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Report Highlights:

France bans the cultivation of crops that are derived from modern biotechnology and limits research into their use. These genetically engineered (GE) crops remain the focus of consumer and popular skepticism. This attitude and policies towards GE products are unlikely to change in the near-term. Regarding new breeding techniques, France is currently caught between legal challenges in French and EU courts.

Attachments:

No Attachments

Executive Summary

The French administration authorizes imports of GE products but restricts research and bans cultivation of GE crops. The current situation is unlikely to change in the short term. Opponents actively campaign against agricultural biotechnology in France yet there is better acceptance among grain producers, animal feed compounders, the livestock industry, and scientists

France conducts some basic research and uses both genetic engineering and innovative biotechnologies in laboratories. No field trials are being carried out in France, due to the destruction of test plots by activists. Research is not expected to lead to the commercialization of plants produced through genetic engineering or innovative biotechnologies in the next several years.

France does not produce any agricultural goods derived from genetic engineering or innovative biotechnologies for commercial purposes. However, the country imports GE feed, mainly soybeans and soybean meal from South America and the United States, and rapeseed (canola) from Canada.

Animal biotechnology is primarily used for medical research purposes. The French administration is opposed to using biotechnology in animal breeding and increasingly, animal rights activism makes it difficult to have a calm and objective debate on this subject. Very few people are aware that animal biotechnology could improve animal welfare. Some scientists believe that the massive reduction in animal suffering disease resistant animals could bring should be publicized in order to increase people awareness.

The European Court of Justice (ECJ) issued its judgment that organisms created through genome editing techniques are to be regulated as GE organisms in the EU. The French seed sector is calling for the European Commission to review EU regulations in view of recent scientific advances, but the French administration is divided on this subject. The general public is not aware of possible agricultural applications of innovative biotechnologies.

In June 2020 France issued France notified the European Commission of its intention to delist in-vitro random mutagenesis with chemical or physical agents to comply with the French Council of State's (France's Supreme Court) ruling in February and several countries protested the move. France is now caught between its own court and EU rules. More details on that decision on mutagenesis can be found in the section on Innovative Biotechnologies.

Acronyms used in this report are the following:

ANSES	Agency for Food, Environmental and Occupational Health and Safety
ECJ	European Court of Justice (or "Court of Justice of the European Union")
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
EFSA	European Food Safety Authority
EU	European Union
GE	Genetically Engineered
HCB	High Council for Biotechnology
INRA	French National Institute for Agricultural Research
MT	Metric Ton
NGOs	Non-Governmental Organizations

Glossary:

"Genetic Engineering" used in this report is the deliberate manipulation of an organism's genetic material through transgenesis (insertion of foreign DNA).

"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 plants or animals resulting from traditional genetic engineering (transgenesis), known in Europe as genetically modified organisms (GMOs).

Note:

The mention "in French" after a link means that this link returns a page that is only available in French.

France is a member of the European Union. For more detailed information on EU Regulations and Directives, please see the EU-wide overview provided by the current Agricultural Biotechnology Annual European Union Report as published on the GAIN website.

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CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

France is active in research and uses both genetic engineering and innovative biotechnologies in lab. However, the level of activity of France depends on the technique used. As far as agricultural biotechnology is concerned (excluding industrial, marine and medical biotechnology) France:

- conducts very limited research involving transgenesis;
- has one basic research project on innovative biotechnologies;
- is active in genomic selection.

Research is not expected to lead to the commercialization of plants produced through genetic engineering or innovative biotechnologies in France in the next several years. However, some French companies use these techniques abroad and develop plants for non-EU markets.

- **France conducts very limited research in agricultural biotechnology involving transgenesis.** Research in agricultural biotechnology is not expected to lead to the commercialization of new varieties of GE plants in the next several years because:
  - Public institutions are constrained by the absence of field trials and a lack of political support for research involving genetic engineering. They cannot afford the regulatory costs associated with commercialization; and
  - The private sector's interest in developing varieties of GE plants suitable for cultivation in the European Union 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.

- **France uses genomics in plant breeding.** Genomic tools (the branch of molecular biology concerned with the structure, function, evolution, and mapping of genomes) are actively used in both public labs and private seed companies.[1] Unlike transgenesis and innovative biotechnologies, the use of genomics is not considered controversial.

- **A few French companies develop biotech plants for non-EU markets.** A few French companies develop plants produced through transgenesis or innovative biotechnologies; their biotech research facilities are based outside of Europe and the plants are commercialized outside Europe. For instance, Calyxt, the U.S. subsidiary of a French company, developed a soybean variety with improved nutritional properties through gene editing. This variety contains less

[1] See for instance INRA's French Plant Genomic Resources Center and Limagrain's website

saturated fatty acids than conventional soybean and no trans fats. It was first commercialized in the United States in February 2019. Ninety-eight percent of the soybean oil produced is expected to be sold to small- to medium-size food companies as a food ingredient.

- **France conducts laboratory research for medical applications.** GE plants and plant cells are used in labs to develop proteins of pharmaceutical interest. Proteins whose structure is simple, such as insulin and growth hormone, can be produced by GE microorganisms. GE plants and plant cells are used to develop more complex molecules for research purposes (vaccines, antibodies, enzymes).

b) COMMERCIAL PRODUCTION

France does not produce any GE crops for commercial purposes and this situation is unlikely to change in the medium term. President Macron, in office until 2022, said during his 2017 presidential campaign that he would not allow the cultivation of GE crops.

MON810 Bt corn is currently the only GE plant approved for cultivation in the EU and, since 2008, its cultivation has been banned in France (see Part B - Policy).

There were 1,800 hectares of GE corn planted in France in 1998, then none during the European *de facto* moratorium between 1999 and 2004. Cultivation was reinitiated between 2004 and 2007 and reached 22,000 hectares before dropping to zero in 2008.

c) EXPORTS

France does not export any GE plants.

d) IMPORTS

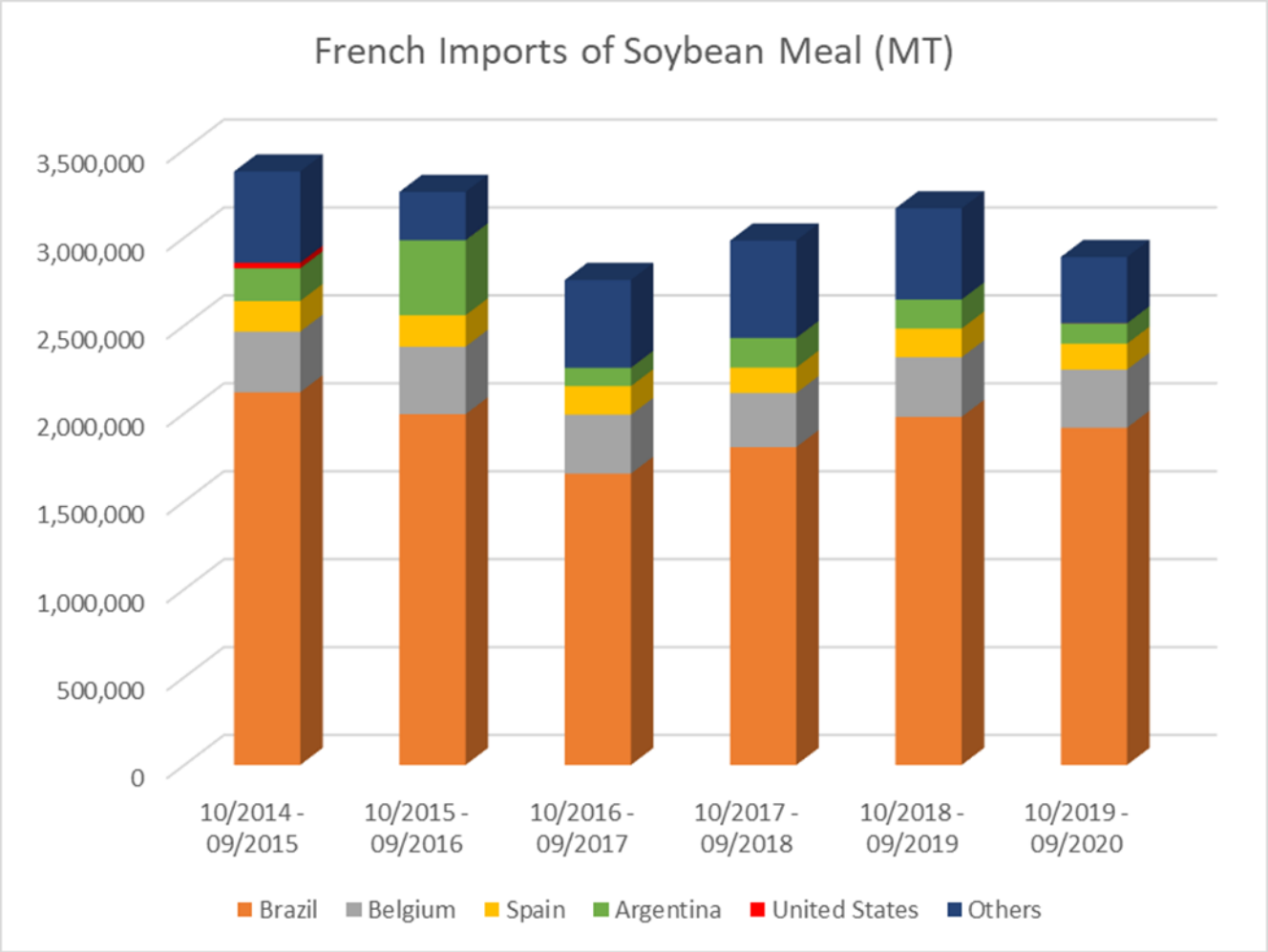
The bulk of France's imports of biotech products consist of soybeans and soybean meal from the Americas and is used as animal feed ingredients. The share of GE products out of total imports is estimated at 60-70 percent. France also imports GE rapeseed from Canada and small quantities of GE corn and corn processing by-products. France has a goal of becoming less reliant on imported proteins for animal feed, and although it is struggling to implement it, there has been more protein from other EU countries and France has a plan to develop its own non-GE seeds for more efficient soy production. Trade data do not differentiate between conventional and GE varieties. The graphs presented in this section therefore include both categories. In each section, a table gives the share of GE crops in total production in France's main supplier countries.

