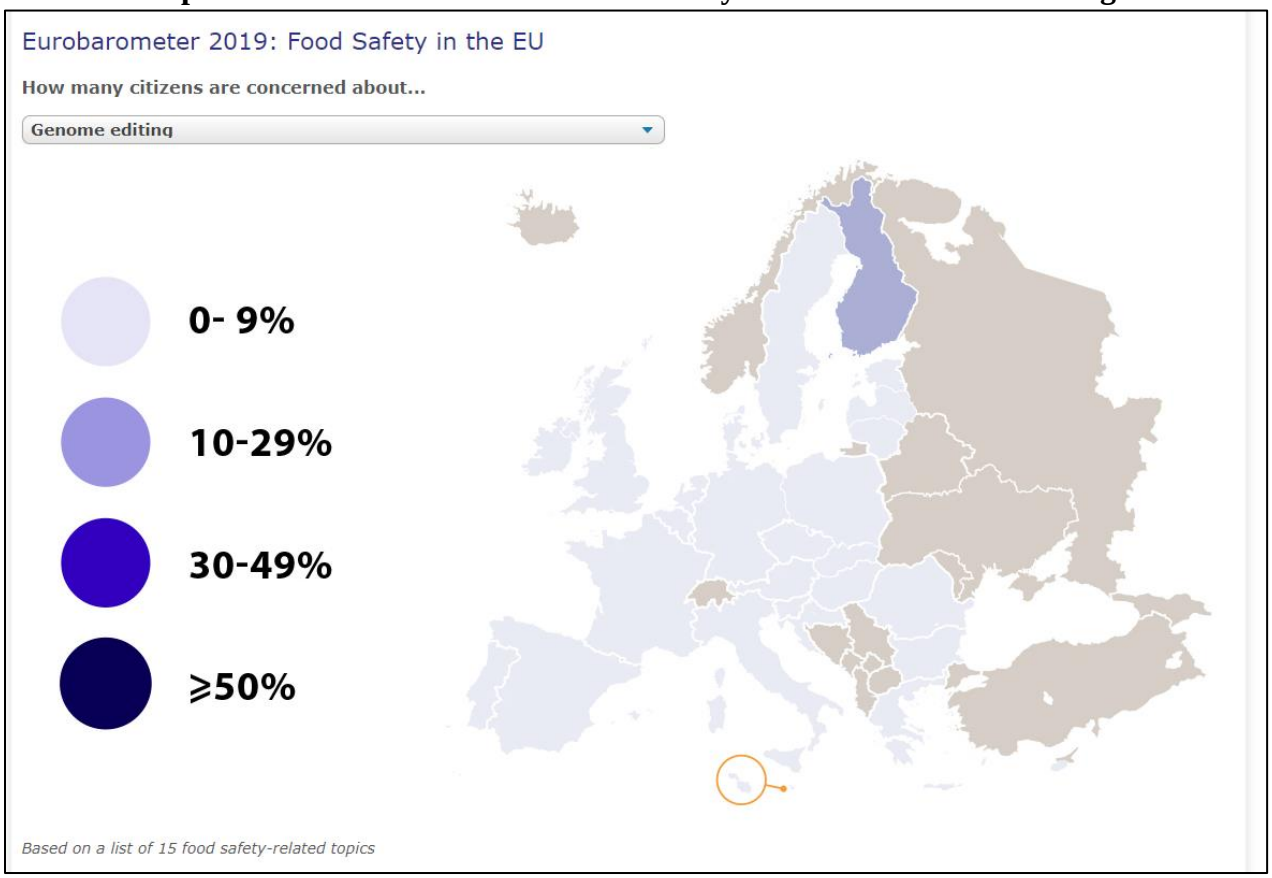
When considering **scientists, professionals in the agriculture and food sectors, the general public, and anti-biotech activists** across Europe, there are some differences between countries, but overall the general trends are as follows:

- **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 2019 Eurobarometer survey in **Map 6** below).

Map 6. Eurobarometer 2019 on Food Safety Concerns: Genome Editing



Source: 2019 Eurobarometer on Food Safety in the EU

- **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 **new Commission** has not spoken out in favor or against innovative biotechnologies. In early drafts of the European Green Deal, there are references to "innovative techniques". The objectives of the Green Deal – reduction of agricultural inputs such as pesticides – will be difficult to obtain without drastic losses in productivity if these innovative techniques are not considered. Both Health Commissioner Kyriakides and the Commission have pointed to the potential outcomes of the April 2021 study on the legal status of these techniques in light of the 2018 ECJ ruling.

