Required Report: Required - Public Distribution **Date:** March 28, 2022

Report Number: FR2021-0013

Report Name: Agricultural Biotechnology Annual

Country: France

Post: Paris

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

France has no commercial production or field trials of genetically engineered (GE) crops. The French livestock industry depends on imported GE products for feed, especially soybean, rapeseed, and corn. While most French scientists and farmers are generally supportive of biotechnology, consumer attitudes toward GE are primarily negative. Some French laboratories conduct fundamental GE research, however most projects are not publicized due to the risk of attack by activist groups.

Executive Summary:

France is one of the most important centers of medical biotechnology in Europe, yet agricultural biotechnology is constrained by strict regulations, minimal research and development, and low public support. The French government has authorized imports of GE products for animal feed, but continues to restrict research, while also banning cultivation. The current situation is unlikely to change in the short term.

France conducts basic research and uses both GE and innovative technologies in laboratories. However, due to public opposition and risk of sabotage, there are currently no field trials in France. Anti-biotechnology groups have been known to destroy crops, even when only suspecting the presence of GE. The last authorized GE field trial was in 2013. Agricultural biotechnology research in France is very limited with no real opportunities for commercialization in the near future.

While France does not produce commercial GE products, the French livestock industry imports GE feed, mainly soybeans and soybean meals from South America and the United States, and rapeseed (canola) from Canada. France and the EU provide incentives to increase European production of plant protein, however restrictions on agricultural biotechnology clearly have had an adverse effect this goal. Opponents of agricultural biotechnology have a very strong influence on public opinion. There is generally better acceptance among French grain producers, animal feed compounders, the livestock industry, and scientists; however, these voices receive little attention. French media outlets rarely report on the potential benefits of biotechnology, including reduced pesticide use and other efficiencies in agricultural production.
Animal biotechnology is used primarily for medical research. The French government is opposed to using biotechnology in animal breeding, and animal rights activists discourage debate on the objective scientific merits of the technology, including ways to improve animal welfare.

However, notwithstanding widespread opposition toward GE, interest in New Breeding Techniques (NBTs) is growing. French Minister of Agriculture Julien Denormandie is a strong proponent of agricultural research and innovation. He and other prominent agricultural stakeholders are advocating for more reasonable approach toward technology to ensure the long-term competitiveness of the sector. NBTs have generally been less controversial, yet discussions on their GE or non-GE status are initiating heated debates between environmental groups and agricultural stakeholders, leading to legal actions. The wider public remains largely unaware of these innovative technologies.

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
GMO Genetically modified organism, preferred term for French stakeholders to speak about genetically engineered organism
HCB High Council for Biotechnology
INRA French National Institute for Agricultural Research
MT Metric Ton
NGOs Non-Governmental Organizations

Glossary:
"Event" within the genetically engineering framework is the insertion of a particular transgene into a specific location in the chromosome. The term "event" is often used
to differentiate genetically engineered crop varieties.

"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 for "New Breeding Techniques" (NBTs) and is generally referred to as gene editing. It excludes plants or animals resulting from traditional genetic engineering (transgenesis), known in Europe as genetically modified organisms (GMOs).

Table of contents

CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

France is active in research and uses both genetic engineering and innovative biotechnologies throughout its national research networks. Research projects include plant and animal genomic selection, innovative techniques, and the utilization of plant metabolic diversity. However, France has fallen behind in experimentation and dissemination and some French companies are working offshore to develop plants for non-EU markets.

As far as agricultural biotechnology is concerned, France:

- conducts very limited research involving transgenesis;
- had one basic research project on innovative biotechnologies that ended in 2020;
- is active in genomic selection and varietal selection.

i. Limited research in agricultural biotechnology

France conducts very limited research in transgenic agricultural biotechnology as poor public acceptance, misconceptions, and regulatory constraints hinder the development of innovative biotechnologies.

One notable initiative was the GENIUS project (Genome Engineering Improvement for Useful plants of a Sustainable agriculture), an 8-year public-private partnership, launched in 2012, that aimed at demonstrating the feasibility of genome editing in various plant species (corn, wheat, rice, rapeseed, tomato, potato, apple tree, poplar tree, rose tree). The project focused on traits concerning resistance to pathogens, salinity tolerance, and increased biomass production. The budget of this project was 21.3 million euros. The project managers published an update on their website on July 31, 2018, stating state that "due to the ECJ decision on EU regulations, future benefits of the Genius project for French agriculture are likely to be very limited." The project has since ended without any further communication.