- France imports around 4 million metric tons of soybean products per year, with the majority being GE.

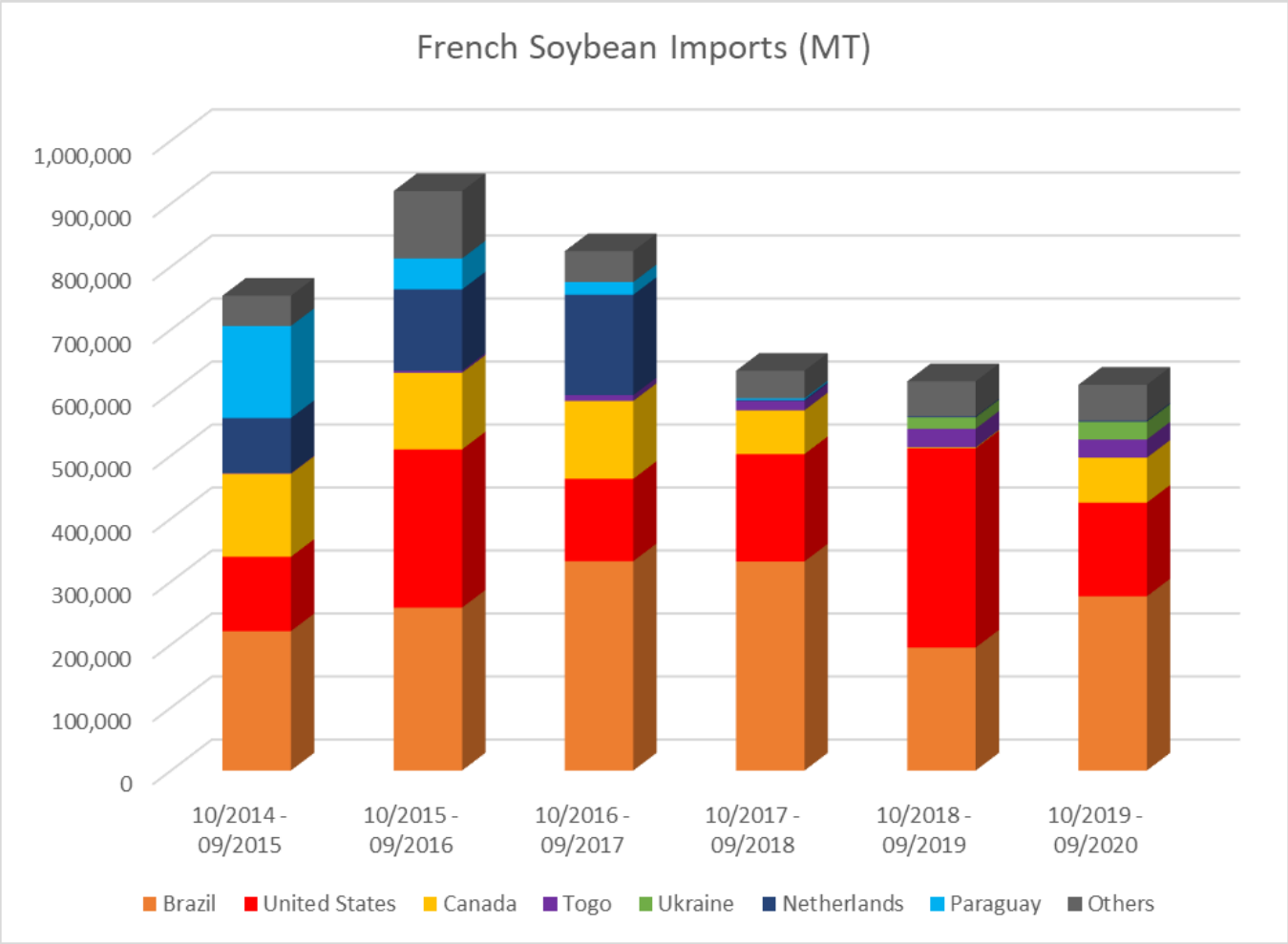
- France used to import about 80 percent GE soybean products, but with increasing imports of non-GE soy from other EU producers, it has reduced the percentage of imports of GE products for animal feed.

As illustrated in the two graphs below, in the last five years, France imported on average:

- 3 million metric tons (MT) of soybean meal per year. The share of GE soybean meal out of France's total imports is estimated at 70 percent.
- 750 thousand MT of soybeans per year. The share of GE soybeans out of total imports is estimated at 80 percent.



Source: Trade Monitor Data



Source: Trade Monitor Data

France is dependent on soybean products to feed animals in its livestock and poultry sectors. Domestic production of soybeans and substitutes is limited, and there is a strong demand for protein to meet basic requirements of compound feed formulations. The decision of French importers on where to source soybean products from year to year is primarily based on price; the protein content of the soybeans is considered only when prices of the different origins are close to one another.

The demand for non-biotech soybean meal is estimated at 35 percent of the total French market. It is mainly supplied by soybeans grown domestically in the EU and imports from Brazil, India, and Nigeria. There is a premium for non-biotech soybeans, which varies between 80 and 100 euros per MT. This elevated pricing is because available supplies are limited, and it is costly to avoid the mixing of GE with non-GE products during transportation and storage. France has a protein plan whose objective is to replace imports of non-biotech soybeans with locally-produced non-biotech soybeans. French production increased from 110 thousand MT in 2013/14 to 410 thousand MT in 2019/20 as a result of subsidies and incentives from the Common Agricultural Policy (CAP) and some French regions. France is now working on a new protein plan and it should be out in 2021, the plan will include the

development of seed varieties for France specifically, including subsidies for companies who invest in such research.

The European Union also wishes to increase local production of plant proteins. For more information, please see the report on The Development of Plant Proteins in the European Union that the European Commission released in November 2018. However, the final report on the EU Protein Strategy does not discuss how EU restrictions on agricultural biotechnology could adversely affect EU goals such as breeding more productive, resilient protein crops adapted to the climatic and environmental conditions of the EU.