- **Studies**

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

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

Report	Comment
2019 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 (2019)
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)
2010 Eurobarometer Survey on Biotechnology	Eurobarometer survey about biotechnology by the European Commission (2010)
Europeans and Biotechnology in 2010, Winds of Change?	A report to the European Commission's Directorate General for Research (2010)
2010 Eurobarometer Survey on Food-Related Risks	Eurobarometer survey about consumers' perceptions of food-related risks by the European Commission (2010)

Source: Compiled by USDA/FAS. See each link for the individual source.

CHAPTER 2 – ANIMAL BIOTECHNOLOGY[34]

PART D – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

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

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

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

Some of these countries (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 cow 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, cows and horses.

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

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

[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.

- In **Hungary**, the Agricultural Biotechnology Institute of the NAIK has three research groups working on applied embryology and stem cell research, ruminant genome and rabbit genome biology.
- In the **United Kingdom**, the Oxitec company is developing GE insects to address human health issues and agricultural issues (e.g., GE olive flies developed as a biological control to protect olive trees from insect infestation, GE medfly to protect fruit, nuts and vegetables from infestation, GE pink bollworm to improve cotton pest control, GE mosquitoes to reduce the populations of mosquitoes that are vectors for diseases like dengue and Zika, and GE diamondback moths).
- Researchers at the Roslin Institute in Edinburgh (**United Kingdom**), where Dolly the cloned sheep was developed in 1996, have produced piglets designed to be resistant to the African Swine Fever virus. Researchers have used genome editing techniques, which can mimic a natural genetic mutation so closely that the piglets are indistinguishable from animals produced by conventional means with natural genetic variation. Genome editing also does not involve the use of antibiotic-resistance genes. Scientists hope 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.
- In **Spain**, in 2018, the Center for Swine Studies (in Spanish) reported research activities on GE hogs. In 2017, the Public Agricultural Research Institute (INIA) notified the National Biosafety Commission (CNB) to study the molecular processes of reproduction on GE rabbits, goats and sheep. Basic research with CRISPR-Cas9 in mice has been carried out since 2013; research on animal genome editing is carried out by public institutions such as the National Center for Biotechnology (CNB).
- In **Belgium**, the Flemish Institute for Biotechnology (VIB) is very active on innovative biotechnologies and was involved in improving the efficacy of the CRISPR techniques. VIB's 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.

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.

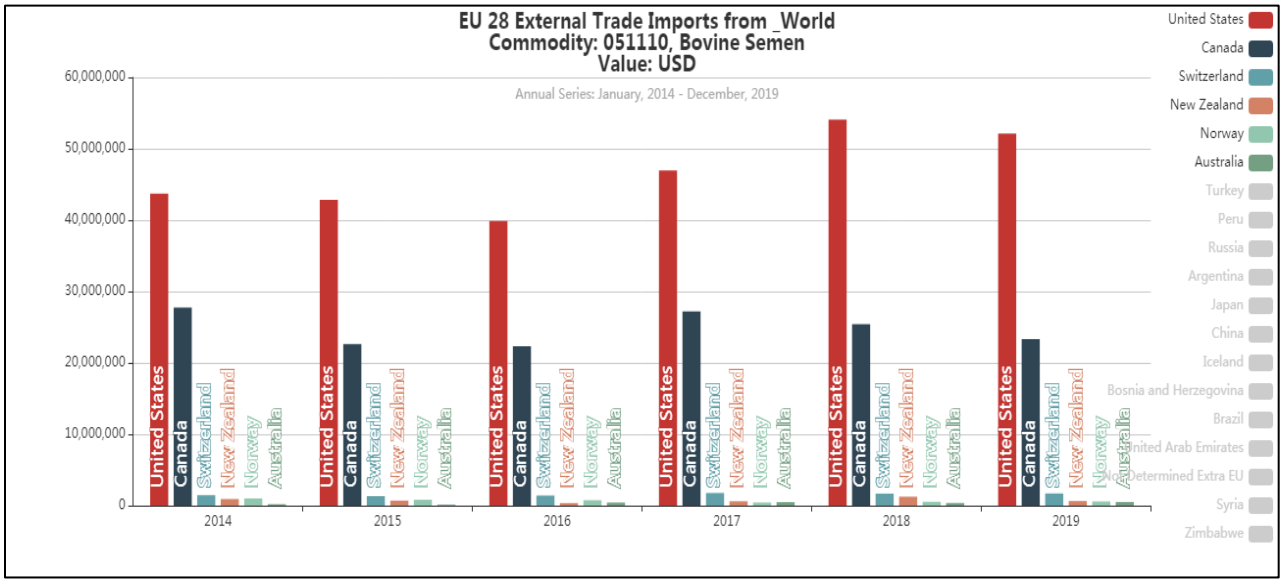
c) EXPORTS

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 60 percent, followed by Canada (over 30 percent).