In September 2018, the French National Institute for Agricultural Research (INRAE) released its Strategy for Plant Genome Editing Technologies. The strategy document states that "INRAE views as one of its public research missions and a social responsibility to explore the potential benefits of genome editing for plant breeding, but also to assess limitations and identify possible health, environmental and socio-economic risks of derived products and the ways in which these products are used. (…) Target traits and species will be chosen with the aim of the common good, for uses and production systems promoting environmental, economic, and social sustainability, for instance to reduce the use of synthetic pesticides or adapt to climate change. (…) The creation and characterization of plants obtained via genome editing are carried out in contained laboratory or greenhouse environments, in accordance with national and European regulations. The justification of field trials to consolidate their agronomic, technological and environmental assessment will be reviewed by a panel of experts." The strategy remains intentionally vague when it comes to field trials. Currently, there is very little political will to prosecute activists that sabotage field trials.

ii. Genomics in plant breeding

Genomic tools (the branch of molecular biology concerned with the structure, function, evolution, and mapping of genomes) are actively used by both public labs and private seed companies. Unlike transgenesis and innovative biotechnologies, the use of genomics is far less controversial.

iii. French companies developing biotech plants for non-EU markets

Some French companies are developing new plants using transgenesis and innovative biotechnologies; their biotech research facilities are based outside of Europe for non-EU commercialization. For example, Calyxt, the U.S. subsidiary of the French Cellectis S.A., has used gene editing to develop a new soybean variety with improved nutritional properties. The Calyxt soybean variety does not have trans fats and contains less saturated fatty acids than conventional soybeans. The French owned variety was commercialized in the United States in February 2019. Ninety-eight percent of the oil produced from this soybean is expected to be sold as a food ingredient to small and medium-size food companies.

iv. Laboratory research for medical applications

GE plants and plant cells are used in laboratories to develop proteins of pharmaceutical interest. Proteins with simple structures, such as insulin and growth hormones, can be produced by GE microorganisms. GE plants and plant cells are also used to develop more complex molecules for research purposes (vaccines, antibodies, enzymes).

v. Commercialization is not expected in the medium term

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 the lack of political support for research involving genetic engineering. The risks and the regulatory costs of commercialization are prohibitively high;
- The private sector's interest in developing varieties of GE plants suitable for cultivation in the European Union has waned. Repeated vandalism, together with the uncertainty and delays of the EU approval process, make genetic engineering an unattractive investment.

b) COMMERCIAL PRODUCTION

France does not produce GE crops for commercial purposes. This situation is unlikely to change in the medium term (see Part B - Policy)., During his 2017 presidential campaign, President Macron said 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, but, since 2008, its cultivation has been banned in France.

In 1998, there were 4,445 acres of GE corn planted in France. This fell to zero during the European *de facto* moratorium between 1999 and 2004. Cultivation briefly resumed between 2004 and 2007, reaching 54,363 acres before dropping again to zero in 2008. Prior to the ban, the cultivation of transgenic plants in France was never significant; in 2007, the share of GE corn represented only 0.7 percent of the total crop.

A GE potato was also authorized in 2010, but in practice, it was never cultivated in France. On the other hand, several thousand acres are currently cultivated with varieties derived from mutagenesis. The term mutagenesis covers several techniques that introduce genetic mutations into living organisms. The recent commercialization of mutated varieties that are tolerant to herbicides (VRTH) has attracted public

attention, which some activists call "hidden GMOs." In France, several varieties of sunflower and rapeseed, made tolerant to herbicides by mutagenesis, are grown in the field. France also grows mutated sunflower varieties with a high oleic acid content. It is practically impossible to find non-mutated sunflowers on the market.[1]

On October 12th, 2021, French President Emmanuel Macron presented a new 2030 economic recovery plan for France, with a total budget of 30 billion euros. With the significant challenges facing the food and agriculture sector, the French government plans to devote 2 billion euros to digital, robotics and genetics to "accelerate the third agricultural and food revolution". According to the government, research projects in genetics will help develop environmentally friendly species and crops. While many agricultural stakeholders, especially those representing larger interests, are very supportive of the government plan, environmental organizations and smaller French farmers accuse the government of opening the door to GMOs.
The inclusion of agricultural biotechnology in President Macron's recovery plan is groundbreaking in terms of opening more dialogue on the role of technology, genetics, and robotics to ensure the future competitiveness of the French agricultural sector. Clearly, many people are recognizing that the challenges of climate change and food sovereignty are inextricably linked to role of technology and science.