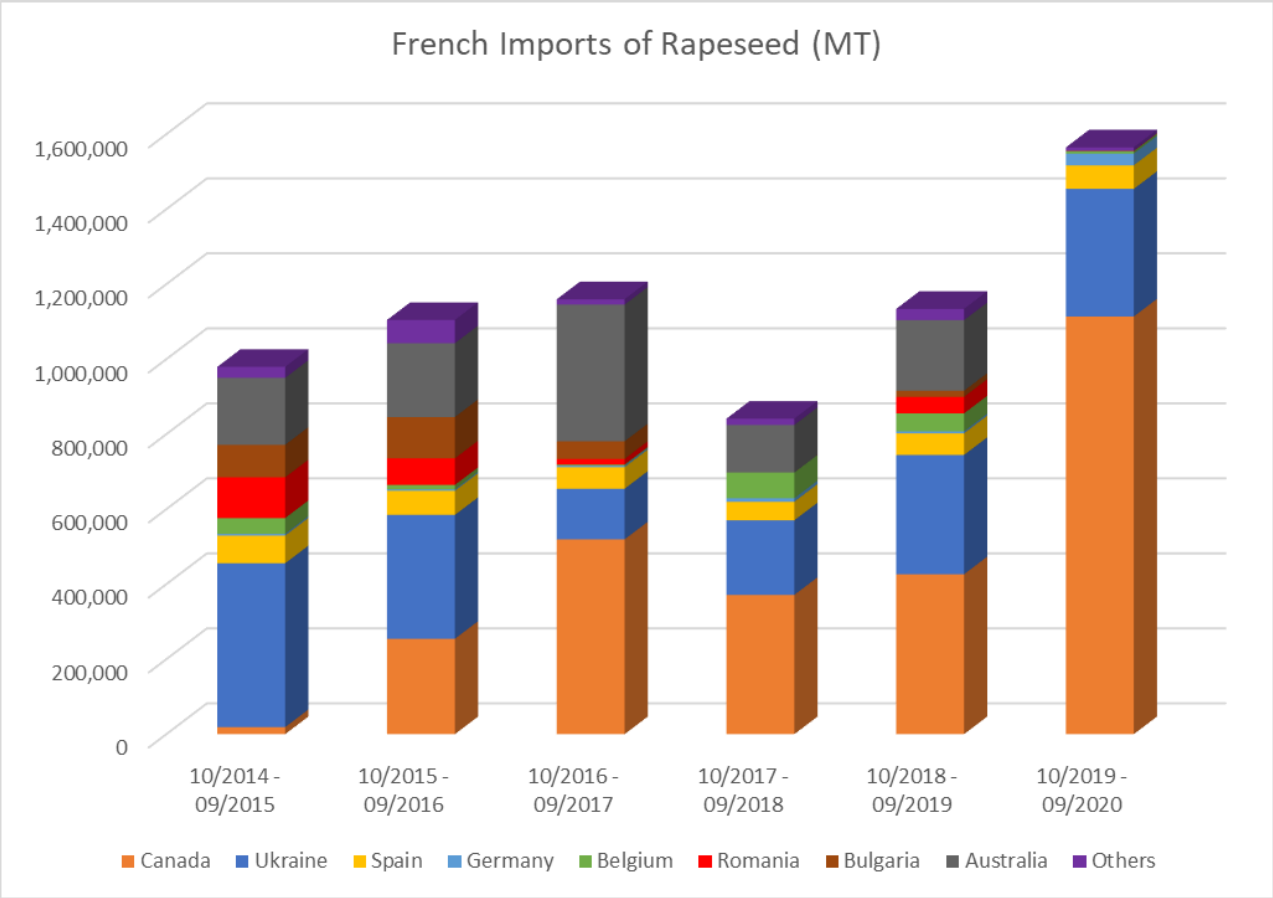
Share of GE Soybeans in Total Soybean Production in France's Major Supplier Countries

Argentina	100%
Brazil	96%
Canada	95%
Paraguay	99%
United States	94%

Source: ISAAA (2018)

- **France imports GE rapeseed from Canada.**

In the last five years, France imported between 840,000 and 1,560,000 MT of rapeseed per year. In MY 2019/20, 71 percent of France's imports came from Canada, where 95 percent of rapeseed is GE; 22 percent came from Ukraine, where the share of GE rapeseed in total exports is estimated at 10 to 25%; France did not import any rapeseed from Australia in MY 2019/20.



Source: Trade Monitor Data

Share of GE Rapeseed in Total Rapeseed Production in France's Major Supplier Countries

Canada	95%
Ukraine	estimated at 10 to 12 % of rapeseed produced for export
Australia	22%
Bulgaria	0%
Romania	0%

Source: ISAAA and FAS

Potential Future Impacts of ongoing disputes on rapeseed imports

If France implements its decision on in vitro mutagenesis (explained in Innovative technologies), this decision will ban *Clearfield* herbicide resistant varieties of rapeseed for use, disallowing these varieties of rapeseed and requiring a zero-tolerance for any unintentional presence. Both planting seeds and rapeseeds for feed and further processing are subject to testing and are primarily imported from Canada, South America and other EU countries. The implication is that even if one bean in a shipment were

found to contain the prohibited gene, the whole shipment would be rejected and would have to be re-exported or destroyed.

France also notified the commission of its intention to amend its official catalog of seed. It will remove seven banned *Clearfield* herbicide resistant varieties of rapeseed registered on the French official seed catalog as well as 103 varieties listed on the official European seed catalog (developed and approved in other EU Member States). This decision could undermine the EU single market principle as those 103 varieties are legally marketable in any EU countries under EU rules.

- **France imports small quantities of corn from countries that produce GE corn**

In the last six years, France imported 350 to 650 thousand MT of corn per year. Table #1 below shows that in Marketing Year (MY) 2017/18, approximately two percent of these imports were from countries that produce GE corn (Spain, Ukraine, and the United States). Table #2 gives the share of GE corn production in Spain, Ukraine, and the United States.

Table #1 Origin of France's Imports of Corn

	2013/14	2014/15	2015/16	2016/17	2017/18	2019/20
Potential GE imports	20%	2%	3%	2%	2%	1.5%
Non-GE imports	80%	98%	97%	98%	98%	98.5%
TOTAL	100%	100%	100%	100%	100%	100%

Source: Trade Data Monitor

Table #2 Share of GE Corn in Total Corn Production in France's Major Supplier Countries

Spain	35%
Ukraine	estimated that less than 1% of corn produced for export
United States	92%

Source: ISAAA and FAS

- **France imports small quantities of corn processing by-products from countries that produce GE corn**

In the last six years France imported 140 to 180 thousand MT of Distiller's Dried Grains with Solubles (DDGS) per year. Imports from Spain have potential to be GE. Imports of DDGS that may be GE also include small shipments from Brazil, the United States, Portugal and Argentina (0 to 0.8 thousand MT per year).

Origin of France's Imports of DDGS[2]

	2013/14	2014/15	2015/16	2016/17	2017/18	2019/20
Potential GE imports	11%	17%	17%	15%	15%	15%
Non-GE imports	89%	83%	83%	85%	15%	15%
TOTAL	100%	100%	100%	100%	100%	100%

Source: Trade Data Monitor

In the last six years, France imported 100 to 250 thousand MT of Corn Gluten Feed and Meal (CGFM) per year. Imports from Spain have potential to be GE. Imports of CGFM that may be GE also include small shipments from Brazil and the United States (0.01 to 0.2 thousand MT per year).

Origin of France's Imports of CGFM[3]

	2013/14	2014/15	2015/16	2016/17	2017/18	2019/20
Potential GE imports	4%	4%	6%	3%	7%	6%
Non-GE imports	96%	96%	94%	97%	93%	94%
TOTAL	100%	100%	100%	100%	100%	100%

Source: Trade Data Monitor

e) FOOD AID

France provides food aid in the form of food, money, equipment, seeds, or veterinary services. This aid does not include GE products. France provides both planned aid and emergency aid when a crisis occurs, whether it is climatic, economic, social, or political. Aid is delivered: via international organizations (more than 75 percent of the total budget) such as the World Food Program and the International Committee of the Red Cross; via non-governmental organizations (NGOs; 15 to 20 percent of the total budget) such as Action Against Hunger; and directly (5 to 10 percent of the total budget).

f) TRADE BARRIERS

- ***Cultivation Ban***

Cultivation of GE corn has been banned in France since 2008 and the situation is unlikely to change in the medium term. Between 2007 and 2014, three decrees that banned cultivation were successively

[2] DDGS are a corn by-product of distillation
[3] CGFM is a corn by-product of wet-milling

released by the Government and cancelled by the Supreme Court because they were illegal. Then a law that banned cultivation of GE corn in France was passed in June 2014.[4] This law was not compatible with EU regulations when it was passed.

In March 2015, with the support of the French Government, the EU released Directive (EU) 2015/412 that allows member states to restrict or ban the cultivation of EU-authorized GE plants in their territory for reasons other than risks to human health, animal health or the environment.

Under Article 26c of the Directive – transitional measures – France demanded in September 2015 that the French territory be excluded from the geographical scope of the authorizations of cultivation for eight GE corn varieties.[5] The companies that developed these varieties did not oppose this decision. The transcription of Directive (EU) 2015/412 into French Law was then released in December 2015.[6]

- ***Import Ban***

In 2015, the European Commission released a proposal for a regulation that would allow member states of the EU to restrict or ban the use of EU-authorized GE crops or products. Opt-outs would have to be based on reasons other than those assessed at the EU level, since the review by the European Food Safety Authority (EFSA) would have already deemed the crops or products to be safe. France opposed the opt-out for use proposal because it is contrary to single market principles and incompatible with international trade agreements. Moreover, if the proposal were adopted, France would be placed in the uncomfortable position of facing great pressure from anti-biotech groups to ban the use of GE products. Such a ban would be detrimental to the already stressed French livestock and poultry sectors, since it would be very difficult and costly to source sufficient non-GE feed ingredients to meet their needs. Given this situation, French policy makers do not want to be in the position of having the responsibility for banning or accepting GE products.

The main farm union in France opposed the proposal, saying that "the European Union is a common market so we need common rules." Anti-biotech activists criticized the proposal as well saying that member states that want to ban the use of GE products would be unable to find justifications compatible with the EU legislation and the international obligations of the EU.

[4] LOI n° 2014-567 du 2 juin 2014 (in French)
[5] The notifications are available on the European Commission's website
[6] Only available in French: « Loi n° 2015-1567 du 2 décembre 2015 portant diverses dispositions d'adaptation au droit de l'Union européenne dans le domaine de la prévention des risques, Titre IV »

PART B – POLICY

a) REGULATORY FRAMEWORK

France operates under the biotechnology regulatory framework of the EU. For more information about the European framework, please refer to GAIN: https://gain.fas.usda.gov/#/.