Graph 10. 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 are no deadlines or timetables for the Council's action. The Council may either accept the EP's amendments or, if they do not accept the EP's position, adopt a common position. However, discussion of the proposals in the Council has not yet gone beyond the technical level. Given the political sensitivity of the issue, the Council is reportedly unwilling to take up full discussions of the proposals.

On January 29, 2020, the European Commission adopted its Work Program setting out the actions the EC aimed to take in 2020. At the same time, 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) INNOVATIVE BIOTECHNOLOGIES[35]

Recent policy developments on animals produced through innovative biotechnologies are reported under Part B) Policy, e) Innovative Biotechnologies.

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

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

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. That they should be examined on a case-by-case basis by the competent authorities and subject to a scientifically sound basis, also taking into account an analysis of the degree of acceptability by society.

c) LABELING AND TRACEABILITY

EU regulations (EC) No 1829/2003 and (EC) No 1830/2003 require food and feed produced from GE animals to be labeled as such (see Part B) g) Labeling).

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

d) INTELLECTUAL PROPERTY RIGHTS (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]

e) INTERNATIONAL TREATIES/FORUMS

The EU is member of the Codex Alimentarius along with its 28 MS. The Codex has working groups and develops guidelines on biotech animals. For example, it has developed guidelines for

[36] Source: European Patent Office

the conduct of food safety assessment of foods derived from GE animals. The EU and its MS draw up EU position papers on the issues discussed in the Codex.

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

Twenty-two[37] out of the current 28 MS of the EU are members of the Organization for Economic Cooperation and Development (OECD), which has working groups and develops guidelines on biotechnology policies.

The EU is a party to the Cartagena Protocol on Biosafety, which aims to ensure the safe handling, transport, and use of living modified organisms (see Part B) Policy, l) Cartagena Protocol).

PART F – MARKETING

a) PUBLIC/PRIVATE OPINIONS

The EU's livestock industry does not favor the commercialization of clones or GE animals for agricultural purposes. However, in some EU MS, the livestock industry is interested in animal genomics and marker-assisted selection for animal breeding. There is limited interest in animal biotechnology among the general public although, if asked, people are generally more hostile to it than to plant biotechnology. 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.