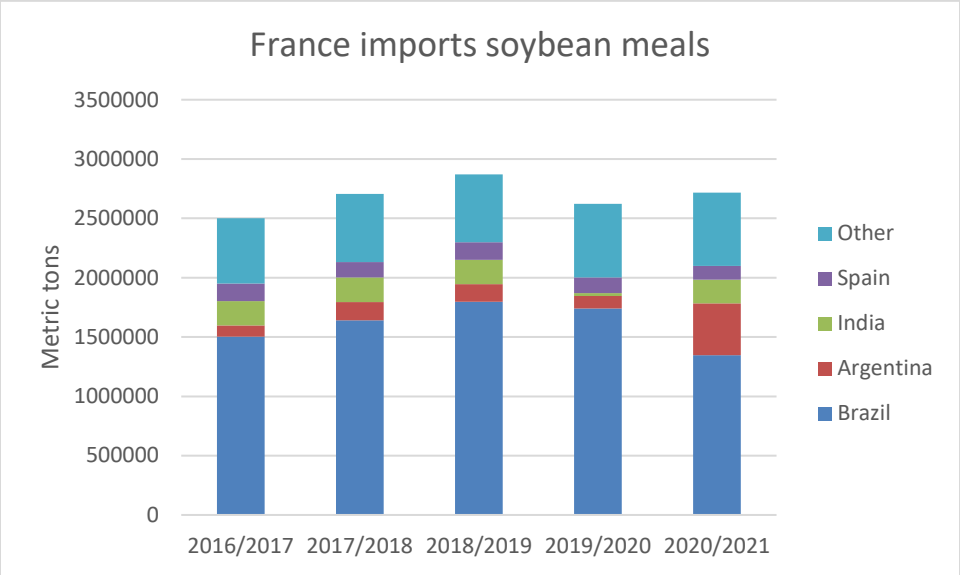
c) EXPORTS
France does not export any GE plants.

d) IMPORTS
The bulk of French biotech imports consists of whole soybeans and soybean meal from the Americas, destined primarily for use as animal feed ingredients. GE products account for an estimated 80 percent of total animal feed ingredient imports. France also imports GE rapeseed from Canada and small quantities of GE corn and corn processing by-products.

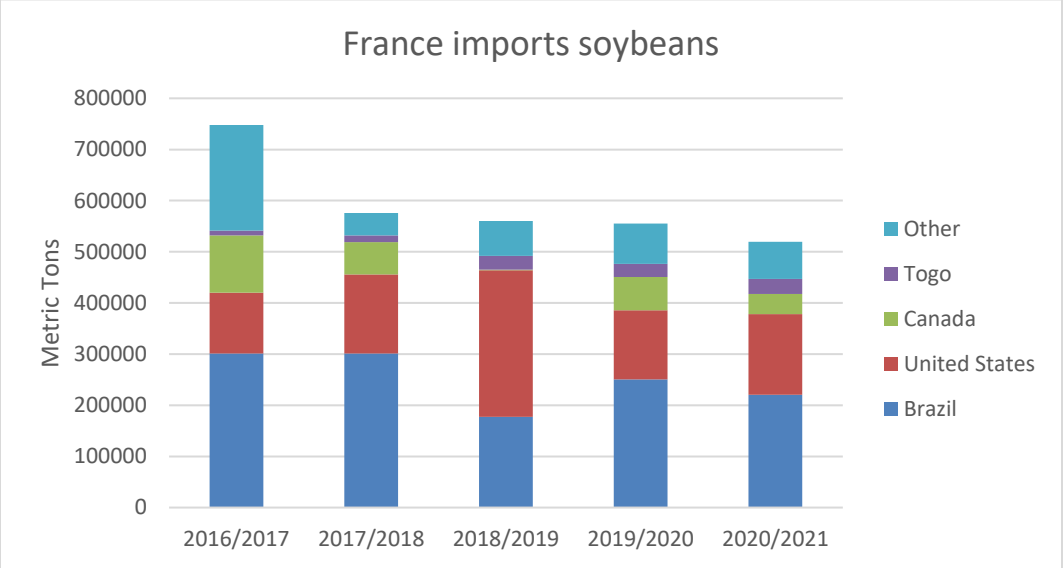
Trade data do not differentiate between conventional and GE varieties. The graphs presented in this section therefore include both categories. In each section, a table gives the share of GE crops from France's main supplier countries.