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

Several ministries are involved in oversight of GE plants in France:

- The Ministry of Environment has the lead;
- The Ministry of Agriculture deals with cultivation and coexistence, as well as plant and animal health issues;
- The Ministry of Economy's Fraud Control Office (DGCCRF) controls imported products and is involved in low-level presence (LLP) issues;
- The Ministry of Research covers public research programs;
- The Ministry of Health is involved in the impact on human health.

ii. Role and membership of the biosafety authority

The High Council for Biotechnology (HCB) was established by the 2008 law on GE organisms.[7] Its composition and functions were modified in September 2014.[8] As part of the European approval framework, it is in charge of evaluating environmental risks of biotech products under review for approval for cultivation or commercialization. Since September 2014, it is no longer responsible for health risks.

The HCB is composed of a science committee (scientists) and a socio-economic and ethics committee (legal experts, researchers, farmers, representatives of the seed industry, consumer associations, and environmental NGOs). Both committees review biotech dossiers and provide their respective conclusions and recommendations to the Government of France and to EFSA.

France's National Agency for Food, Environmental and Occupational Health and Safety (ANSES) is in charge of reviewing the food safety aspects of GE crops and their derived products in food and feed.[9] It transmits its conclusions and recommendations to EFSA, as part of the European approval framework.

iii. Political factors influencing regulatory decisions related to plant biotechnology

[7] Loi n° 2008-595 du 25 juin 2008
[8] See decree (in French), September 2014
[9] See ANSES website dedicated to agricultural biotech products (in English)

Biotech opponents have played an important part in the adoption of the regulatory decisions related to plant biotechnology, both directly and through their impact on public opinion.

iv. Distinctions between regulatory treatments of the approval for food, feed, processing and environmental release

Since the beginning of the commercialization of biotech plants in the early 1990s, France has authorized biotech imports (due to the need for protein-rich ingredients in animal feeds), but restricted research and banned cultivation of biotech crops. The process for approval of biotech products is carried out at the EU level, but the French Government has some latitude to implement its own regulations if they comply with EU regulations. A large number of transgenic events[10] have been approved for feed and food use at the European level and have not been questioned by French authorities. However, France has banned the cultivation of MON810 corn, even though it was approved by the EU.

v. Legislation and regulations with the potential to affect U.S. trade

Legislation and regulations with the potential to affect U.S. trade include the national ban on GE crops cultivation and the non-biotech labeling system implemented at the national level.

vi. Timeline followed for approvals

European Directive 2001/18/EC provides the framework for the deliberate release into the environment of GE plants. Regulation (EC) No 1829/2003 covers the authorization for placing GE products on the market for food and feed.

b) APPROVALS

All the biotech events approved for **feed and food use** in the EU under Regulation EC 1829/2003 are authorized in France. The full list of these products, including events for which an authorization procedure is pending, is available on the European Commission's website.

MON810 corn is the only GE plant approved for **cultivation** in the EU. Its cultivation is banned in France under a national law (in French) and under Directive (EU) 2015/412.

c) STACKED OR PYRAMIDED EVENT APPROVALS

[10] An event is the insertion of a particular transgene into a specific location on a chromosome. The term "event" is often used to differentiate genetically engineered crop varieties.

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

d) FIELD TESTING

In France, the deliberate release of GE plants in open environments for research purposes is subject to prior approval by the Ministry of Agriculture.[11] The Ministry of Agriculture must consider the opinion of the HCB regarding possible risks for public health and the environment before granting an authorization. The Ministry of Agriculture must also hold a public consultation on the Internet and provide advance notice to the local authorities of areas where test plots for GE plants are located. The authorization may be amended or suspended if justified by new information.

No open-field testing is currently conducted in France because continued destruction of test plots by activists has discouraged both public and private organizations from conducting research in open fields. Some labs develop biotech plants in France and conduct field tests in other countries.

e) INNOVATIVE BIOTECHNOLOGIES

On July 25, 2018, the European Court of Justice (ECJ) issued its judgment that organisms created through genome editing techniques are to be regulated as "genetically modified organisms (GMOs)" in the EU.[12] For more information see GAIN USEU Report FAS E18052.

France's *Conseil d'Etat* (French Supreme Court) found in February 2020 that France must tighten its interpretation of mutagenesis based on that ruling, see FAS GAIN report: French Council. France notified the European Commission of its intention to delist in-vitro random mutagenesis with chemical or physical agents to comply with the French Council of State's ruling. The French Court ordered that this decision be implemented by August 7, 2020 but first France had to complete an EU TRIS (Technical Regulation Information System) consultation, hold a French public debate, and review the rule though France's High Council for biotechnology.

On May 6, 2020 France notified the European Commission its intention to issue a decree delisting "in-vitro random mutagenesis with chemical or physical agents" as an unregulated method. The French notification opened a TRIS (Technical Regulation Information System) consultation period until August 7, 2020. The French legislation will establish a positive list of unregulated techniques "which are not

[11] Environmental Code art. L533-3 (in French)
[12] For more information, see GAIN report EU Court Extends GMO Directive to New Plant Breeding Techniques

considered to result in genetic modification, or which have been the subject of traditional use without proven harm to public health or the environment." The method of categorization was criticized by anti-biotech NGOs and anti-biotech activists as too vague. Plants developed outside this list, namely with in-vitro random mutagenesis, would have to follow the same approval as those that are GE . Marketing and sales of such plants already on the French market will be prohibited. EU Member States provided comments officially using TRIS and unofficially, which initially delayed France's ability to implement the new rule until November 8, 2020. Currently, France has neither responded to the TRIS concerns raised by the other countries nor tried to implement its rule. France must respond to the comments detailing how they will handle the specific concerns of the Member States by adjusting the rule or countering the arguments. If France changes the rule significantly a new TRIS process will be required. If not, and France tries to implement the rule as is, it is likely the EU will take France to the European Court of Justice.

In October 2020 a small farmers' union (Confederation Paysanne) and several anti-biotech groups who had initiated the ECJ genome editing case that resulted in the 2018 ruling applied to have a hearing at the French Supreme Court as to why this decree remains unenforced at this time as the Court had ordered its implementation for August. Thus far, the Court has not yet announced a date for the audience.

The new French Minister of Agriculture Denomandie has been quiet on this case, although before his appointment as Minister, was supportive of innovative biotechnologies. He strongly condemned the destruction of test fields and supports their development. He also has said that following the 2018 ECJ ruling, legal framework for NBT based on 90/220 is obsolete. That said, the French Ministry of Environment pushing for a quick adoption of the current decree, even if it means France would be taken to the ECJ. The issue of its implementation seems to be in the hand of legal experts trying to find a legally viable solution.

In addition, France has promised a public consultation on biotech and NBTs in November 2020. However, that is on hold because France is in a country-wide second lockdown due to the COVID-19 pandemic. Some biotech experts believe that France may wait for the outcome of the debate in the European Union about the status of genome editing before issuing the decree, even if it means a lengthy delay. France could also wait on the European Commission's Public report on the revision of Directive 90/220.

When the ECJ issued its judgment in July 2018, the French **Ministers of Agriculture, Economy, Environment, and Research** released a joint statement that says that they "welcome this long-awaited clarification" that will "enable courts and the competent authorities to have a harmonized framework at European level to protect consumers and the environment while respecting the precautionary principle." However, these ministers have conflicting positions on innovative biotechnologies:

- The Ministry of Agriculture theoretically supports agricultural biotechnology if it brings environmental or consumer benefits. However, in practice, the Ministry's impact is limited since they need to negotiate with other ministries in charge of biotechnology and few decision-makers have strong political will on this subject. This continues to be true with the recently appointed Minister of Agriculture Denormandie, who seems to have more political weight than his predecessors, but hasn't publicly made statements about the technology since his appointment summer 2020. Prior to this, he has supported the technology.
- The Ministry of Ecology refuses to acknowledge the environmental benefits innovative biotechnologies can bring, including to reduce pesticide use, which is supposed to be one of their priorities. In the last several years French administration has been generally supportive of green and eco-group positions, over farmers' and researchers' positions.
- Some at the Ministry of Economy are aware of the importance of biotechnology but they have very little political voice on issues related to agriculture.
- The Ministry of Research is fully aware of the importance of this subject, but their influence is low.

Scientists warn that the ECJ judgment could put an end to a promising field of research in the EU. They have been very active since the release of the ECJ judgment:

- In November 2018, the French Academy of Agriculture organized a symposium (in French) on innovative biotechnologies for agriculture and food production.
- In April 2019, the French Academies of Sciences and Agriculture organized a joint event on CRISPR-Cas9 (in French).
- In September 2019, AFBV and the German Scientific Committee on Green Genetic Engineering (WGG) proposed changes to Directive 2001/18/EC in order to reflect scientific and technical progress made since its implementation.
- In October 2019, AFBV annual meeting focused on the ability of biotechnology to help reduce pesticide use.

The anti-biotech activists that initiated the legal procedure in 2015 welcomed the ECJ judgment as a victory.[13] They have continued to push for France's implementation of the 2020 French ruling, including a threat to sue France if it is not implemented this year. They also call for France and the EU to ban all herbicide tolerant crops, to conduct research to be able to identify the technique used to produce any seed, and to require seed companies to make the techniques they use public for all the seeds they commercialize.