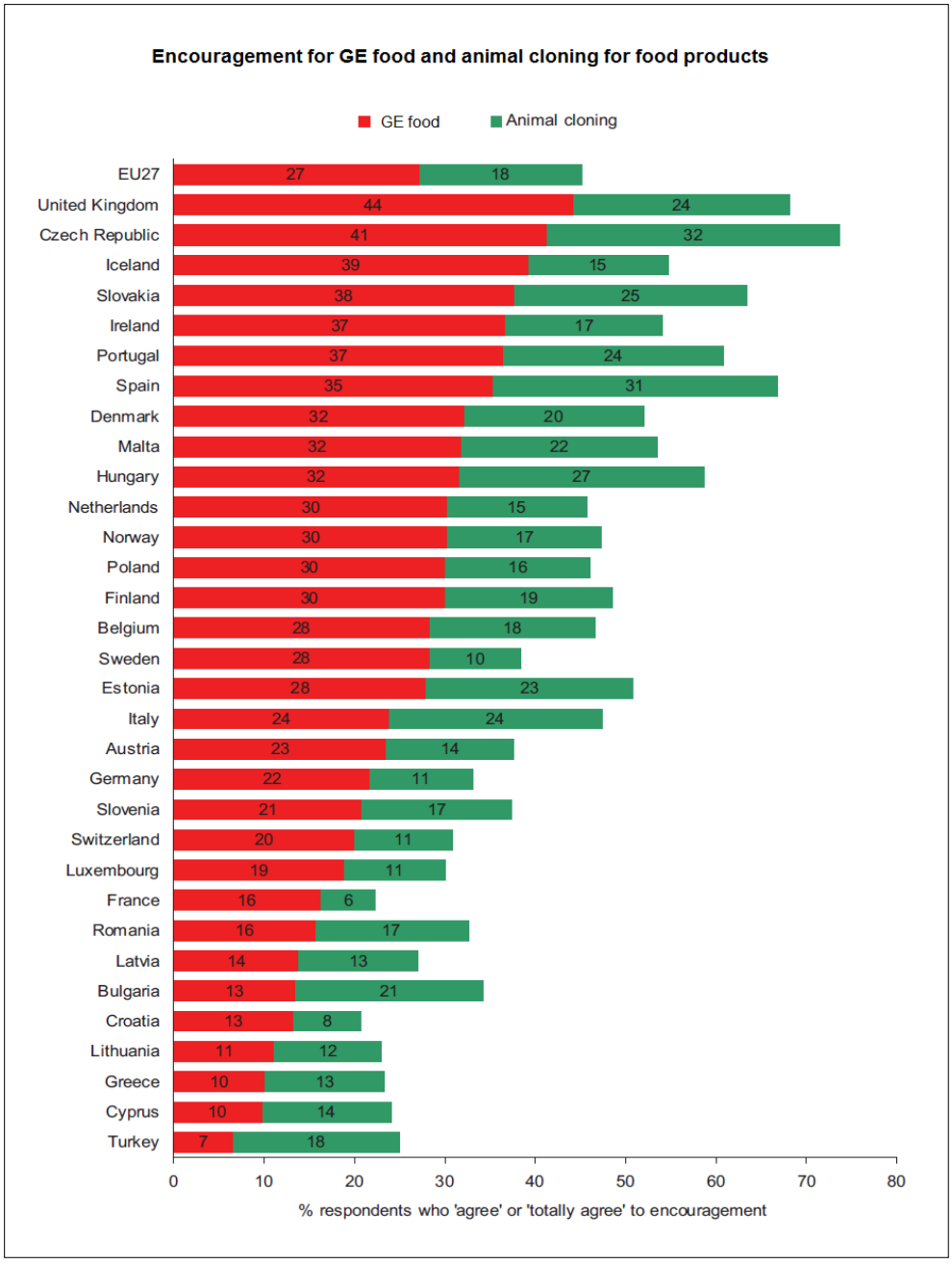
b) MARKET ACCEPTANCE/STUDIES

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.

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

The latest European survey on biotechnology that includes cloning dates back to 2010. It states that "cloning animals for food products is even less popular than GM food with 18 percent of Europeans in support." **Chart 5** below reflects the combination of consumer acceptance of food derived from GE plants and animal cloning in each MS.

Chart 5. Consumer Acceptance of Food Derived from GE Plants and Animal Cloning by MS



Source: European Commission 2010 survey on biotechnology

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.

b) EXPORTS

The EU exports products that contain microbial biotech-derived food ingredients to the United States or other countries. In the EU, the end product does not need to be labeled as containing "GMO" if it is free from the GE microbe and its modified genetic material.

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." U.S. food company Impossible Foods 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

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

[38] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_enzymes_register.pdf
[39] https://ec.europa.eu/food/safety/food_improvement_agents/common_auth_proc_guid_en
[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)

techniques fall within the scope of the EU GMO Directive 2001/18/EC.[42] Currently, the Commission is performing a study on the status under EU law of "novel genomic techniques."[43]

b) APPROVALS

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)

EU Directive No. 98/44/EC on the legal 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

[42] See the ECJ press release and ruling: https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf.
[43] See European Commission study on New Genomic Techniques: https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en

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.

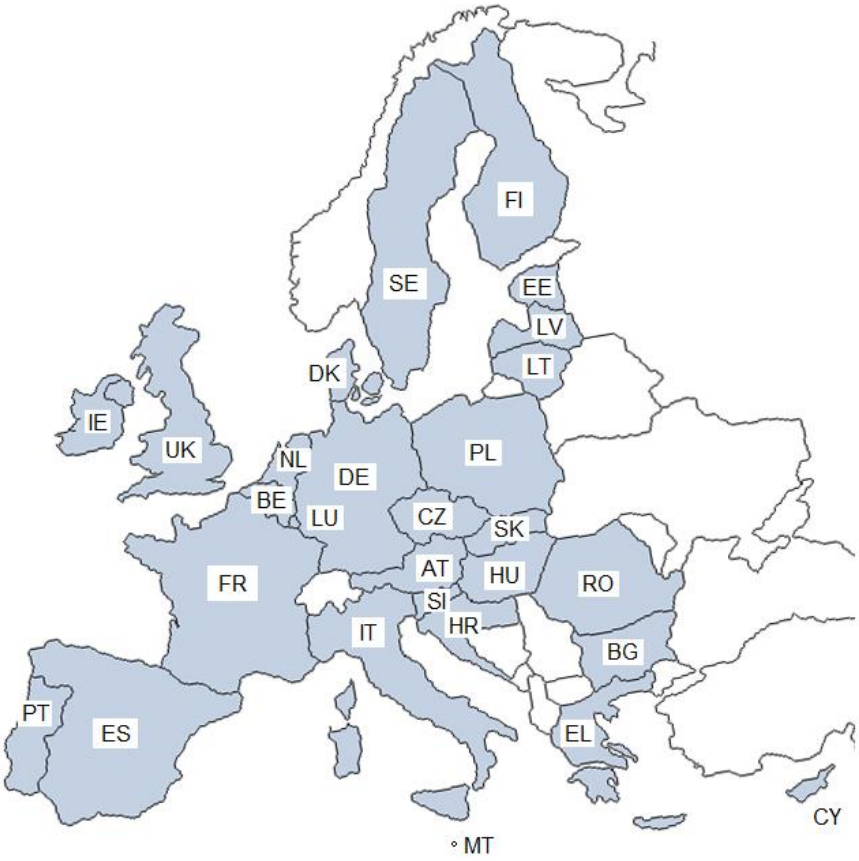
Passing the Green Deal and stimulating the circular economy, the EU has signaled a clear commitment to become more environmentally-friendly.[44] Consumer demand for animal substitutes and dairy-free products and the need for new food packaging material are on the rise. GE microbes are able to produce 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.