France imports on average between 3.5 and 4 million metric tons of soybean products per year, of which 80 percent are GE.

[1] Following anti-GMO groups' legal complains, France is currently discussing the GMO status of mutagenesis crops. More on this subject in the Innovative Biotechnologies section of this report.



Source: Trade Data Monitor



Source: Trade Data Monitor

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

- 2.7 million metric tons (MT) of soybean meal per year. The share of GE soybean meal out of France's total soybean meal imports is estimated at 80 percent.
- 591 thousand MT of whole soybeans per year. The share of GE soybeans out of total imports is estimated at more than 90 percent. Brazil, Canada, and the US are historical soybean suppliers to the French market. Relative newcomer, Togo is gaining market shares with non-GE and/or organic soybeans. In 2020, for the second consecutive year, Togo was the country that exported the largest volume of organic soybeans to Europe.

France depends on imported soybean products for animal feed in the 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. French importers decide where to source soybean products primarily based on price, and, to a lesser extent, on protein content.
The demand for non-biotech soybean meal is estimated at 20 percent of the total French market. It is mainly supplied by soybeans grown domestically in the EU and by imports from Brazil, India, and Spain.

There is a premium for non-biotech soybeans, which varies between 60 and 100 euros per MT. Premium prices are mainly due to limited supplies and the higher logistical costs of segregating transportation and storage.
In 2021, the French feed inter-branch organization SNIA reported higher prices due to supply difficulties. A non-GE soybean shortage had a significant financial impact on French meat-origin products (meat, cheese), especially those with protected geographical indications (PGI) with strict non-GE feed requirements. 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 under the EU Common Agricultural Policy (CAP) and different regional support schemes.

The European Union is also seeking to increase local production of plant proteins. For more information, please see the report on The Development of Plant Proteins in the European Union released by the European Commission in November 2018. It is particularly noteworthy that the final report on the EU Protein Strategy does not discuss how EU restrictions on agricultural biotechnology are adversely affecting the objectives of breeding more productive, more resilient crops that can adapt to climatic and environmental conditions of the EU.

Table 1 below gives the share of GE soybeans in total soybean production in France's main supplier countries.

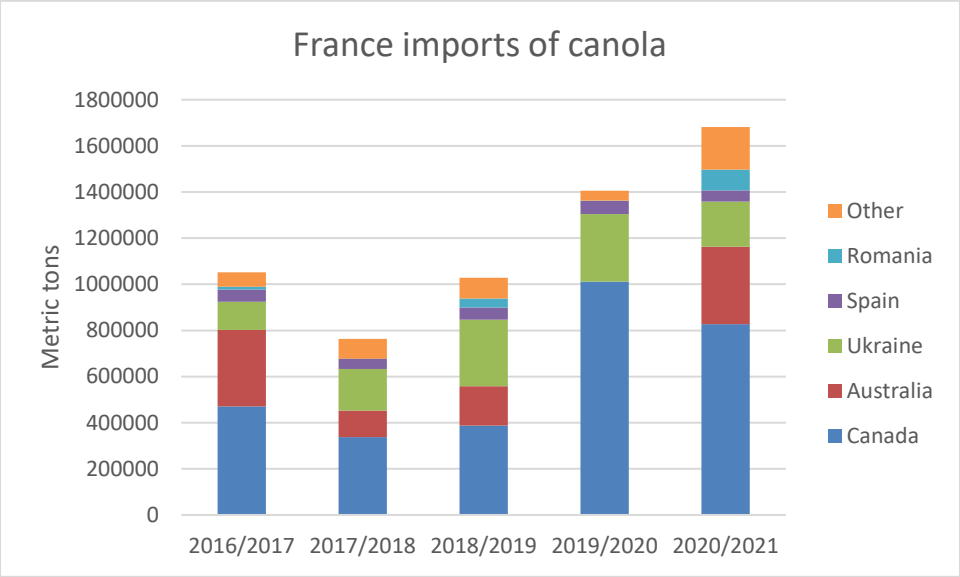
Table 1 - Share of GE Soybeans in Total Soybean Production

Argentina	100%
Brazil	96%
Canada	95%
India	0%
Spain	0%
Togo	0%
United-States	94%

Source: ISAAA 2018

France imports GE canola (rapeseed) from Canada

In the last five years, France imported between 763,000 and 1,681,000 MT of canola per year. In 2019/20, 72 percent of France's imports came from Canada, where 95 percent of canola is GE; 21 percent came from Ukraine, where the share of GE canola in total exports is estimated at 10-12 percent.