The main farm organizations[14] think that the ECJ judgment is:

[13] Nine groups submitted a complaint with the Conseil d'Etat in March 2015: Confédération paysanne, Réseau semences paysannes, Amis de la Terre France, Collectif vigilance OGM 16, Vigilance OG2M, CSFV 49, OGM dangers, Vigilance OGM 33, Fédération nature et progrès

[14] FNSEA, AGPB, AGPM, CGB, FOP

- bad for consumers because biotechnology is a useful tool to produce healthy food and reduce the environmental impact of agriculture. Biotechnology has potential to contribute to a reduction in pesticide use and could help agriculture adapt to a changing climate.
- bad for French agriculture because farmers need innovation to fight crop pests and diseases.

The seed industry[15] released public statements emphasizing that if the ECJ judgment was implemented, there would be no public or private research on agricultural applications of genome editing in the EU. The EU would be unable to answer the biggest agricultural challenges of the 21st century including protecting the environment (using less pesticides, adapting to climate change) and increasing food quality. The French seed industry calls for the European Commission to reopen Directive 2001/18/EC and adapt EU regulations to recent advances in science.

Media coverage of the ECJ and Council d'Etat decisions remained limited and **public awareness** remains low. Some of the main French newspapers released short factual articles. The two deputies of the French Parliamentary Office for the Evaluation of Scientific and Technological Choices that had released a pro-science report on innovative biotechnologies in 2017 wrote an article in a major newspaper that warns of potential negative effects of the ECJ judgment on innovation and competitiveness.[16]

f) COEXISTENCE

French legislation aims to limit the spread of GE plants beyond their intended fields. It thus states that the cultivation, harvest, storage, and transportation of GE crops should be subject to certain technical rules established by the Minister of Agriculture, such as distances between GE crops and other fields.[17] In practice, when GE corn was grown in France, a buffer zone of 24 rows and 50 meters was put in place around the fields. Research programs were conducted to study the feasibility of coexistence in real field conditions (from seed to storage facilities), good harvesting and processing practices aimed at managing the coexistence of GE and non-GE sectors affordably were defined, and a guide for GE corn cultivation was released.

Moreover, legislation provides for "biological monitoring" of the French territory, to observe the health of plant life and watch for possible unforeseen consequences of agricultural practices, including the use of GE plants.[18] This is coordinated by the Committee for Biological Monitoring of the Territory, which was created for that purpose by the 2008 law on GE plants.[19] This body submits an annual report to both

[15] The French Seed Industry Association (UFS) and the Seed Inter-Branch Organization (GNIS)
[16] Article only available in French, entitled "Il faut évaluer au cas par cas les organismes obtenus par mutagénèse" published in Le Monde newspaper on August 21, 2018
[17] Rural Code art. L663-2 (in French)
[18] Rural Code art. L251-1 (in French)
[19] « Comité de surveillance biologique du territoire » in French

houses of the French Parliament and can alert the government if it finds that certain unintended consequences require that special measures be taken.

French legislation provides that a GE crop cultivator would be liable if there were an accidental spread of GE plants causing economic harm to a non-GE crop cultivator.[20] If a non-GE crop cultivator ended up needing a GE label because the GE crop had spread from a nearby field, the injured party could seek compensation for the resulting in the depreciation of the crop's value. It is also mandatory for any cultivator who uses GE crops to obtain liability insurance coverage. However, insurance companies have been unwilling to cover GE crops in France.

g) LABELING AND TRACEABILITY

- **European Mandatory Labeling of GE Products**

Labeling in France complies with EU regulations that require food and feed produced from or containing GE products to be labeled as such.

The French Fraud Control Office of the Ministry of Economy, Finance and Industry (DGCCRF) enforces compliance with the regulation.[21]

- **France's Voluntary "GE Free" Labeling System**

In addition to EU regulations, a "GE Free" labeling system has been in place at the national level since 2012. This system is based on a 2012 decree.[22] It only applies to food produced in France, not to imported products. It states that:

- Plant products can be labeled as "GE Free" if they contain less than 0.1 percent GE plants. Because some companies might try to differentiate their products by using "GE Free" labels on products that have never been GE, if no GE variety of a given plant species is allowed for use in the EU, the products derived from this species cannot be labeled as "GE Free."
- For animal products, two thresholds are set and must be indicated on the label: first, if an animal was fed with GE feed by less than 0.1 percent of total feed, it is labeled as "fed without GE plants (0.1 percent);" and the other threshold is for animal fed with GE feed under 0.9 percent of total feed as "fed without GE plants (0.9 percent)."
- Processed animal products, milk and eggs can be labeled as "sourced from animals fed without GE plants (0.1 or 0.9 percent)," for animals fed with GE feed under those limits.

[20] Rural Code art. L663-4 (in French)
[21] An explanation on biotech labeling regulation is available on the Fraud Control Office's website (in French).
[22] See the 2012 decree (in French)

- Apiculture products including honey can be labeled as “GE Free” if there are no biotech plants closer than three kilometers to the apiary.

For processed products that contain several ingredients, the rules above apply to the ingredients themselves. “GE Free” can be written in the list of ingredients, after the name of the ingredient concerned. It can also be placed on the front of the product but only if this ingredient accounts for at least 95 percent of the dry weight of the product.

It is forbidden to state that the products have a better nutritional, health or environmental value because they are GE free.

- **Voluntary Private Initiatives**

Some food manufacturers and retailers voluntarily label their products as “GE Free.” Such labels are mainly found on animal products (meat, dairy products, and eggs), canned sweet corn and soybean products.

h) MONITORING AND TESTING

Monitoring and testing is performed randomly by government agents on food products, feed products, seeds and crops in order to make sure that GE products approval and labeling regulations are met. In addition, GE products on the market must be monitored by the holder of the approval (the developer) in order to detect any potential non-intentional effects.

i) LOW LEVEL PRESENCE POLICY

In 2011, the European Commission put in place a tolerance of 0.1 percent for unauthorized GE products in feed. This tolerance applies to GE products authorized for commercialization in a non-EU country and for which an EU authorization request has been lodged with EFSA. It does not apply to food and seeds.

j) ADDITIONAL REGULATORY REQUIREMENTS

French legislation subjects the cultivation of GE crops to transparency rules. The location where GE crops are grown must be declared to the government and this information is entered into a national

register, available online.[23] This rule has been controversial, since this public register has been used by activists to locate and destroy open-field trials of GE crops.

French lawmakers therefore established a dual penalty system whereby not declaring the location of GE crops is punishable by a 30,000 euro fine and six months of incarceration, and the destruction or degradation of authorized GE crops is punishable by a 75,000 euro fine and two years of incarceration.[24] The destruction or degradation of GE crops that were planted for research purposes is punished by a 150,000 euro fine and three years of incarceration. However, in practice, court decisions have varied widely, and the penalties have not deterred activists from destroying open-field trials of GE crops.

In addition to informing the government authorities, a GE farmer is required to notify the farmers of surrounding land of his intention to plant GE crops, prior to sowing.[25]

k) INTELLECTUAL PROPERTY RIGHTS

France supports the plant certificate system[26] under the International Union for the Protection of new Varieties of Plants (UPOV), rather than the patent system.

French law limits the patentability of living organisms:

- Article L611-19 (in French) of the Code of Intellectual Property states that "products obtained exclusively through essentially biological processes, the elements that compose them and the genetic information they contain" are not patentable. "Essentially biological processes" means naturally occurring processes such as the crossing of whole genomes and the subsequent selection of plants or animals.
- Article L613-2-3 (in French) of the Code of Intellectual Property states that when a plant obtained through essentially biological processes has the same characteristics as a patented biological material, the patent does not apply to this plant.[27]

These articles apply to patents, not to plant variety protection certificates.

In December 2018, the European Patent Office (EPO) reversed its 2017 decision establishing that European patents shall not be granted for plants or animals exclusively obtained by means of

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[23] Rural Code art. L663-1 (in French)
[24] Rural Code art. L671-14 and L671-15 (in French)
[25] Rural Code art. L663-1 (in French)
[26] In French: *Certificat d'Obtention Végétale (COV)*
[27] In French: "La protection conférée par un brevet relatif à une matière biologique dotée, du fait de l'invention, de propriétés déterminées ne s'étend pas aux matières biologiques dotées de ces propriétés déterminées, obtenues indépendamment de la matière biologique brevetée et par procédé essentiellement biologique, ni aux matières biologiques obtenues à partir de ces dernières, par reproduction ou multiplication."

"essentially biological processes." The French seed industry deplored this reversal that creates legal uncertainty for plant breeders due to the contradiction between French and EU regulations.

l) CARTAGENA PROTOCOL RATIFICATION

The Cartagena Protocol on Biosafety (CPB) aims to ensure the safe handling, transport, and use of living modified organisms. France signed it in 2000 and ratified it in 2003. Regulations implementing the CBP are in place.