[44] 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[45]

[45] 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
Germany
Hungary
Italy
The Netherlands
Romania
Spain
Sweden

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.

Wilding Pine and GM

- Wilding pine is a significant issue for the country
- GM - including gene editing - is promoted as an answer
- But it is not yet demonstrated and would not deal with:
  - Legacy wilding pines
  - Species no longer actively planted
  - Plantings over the next decade
- Then there is the question of how use of GM would impact on the value of forestry exports

GM Sterility a Risky Pathway

- GM is not the only option to deal with wilding pine
- Its appeal is presumed cost-effectiveness (no labour costs)
- But unlike other methods, **the risk/benefit calculation for GM sterility extends well beyond on-plantation costs** of wilding pine management strategies
- GM sterility carries significant **market risks that other methods do not**

FSC Certification Means No GM Trees

- **GM forestry rejected by leading international sustainable forestry schemes**

  Forest Stewardship Council (FSC) and Programme for the Endorsement of Forest Certification (**PEFC)** prohibit GM trees.

- **71%** (1,220,449 ha) of New Zealand plantation forests is FSC certified (FOA Facts and Figures 2017/2018)
- FSC certification pivotal to NZ forestry's positioning in the global marketplace

FSC More Important to NZ than Elsewhere

> “ FSC certification predominates in New Zealand […] Thus, the FSC’s current position on GM trees is **a greater obstacle to their possible commercialization in New Zealand than would be the case in many other countries**
>
> **The simplest means of proving compliance is if there are no commercial GM trees in New Zealand**

New Zealand Forestry Institute. 2010 Policy Paper

Use of GM by one operator has sector-wide implications

> “ any commercial use of GMOs in New Zealand forestry would result in withdrawal of certification and therefore **loss of access to some of the highest value overseas markets** for our wood products.
>
> The government should be aware that the public concern currently aroused risks being picked up in overseas markets and that this perception could undermine the value of our in-market brands.

Wood Processors and Manufacturers

2015 Submission on Plantation Forestry Standard

No case for a change of law now

- No case for deregulating new GM techniques at present
- Research using these new techniques can and is proceeding:
  - Scion gene editing experiments with pine is progressing in the lab and will be ca 2 years before results are known
- The value of regulation now is that it keeps strategic pathways open

> “ because the project can be carried out inside, any risks are easier to contain than with trees planted outside
>
> Scion 2017

Deregulation a strategic risk for NZ

- New Zealand is a standards-taker
- Currently no global consensus on whether gene editing is regulated
- Europe regulates gene editing as GM (like NZ)
- Other jurisdictions like US do not
- A country needing to deliver to high-value markets must work to higher standard across the board

> “ the existence of different regulatory systems will undoubtedly create many challenges, particularly for those nations with strong trading links with the EU

Scion GM Forestry Scientists, 2019

Long-term Positioning for the Sector

- Any introduction of GM forestry would become **a defining and potentially indelible feature** of brand NZ and NZ forestry
- Decisions on GM Forestry must be made with a view to the **long-term vision and strategic positioning** of the forestry sector
- For now, **retaining GM free positioning is the high-value, no regrets position**

Strategic Control Lost with Deregulation

- Deregulation of gene editing might make it easier for scientists to develop new GMOs
- This is **a paltry gain against the commercial risks** for the sector
- **Deregulation would remove the sector's control over its future.** The sector – not a lone operator - should make the call on when to apply any GM technology.
- Regulation ensures GM release only happens if there is a net benefit to the economy