Source: Trade Data Monitor

Table 2 below gives the share of GE canola in total the production of France's main supplying countries.

Table 2 - Share of GE Rapeseed in Total Rapeseed Production

Australia	**22%**
Canada	**95%**
Romania	**0%**
Spain	**0%**
Ukraine	**10-12% estimated – no official industry figure (Source: FAS)**

Sources: ISAAA 2018 and FAS

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

In the last six years, France imported on average 590 thousand MT of corn per year. Table 3 shows a declining trend in the share of GE-corn imports due to decreasing imports from Spain and the United States while imports of non-GE corn from EU member states (Bulgaria, Romania, Hungary) are increasing.

Table 3 - Origin of France's Imports of Corn

	2016/2017	2017/2018	2018/2019	2019/2020
Total world imports – Metric tons	555,665	544,794	780,650	612,800
Potential GE imports - tons	15,374	11,858	14,043	10,152
Potential GE imports %	2.8	2.2	1.8	1.7

Source: Trade Data Monitor

Table 4 gives the share of GE corn production in France's leading suppliers, Spain, the Ukraine, and the United States.

Table 4 -Share of GE Corn in Total Corn Production - 2018

South Africa	87%
Spain[2]	35%
United States	92%

Source: ISAAA and FAS (2018)

[2] The share of GE corn in Spain has been lowering and reached 28 percent in 2020.

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

Over the last six years, France has imported on average 250 thousand MT of Distiller's Dried Grains with Solubles (DDGS) per year. Imports are mainly from Spain and to a lesser extent from Vietnam and the United-States.

Origin of France's Imports of DDGS

	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021
Total world imports – Metric tons	214,977	260,656	234,562	256,246	282,211
Potential GE imports - tons	9,688	20,533	12,118	7,399	6,562
Potential GE imports %	4.5	7.9	5.2	2.9	2.3

Source: Data Trade 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;
- directly (5 to 10 percent of the total budget).

The food aid budget for France for the period 2021-2027 is of 869 million euros; the budget increased by 48 percent compared to the previous budget period in order to support the high demand for support due to the COVID-19 crisis.

f) TRADE BARRIERS

- ✓ ***Cultivation Ban***

The commercial cultivation of GMOs has been banned in France since 2008 and this is unlikely to change in the medium term. France has invoked the use of safeguard clauses and emergency measures provided for in Directive 2001/18/EC and Regulation 1829/2003 to ban the cultivation of MON810 maize; law n°2014-567 of June 2, 2014, bans the cultivation of genetically modified corn varieties. Between 2007 and 2014, three decrees that prohibited cultivation were successively released by the Government and cancelled by the Supreme Court because they were illegal. The law forbidding cultivation of GE corn in France was passed in June 2014. This law was not compatible with EU regulations when it was passed.

Since 2015, France has used the new provisions introduced by Directive 2015/412 on the cultivation of GMOs and requested to be excluded from the European Union's geographical scope of authorizations

and applications for authorization of cultivation. On March 3, 2016, the European Commission adopted a decision modifying the geographical scope of the authorization to cultivate genetically modified maize MON810. This decision prohibits the cultivation of MON810 maize in France and in all Member States or regions that have applied for geographical exclusion.

- ✓ ***Import Ban***

In 2015, the European Commission released a proposal for a regulation that would allow EU member states to restrict or ban the use of already 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 it is widely believed to be incompatible with international trade agreements. Moreover, if the proposal were adopted, France would be placed in a very difficult position with respect to anti-biotech groups The French Government is eager to avoid adding stress to the French livestock and poultry sectors which are already facing challenges in sourcing non-GE feed ingredients. With this is mind, French policy makers are comfortable with the ambiguity of neither completely banning nor completely accepting GE products. FNSEA, one of the main farm unions in France is also opposed to the opt-out proposal, noting that "the European Union is a common market, so we need common rules." Anti-biotech activists have criticized the proposal 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 international obligations.