The competent national authorities are:

- the Ministry of Higher Education and Research;
- the Ministry of Ecology;
- the Ministry of Economy;
- the National Agency for Food, Environmental and Occupational Health (ANSES);
- the Ministry of Agriculture.

Focal points for France are in the Ministry of Ecology and Sustainable Development (Biosafety Clearing House Focal Point) and Ministry of Foreign Affairs (Cartagena Protocol on Biosafety National Focal Point, Convention on Biological Diversity National Focal Point).

m) INTERNATIONAL TREATIES AND FORUMS

As a member state of the EU, France's position in international organizations is generally like that of the EU.

France is a member of several international organizations dealing with food and plants like most importantly the Organization for Economic Cooperation and Development (OECD), the Food and Agriculture Organization of the United Nations (FAO), the European and Mediterranean Plant Protection Organization (EPPO), and Codex Alimentarius. France takes an active role in these fora regarding biotechnology.

In May 2018, the HCB released its comments (see pages 17 to 25 in English) regarding OECD's document on environmental risk assessment of GE plants. The HCB recommends that better account be taken of biodiversity and that clear consideration be given to the long-term effects of the release of a GE variety, the possibility of horizontal gene transfer and the possibility of resistance development in target organisms.

PART C - MARKETING

a) PUBLIC/PRIVATE OPINIONS

Public awareness of agricultural applications of innovative biotechnologies is limited. There is limited awareness about possible agricultural applications of innovative biotechnologies among the general public. Since 2016, the mainstream media has covered actions of anti-biotech groups but almost never explained the applications of innovative biotechnologies for agriculture and food production. A few articles that mention potential benefits were published in August and September 2018 after the release of the ECJ ruling. Overall, the medical applications of genome editing and the ethical questions they pose are publicized more than those of agricultural applications. Most journalists focus on risks rather than opportunities. CRISPR-Cas9 has the highest media coverage.

The government says it differentiates between two categories of biotech plants. The French government differentiates between what it calls "first generation" and "second generation" biotech plants. The "first generation" includes herbicide and insect resistant plants, which the government opposes. The "second generation" consists of "crops that bring consumer or environmental benefits," with for instance enhanced nutritional content, reduced nitrogen use or improved water efficiency, which the government says it does not oppose. However, French authorities keep supporting stringent regulations and have not taken any strong action to prevent the destruction of field trials by activists; these regulations and destructions prevent French researchers from developing and commercializing second-generation biotech plants.

Several studies have concluded that the varieties of GE corn tested by Séralini in 2012 were safe but media coverage and policy impact are limited in France. In 2012, French biologist Gilles-Eric Séralini became an instant celebrity when local newspapers and television channels widely reported on his study supposed to prove that a variety of GE corn had serious health effects on rats. The general public remembers the spectacular and horrifying images of rats deformed by giant tumors Séralini exposed. This study had a major impact on public opinion. In contrast, few among the general public remember the analyses of the French food safety agency (ANSES) and of the High Council for Biotechnology (HCB) that reviewed Séralini's study and concluded one month later that it did not prove anything regarding a possible effect on health. However, ANSES remained very cautious and called for additional experiments on possible long-term effects of GE products associated with pesticides. It cost the European Union and France 15 million euros ($16 million) to feed thousands of rats GE corn throughout three months, one year, or their entire lives (two years). The result of the last of these taxpayer-funded studies was released in December 2018; all the experiments led to the conclusion that the varieties of GE corn tested had had no impact on the health of rats.

In France, different types of civil society organizations have formed agricultural biotechnology since it was first introduced. They are close to groups that are 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. Biotech opponents are skeptical of new technologies, in general, and they feel biotechnology in particular is dangerous, of little public benefit, and developed by companies that seek private profit at the expense of the common good. They also believe that independent experts that work for regulatory authorities have links with these companies (whether they do or not) and that it creates a conflict of interest. As part of their political strategy, their actions include lobbying public authorities, communication campaigns to increase public fears, and acts of sabotage (destruction of research trials, cultivated fields, and imported products). Many of these actions have led to arrests and criminal charges. Courts decisions have varied widely, with results ranging from acquittals to prison sentences. The penalties have not deterred these groups.

Although these groups are a minority, they are passionate about their cause and very active in the media. They have developed communication skills and the effectiveness of their campaigns, amplified by the media, has had a strong effect on public opinion. Moreover, the public opinion generally expresses distrust of biotech companies that are the most visible. Academic and public research exists but is less visible. Activists have played an important part in the adoption of regulations that have restricted the adoption of biotechnology in the EU, directly through lobbying and indirectly through their impact on public opinion. Their actions have made biotechnology a sensitive political issue, and it has now become difficult for an elected official to remain neutral on biotechnology. They are generally forced to take a position for or against and suffer the political consequences.

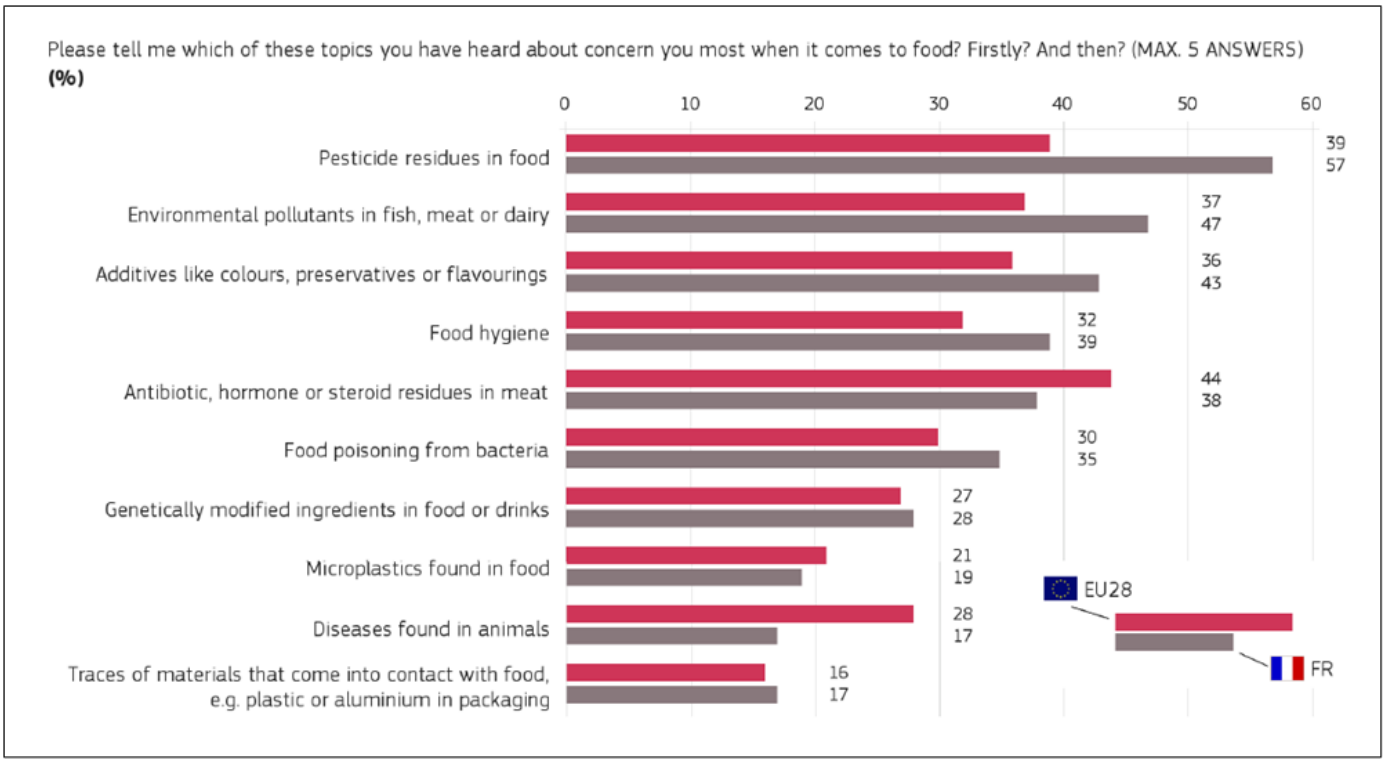
In the past, activists destroyed GE crops (both commercial crops and field trials). Now that the area planted in GE crops has fallen to zero, they focus on:

- Herbicide-resistant plants produced through conventional mutagenesis. Activists destroyed test plots of rapeseed or sunflower in April 2015, August, September, and November 2016, January and April 2017, August 2018, May, July, and August 2019.
- Imports of GE feed. Activists destroyed imported GE soy stocked in French ports in 2010, 2012, 2014, and 2016. In 2018, they organized a protest in front of an agricultural cooperative that imports GE soy. In 2019, they blocked a shipment of 50,000 tons of GE soy from Brazil for one day in the French port of Sète. However, the political messages of the activists have changed; they do not highlight the fact that these imports are GE. They focus on the link between soy cultivation and deforestation in South America.

b) MARKET ACCEPTANCE/STUDIES

Acceptance of GE crops in France must be viewed from the differencing positions of consumers, retailers, the food industry, and farmers. Consumers: Consumer attitudes towards GE products are primarily negative in France. However, 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 French consumers (see

chart below). Only 28 percent of French 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; pesticides have received much more media attention than other topics in recent years. The French media does not report on the fact that biotechnology has potential to help reduce pesticide use.