PART B - POLICY

a) REGULATORY FRAMEWORK

European regulations stipulate that a GE product may not be placed on the European market or released into the environment without prior authorization. This authorization can only be given after a case-by-case assessment of the risks to health and the environment and will require monitoring, traceability, and labeling.

France operates under the EU biotechnology regulatory framework. For more information, please refer to the GMO documentation from the European Commission and USDA EU-28 Agricultural Biotechnology Annual reports.

The main regulatory texts governing the cultivation and marketing of GMOs are

- Directive 2001/18/EC on the deliberate release of GMOs into the environment;
- Regulation (EC) No 1829/2003 on genetically modified food and feed;
- Regulation (EC) n°1830/2003 concerning the traceability and the labeling of GMOs.

European legislation on GE applies directly to France, and indirectly also through French law.

French national legislation on GMOs is mostly encapsulated in the Environmental Code and the Rural and Maritime Fishing Code:

- Environment Code, articles L. 125-3, L. 531-1 to L. 537-1, D. 531-1 to R. 536-11
- Code rural et de la pêche maritime, articles L. 251-1 and L. 251-2, L. 251-18-1, L. 663-1 to L. 663-4, D. 663-1 to D. 663-6

i. Responsible government ministries and their role in the regulation of GE plants
The French Ministry of Agriculture & Food and the Ministry for Economy & Finance through the Fraud Control Office (DGCCRF) carry out controls to verify proper enforcement of commercialization and cultivation of GMOs. These controls include:

- crops: verification of compliance with the ban on the cultivation of GMOs (Ministry of Agriculture);
- seeds: search for the presence of GMOs and verification of compliance with labelling rules (Ministry of Agriculture and the Fraud Control Office)
- foodstuffs and animal feed: search for the presence of unauthorized GMOs and verification of compliance with labelling rules (Fraud Control Office).

The current Minister of Agriculture, Julien Denormandie, is an advocate of technology, and on multiple occasions, he has spoken publicly about the potential benefits of new breeding techniques (NBTs).

The French authorities have designated three national reference laboratories for the detection of GMOs.

The Ministry of Higher Education, Research and Innovation is the competent authority to issue approvals for the use of genetically modified GMOs for research, development, and teaching purposes.

The Ministry of Health has an advisory role regarding health issues linked to GMOs and periodically publishes reports, mostly through joint work with French Agency for Food, Environmental and Occupational Health & Safety (ANSES).
The Ministry of Ecology also has an advisory role. The current Minister Barbara Pompili has spoken publicly against GMOs and New Breeding Techniques alike.

ii. Role and membership of the biosafety authority
Prior to 2022, two independent public organizations were involved in the monitoring and risk assessment for genetically engineered products and associated research projects: the French Agency for Food, Environmental and Occupational Health & Safety, ANSES, is in charge of food and feed perspectives while the High Council for Biotechnology, the HCB, is responsible for the environmental component.

The High Council for Biotechnology was established by the 2008 law on GE organisms and consisted 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 reviewed biotech dossiers and provide their respective conclusions and recommendations to the Government of France and to EFSA.

After years of confusion, the French government finally decided to disband the council as of January 1, 2022. The dismantlement of the HCB underscores the difficulty in having reasoned debates on agricultural biotechnology in France.

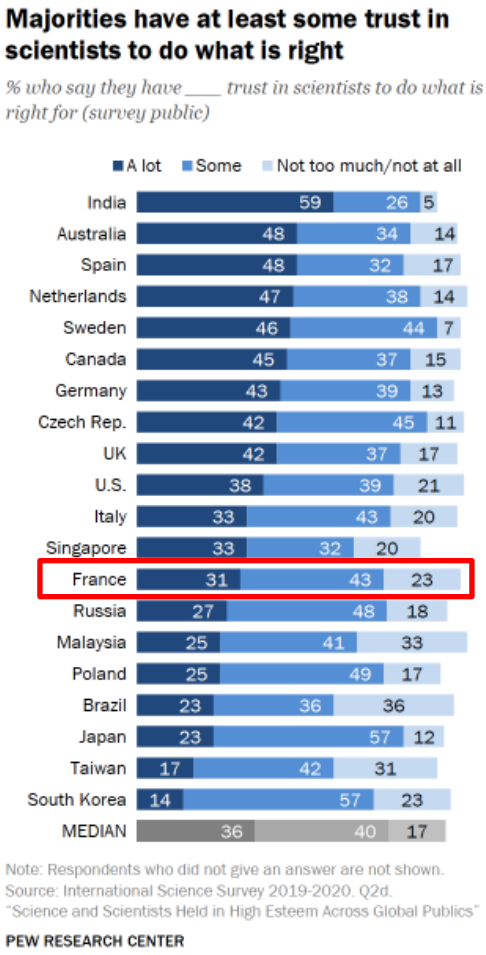
The scientific expertise of the HCB has been transferred to ANSES; the economic, ethical and social committee missions will be carried out by ANSES, the Conseil économique social et environnemental

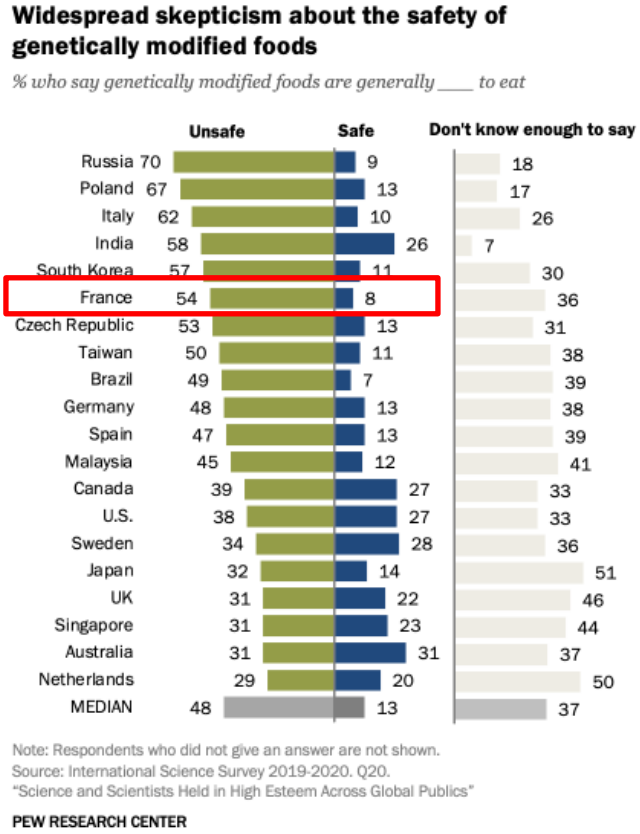
(the French Economic, Social and Environmental Council) and the Comité consultatif national d'éthique (French governmental advisory council on bioethics issues).

iii. Political factors influencing regulatory decisions related to plant biotechnology
Biotech opponents have been very successful in mobilizing public opinion, playing on fear and misinformation to influence the political process and regulatory decisions (see Part C. Marketing – a. Public /Private Opinion). French environmentalist lobbies and anti-GMOs (and even anti NBTs) are very well organized and well connected with media outlets.

French Presidential elections will take place in April 2022.

In France, skepticism over science has only gotten stronger as a result of the COVID 19 pandemic. According to a Pew Research Center survey conducted between October 2019 and March 2020, 23 percent of the French respondents did not have much trust or had no trust at all in scientists, and 54 percent felt that GE foods are unsafe.





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

Since the beginning of GE commercialization in the early 1990s, France has authorized GE imports to meet the demand for protein-rich animal feed ingredients. However, research and cultivation of biotech crops is banned. The process for approving biotech products is managed by the EU, but the French Government has latitude to implement its own regulations as long as they are consistent with EU regulations. Many transgenic events 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 crop cultivation and the non-biotech labeling system implemented at the national level.