Retailers: Because consumer perceptions are primarily negative, food retailers, especially major supermarkets, promote themselves as carrying only non-GE products. They also fear that if they carry GE products, they will attract actions by activist organizations, such as protests and destruction of products in stores, which would generate negative publicity. In the past few years several supermarket chains have gone further and announced that they were taking steps to decrease the share of meats from animals fed GE products.[28]

Food Industry: Since the European regulation on mandatory biotech labeling has been implemented in France, the food industry has reformulated their products to exclude potential GE ingredients, such as corn starch, soy lecithin, and soy oil. The food industry is also developing initiatives that aim at reducing the use of GE feed in livestock production.

[28] For more information, see the websites of the main supermarket chains in France: Carrefour (in French), Les Mousquetaires (in French), Systeme U (in French)

Farmers: The animal production sectors and their feed supply chains (importers; animal feed compounders; poultry, swine, and cattle farmers) depend on imported soybean products to provide nutritionally balanced animal feeds. Market acceptance of GE products is rather high in these sectors. Feed grain producers in France generally support the use of GE varieties, due to the proven yield gains and lower production costs. French farmers cultivated Bt corn between 2005 and 2007, and most of them welcomed the technology. Due to negative consumer perceptions, acceptance of biotech cultivation is lower among producers in sectors where the products are consumed directly, such as vegetables and fruit.

As for organic farmers, the political spectrum of their movement goes from dogmatic people who believe that nature is good to market-oriented people who turn to organic farming to maximize their profits. Dogmatic people reject everything they perceive as "unnatural;" they reject modern techniques and tend to use seeds whose genes were modified decades or even centuries ago. For market-oriented organic farmers, being "GMO free" is a marketing argument; they may accept to use some seeds produced through innovative biotechnologies if they brought environmental benefits and had a clearly positive image among consumers.

CHAPTER 2 – ANIMAL BIOTECHNOLOGY

PART D – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

France uses animal biotechnology and cloning in research units:

- 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 whites from chicken eggs. Proteins can also be produced by animal cells in-lab.
- To improve animal breeding.

b) COMMERCIAL PRODUCTION

No GE animals for food use are commercialized in France.

c) EXPORTS

A French company called Cryozootech used to export some cloned horses but the company has ceased its operations.

d) IMPORTS

France has most likely imported semen and embryos from cloned animals or their offspring. The specific quantity of these imports is not available.

e) TRADE BARRIERS

Public and governmental opposition limits the use of products obtained through animal biotechnology and cloning.

PART E – POLICY

a) REGULATORY FRAMEWORK

France operates under the biotechnology regulatory framework of the EU. For more information about the European framework, please refer to USDA

i. Responsible government ministries

Several ministries are involved in oversight of animal biotechnology and cloning in France. The Ministry of Agriculture regulates the techniques used for food production purposes. The Ministry of Ecology is in charge of environmental issues. The Ministry of Research covers public research programs. The Ministry of Health is involved in human health issues.

The **High Council for Biotechnology** (HCB) is in charge of environmental risk assessment, while the Agency for Food, Environmental and Occupational Health and Safety (ANSES) is in charge of food safety risk assessment.

ii. Political factors influencing regulatory decisions

ANSES has conducted an analysis and concluded that cloning is not an issue in terms of food safety. France's government is opposed to using biotechnology and cloning in animal breeding for food production purposes due to low public acceptance.

In 2008, the official French Advisory Committee on Food (CNA) to the Ministry of Agriculture released a report on the consumption of products derived from cloned animals and their offspring that

recommended a ban on the marketing of food products derived from cloned animals or their offspring, cloning practices for breeding, and importing cloned animals and their offspring.

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

The regulation in place in France is that of the EU for the regulation of GE animals and for cloned animals

b) APPROVALS

No biotech animals are approved for feed and food use in the EU because no such application has been submitted since the regulations on GE organisms and on novel food entered into force.

Food from clones falls under the scope of the "Novel Food Regulation" and is subject to authorization. No such application has been submitted since this Regulation entered into force.

c) INNOVATIVE BIOTECHNOLOGIES

France has no regulation in place regarding the use of innovative biotechnologies in animals.

In June 2017, the HCB released its opinion on the use of GE mosquitoes as a vector-control solution to prevent the transmission of human diseases. Two reports are available online: the opinion of the scientific committee and the opinion of the ethics committee.

The scientific committee concluded that:

- Only one technique has been developed to an operational level: Oxitec's RIDL technique.[29] Two other techniques at an earlier stage of research and development are based on gene drives. An assessment of all existing and emerging techniques has been conducted with respect to possible objectives, efficiency, sustainability, technical constraints, and environmental and health risks.
- Techniques using GE mosquitoes do not have specific features associated with their GE character but are comparable to other vector control techniques. The gene drive techniques are distinguished by their unique invasive potential to date.
- The criteria listed in Directive 2001/18/EC, applicable to environmental risk assessment for release of GE mosquitoes in the EU, are sufficient for assessment of the risks associated with use of GE mosquitoes for vector control. As provided for in the case-by-case approach of the directive, the specific information required for assessment of GE mosquitoes for gene drives must be determined and outlined.

[29] RIDL consists in repeated mass releases of sterilized GE males

- Employing the incompatible insect technique, the standard sterile insect technique, or the release of insects carrying a dominant lethal gene on any French lands would help reduce insecticide use. Insecticides could be reserved for epidemics and public health emergencies.
- It is premature to contemplate deployment of gene drives in the environment.

The ethics committee concluded that:

- GE mosquitoes can be a useful additional tool in the panoply of vector control strategies.
- Citizens' debates are needed.
- The legal framework needs to be clarified. Precise monitoring is needed, as well as strengthened assessments of the consequences of disseminating GE mosquitoes.

In June 2019, the Veterinary Academy of France unanimously voted for a position paper on Genome Editing in domestic animals at its General Assembly in Paris. The Academy recommends that:

- "research projects making use of modern genome engineering technologies be encouraged at all levels and adequately funded, otherwise it will lead to detrimental delay.
- EU legislation adapted to the case of genetically modified domestic animals should rapidly be introduced in order to establish a regulatory framework which is a function of the type of genetic modification and takes account of the rapid evolution of the technology in this field, so as to foster innovation. This legislation should take into account 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.
- projects relating to the production or importation of domestic animals whose genomes have been modified by editing certain segments of DNA 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."

d) LABELING AND TRACEABILITY

Laboratory animals developed through biotechnology are all labeled and traced and are not released into the environment.[30]

Some cloned sport horses are released into the environment.

e) INTELLECTUAL PROPERTY RIGHTS

The regulation in place in France is that of the EU.

[30] LOI n° 2008-595 du 25 juin 2008

f) INTERNATIONAL TREATIES AND FORUMS

As a member state of the EU, France's position in international organizations is generally expressed as like that of the EU. France is a member of several international organizations dealing with food and animals like most importantly the Organization for Economic Cooperation and Development (OECD), the World Organization for Animal Health (OIE), the Food and Agriculture Organization of the United Nations (FAO), the European and Mediterranean Plant Protection Organization (EPPO), and Codex Alimentarius. France takes an active role in these fora regarding biotechnology.

PART F – MARKETING

a) PUBLIC/PRIVATE OPINIONS

France's livestock industry does not favor the commercialization of GE animals, clones and their offspring for food or agricultural purposes, but is interested in animal genomics and marker assisted selection for animal breeding.

Animal rights activists are becoming increasingly vocal in France. According to the French Ministry of Interior, they conducted more than 800 actions in the country in 2019, including acts of violence. They target research facilities, farms, and slaughterhouses but also hunting facilities and animal parks. Since 2018, dozens of butcher shops have been damaged by vegans (broken windows, graffiti tags, false blood sprayed). A few recent actions are listed below:

- In 2017, a group called "butchery abolition" broke into a public research center that works on livestock genetics, "released" animals and sprayed the building with false blood.
- A group called L214 regularly puts hidden cameras in slaughterhouses and broadcasts the most shocking images; their long-term objective is to "abolish livestock farming." Some say that L214 "defends American interests" because this association has received funding from a U.S. organization called "Open Philanthropy Project" that supports a large number of projects including research on cultured meat (meat produced by in vitro cultivation of animal cells).
- In 2019, the French branch of DxE, an international network based in California whose objective is to ban meat by 2040, encouraged young vegans to work for livestock farmers during the summer and trap the farmers with hidden cameras. DxE also released a map on the Internet giving the localization of 5,000 farms considered "industrial" and incited journalists to visit them and "report the downward slide of industrial farming."

Five percent of French people say they are vegetarian or vegan and activists are very small in number. However, they have an influence on public opinion.

The general context of the country with widespread opposition to industrial farming and increasing violence of animal rights activists makes it difficult to have a calm and objective debate on animal biotechnology. Any type of research involving animals is at risk of becoming a target. It is more and more difficult for farmers to do their jobs and they are concerned that using biotechnology could make the situation even worse. Few people are aware that animal biotechnology has potential to help improve animal welfare. Some scientists believe that the massive reduction in animal suffering disease resistant animals should be publicized in order to increase people awareness.

b) MARKET ACCEPTANCE/STUDIES

Market acceptance of GE animals, clones, and their offspring is low among producers and consumers. There is low awareness of biotech research on insects such as mosquitoes and GE olive flies among the general public.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION: France commercially produces food ingredients derived from microbial biotechnology using bacteria, yeasts, fungi, and enzymes for application in food & beverage, pharmaceutical, bio-industrial, and veterinary areas.

b) EXPORTS: France does not have statistics or estimates on exports of microbial biotechnology products. However, France does export wine and dairy products, and some processed products that may contain microbial biotech-derived food ingredients.

c) IMPORTS: France does not have statistics or estimates on imports of microbial biotechnology products. However, France does import wine and dairy products, and some processed products that may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS: Although France generally follows EU regulations, it is possible the additional legal concerns regarding NBTs discussed in Part B Policy and Innovative Technologies. could have implications for microbiology.

PART H: POLICY

a) REGULATORY FRAMEWORK: As a member of the EU, generally EU regulations on biotech-derived microbes or microbial biotech-derived food ingredients apply to France

Food additives and enzymes are regulated under the French Agency for Food, Environmental and Occupational Health & Safety (ANSES). It is an administrative public establishment accountable to the French Ministries of Health, Agriculture, the Environment, Labor and Consumer Affairs.

The additives and enzymes are subject to standard European regulations that are currently being implemented. There are two main regulatory texts and several additional regulations:

- a Regulation on food additives, food enzymes and food flavorings (Regulation (EC) No 1331/2008) and (Regulation (EC) No 1332/2008).

These EU regulations provide for a common evaluation and authorization procedure leading to the establishment of a list of approved food enzymes within the European Union.

Novel Foods: EU Regulation No. 2015/2283 defines novel food as food that has not been consumed to a significant degree in the EU before May 15, 1997, and falling within at least one of the categories listed in Article 3 of the Regulation It can be a newly developed, innovative food resulting from new production techniques (e.g. nanotechnology) as well as a traditional - but unknown to EU consumers - food from a non-EU country.

Food consisting of, isolated from, or produced from microorganisms, fungi, or algae shall be subject to EU Regulation No. 2015/2283 on Novel Foods (applicable since January 1, 2018) if it was not used for human consumption to a significant degree within the EU before May 15, 1997. A guidance document on "human consumption to a significant degree" is available on the European Commission's website. Moreover, the European industry group Food Supplements Europe offers guidance for food business operators on "The verification of the status of a new food under the Novel Food Regulation".

Novel foods require a pre-market authorization. Applications for authorization must be submitted to the European Commission via an e-submission system. The Commission may request the European Food Safety Authority (EFSA) to carry out a risk assessment. An overview of the different steps of the authorization procedure is available on EFSA's website. Authorizations are generic and no longer applicant-linked as was the case under the previous rules.

Food business operators are responsible for verifying whether the food they intend to market in the EU is novel or not. Novel Food Regulation provides for a consultation process when the status of a food or food ingredient is unsure.

The Novel Food Regulation does not apply to GEs falling within the scope of Regulation No. 2003/1829; food enzymes falling within the scope of Regulation No. 2008/1332; food additives falling within the scope of Regulation No. 2008/1333; food flavorings falling within the scope of Regulation No. 2008/1334; and extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive No. 2009/32.

b) APPROVALS: Approval of biotech microbes and/or derived food ingredients in France are subject to EU procedures. The EU's "Package on Food Improvement Agents" includes four Regulations:

Regulation No. 2008/1331 establishing a common authorization procedure for food additives, food enzymes, and food flavorings; Regulation No. 2008/1332 on food enzymes; Regulation No. 2008/1333 on food additives; and Regulation No. 2008/1334 on food flavorings.

In France, food enzyme authorizations fall within the scope of the Decree dated 10 May 2011, stipulating the conditions for authorization and use of processing aids. A list of approved food enzymes and conditions of authorization are provided in the Ministerial Order dated 19 October 2006, as amended.

Applications for authorization to use food enzymes are submitted by applicants to the General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF), which then makes a formal request to ANSES. In accordance with Article 1 of the Ministerial Order dated 7 March 2011, these applications must be prepared as per the EFSA Guidance on submission of a dossier on food enzymes for safety evaluation.

Food enzymes: Regulation No. 1332/2008 on food enzymes introduced harmonized rules for their scientific evaluation and authorization in the EU. EFSA is currently evaluating industry applications for authorization of existing and new food enzymes. Until the Commission draws up an EU-list of authorized food enzymes, national rules on the marketing and use of food enzymes, and food produced with food enzymes will continue to apply.

For more information, see the European Commission's website: https://ec.europa.eu/food/safety/food_improvement_agents/enzymes/eu_rules_en.

Food additives: Annex I to Regulation No. 2008/1333 lists the definitions of 26 different categories of food additives. Only additives included in the EU's positive list (annex II to Regulation No. 2008/1333) are authorized for use in food products marketed in the EU. Annex III to Regulation No. 2008/1333 contains a second list of food additives approved for use in food ingredients, such as other food additives, food enzymes, food flavorings, and nutrients. Commission Regulation No. 2012/231 sets out specifications for food additives listed in Annexes II and III.

Inclusion in the EU positive list is based on a risk assessment by EFSA. An important difference from U.S. legislation is that the EU does not allow the use of flour beaching agents, chlorine, bromates, and peroxides. Commission Regulation No. 257/2010 sets out a re-evaluation program for EFSA to assess food additives that were approved before Regulation No. 1333/2008 entered into force. The re-evaluation of approved food additives is scheduled to be completed by the end of 2020. Please find a link to the summary table of permitted food additives and status of their re-evaluation by EFSA (as of September 9, 2019). For more information on the re-evaluation of food additives, see: https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

Food flavorings: Part I of Annex I of Regulation No. 1334/2008 establishes a list of authorized flavoring substances. Commission Implementing Regulation No. 2013/1321 establishes the EU positive list of authorized smoke flavoring primary products for use as such in or on foods, and/or for the

production of derived smoke flavorings. Regulation No. 2003/2065 establishes a safety assessment and authorization procedure for smoke flavorings intended for use in or on foods.

Novel Foods: Commission Implementing Regulation No. 2017/2470 establishes a list of novel foods authorized in the EU. Entries in the list include specifications, conditions of use, additional labeling requirements, and post-monitoring requirements.

c) LABELING and TRACEABILITY: Labeling and traceability of microbial biotech-derived food ingredients in France are subject to EU procedures.

Food enzymes: Annex VII, Part C of Regulation No. 2011/1169 lists the categories of food enzymes, which must be designated by the name of their category, followed by their specific name or E-number. Articles 10-13 of Regulation No. 2008/1332 set out specific labeling requirements for food enzymes and food enzyme preparations.

Food additives: Annex VII, Part C of Regulation No. 2011/1169 on the provision of food information to consumers lists the categories of food additives, which must be designated by the name of their category, followed by their specific name or E-number. In 2016, EFSA completed a re-evaluation of EU-approved food colors. As a result, Annex V to Regulation No. 1333/2008 on food additives was amended to introduce mandatory labeling information for six food colors: Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Tartrazine (E102), Azorubine/Carmoisine (E122), and Allura Red AC (E129). Foods containing these colors have to be labeled "may have an adverse effect on activity and attention in children". Commission Regulation No. 2012/232 lowered the limits for food colors Quinoline Yellow (E104), Sunset Yellow (E110), and Ponceau 4R (E124). Food color Red 2G (E 128) was removed from the EU's positive list in 2007.

Food flavorings: Annex VII, Part D of Regulation No. 2011/1169 sets out rules for the indication of food flavorings, smoke flavorings, and the use of the term "natural". Regulation No. 2008/1334 lays down additional rules on the use of the term "natural".

Novel Foods: Annex, Table 1 of Commission Implementing Regulation No. 2017/2470 sets additional labeling requirements for novel foods authorized in the EU.

d) MONITORING AND TESTING: Under Authority of the French Ministry of Health and the Ministry of Agriculture and food, officials at the border can perform random controls on food additives, food flavorings, and food enzymes at the point of entry. Standard controls involve documentary, identity and physical checks, and sampling.

e) ADDITIONAL REGULATORY REQUIREMENTS: N/A

f) INTELLECTUAL PROPERTY RIGHTS (IPR): France follows EU Directive No. 98/44/EC.

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS: There is no public debate or awareness of microbial biotechnology in France beyond cellular meat production.

b) MARKET ACCEPTANCE/STUDIES: There is no public debate or awareness of microbial biotechnology in France beyond cellular meat production, and that is currently very limited to those who are in the livestock industry and the French Ministry of Agriculture. Those NGOs in France generally against the use of any new technology in agriculture also are those NGOs who are most vocal about environmental protection and animal welfare, so how all those groups will decide to support or reject cellular production of meat using cellular growth technology remains an open question.