On January 1, 2022, France assumed the 6-month Presidency of the European Union and several GE regulations are currently under review. One of the main priorities of the French Presidency is the introduction of "mirror clauses" for all EU food and agricultural imports. Mirror clause would compel EU trading partners to adopt the same standards that are imposed on EU agricultural producers. Such clauses could have an impact on GE products entering the EU market, with challenges for the EU feed industry.

vi. Timeline followed for approvals
European Directive 2001/18/EC provides the framework for the deliberate release of GE plants into the environment. Regulation (EC) No 1829/2003 covers the authorization for placing GE products on the market for food and feed. For more information, please refer to the USDA EU-28 Agricultural Biotechnology Annual report.

b) APPROVALS
All GE events approved for **feed and food use** 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
EU regulations apply to France. 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;
c) potential interactions between the events.

d) FIELD TESTING
In France, the deliberate release of a GE plant into an open environment, even for research purposes, must receive prior approval by the Ministry of Agriculture. The Ministry of Agriculture will consider the opinion of the HCB regarding possible risks for public health and the environment before granting such an authorization. The Ministry of Agriculture must also hold a public consultation 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.

The last open-field test was in 2013. There are currently no field tests in France because of the continued risk of sabotage by anti-GE activists. Activists (also known as "voluntary reapers") have not only destroyed property, but they have launched effective media campaigns to intimidate and discourage any form of biotechnology research. French authorities have generally done nothing to punish acts of sabotage, and this has discouraged both public and private organizations from conducting further research. Some French laboratories are developing GE plants and are conducting field tests in other countries.

e) INNOVATIVE BIOTECHNOLOGIES

On July 25, 2018, the European Court of Justice (ECJ) issued a judgment that organisms created through genome editing techniques are to be regulated as "genetically modified organisms (GMOs)" in the EU. On November 8, 2019, the Council released a decision "requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under European Union law, and a proposal, if appropriate in view of the outcomes of the study."

On April 29, 2021, the European Commission published a report titled, "Study on the status of new genomic techniques under EU law and in light of the Court of Justice ruling in Case C-528/16." The study concludes that the 2018 European Court of Justice directive is not "fit for purpose" for the newer biotechnology products (New Breeding Techniques) and a targeted policy action is needed. The study also noted that genome editing can contribute to the objectives of the European Green Deal's Farm to Fork and Biodiversity Strategies.

The 2018 ruling from the European Court of Justice on genome editing and its 2021 dismissal by the European commission has created a lot of confusion in France. One technique in particular, mutagenesis, has been brought to center stage recently by environmentalist lobbies. They reached out to the highest legislative government branch, the State Council (Conseil d'Etat) to force the French government to implement mutagenesis bans based on the 2018 Court of Justice of the European Union's directive. This led to a legal conundrum as the Council sided with the environmentalist groups, making it compulsory for the French government to ban mutagenesis, even though this ban jeopardizes the proper functioning of the internal European market, and could expose France to sanctions. The situation remains at a standstill and is unlikely to change before the presidential elections in the spring of 2022.

f) COEXISTENCE

French legislation aims to limit the spread of GE plants outside specially designated zones. Cultivation, harvest, storage, and transportation of GE crops are subject to certain technical rules established by the Minister of Agriculture. This includes safety zones between GE crops and other fields. In practice, when GE corn was grown in France, a buffer zone of 24 rows and 50 meters enforced around the fields. Research programs were conducted to study coexistence under real field conditions (from seed to storage facilities). A guide for GE corn cultivation was published to provide recommendations on good harvesting and processing practices to efficiently manage the coexistence of GE and non-GE sectors. French legislation provides for nationwide "biological monitoring," observing plant health and evaluating the impact of specific agricultural practices, including the use of GE. This is coordinated through the Committee for Biological Monitoring of the Territory, which was created by the 2008 law on GE plants. The Committee submits an annual report to both houses of the French Parliament and can alert the government if it finds unintended consequences that require special intervention.

French legislation provides that a producer of GE crops is liable if there is an accidental spread of GE plants causing economic harm to a non-GE crop producer. GE crop producers are also required to obtain liability insurance coverage. However, due to inadequate law enforcement mechanisms, insurance companies have been unwilling offer GE crop coverage in France.

g) LABELING AND TRACEABILITY

i. The Voluntary "GE Free" Labeling System

French labeling regulations comply with EU regulations requiring the labeling of food and feed produced from or containing GE products. For more information, please see USDA EU-28 Agricultural Biotechnology Annual report .The French Fraud Control Office of the Ministry of Economy, Finance, and Industry (DGCCRF) enforces compliance with the regulation.

In addition to EU regulations, a French voluntary "GE Free" labeling system has been in place since 2012. Decree No. 2012-128 of January 30, 2012, provides different criteria for claiming GMO-free status depending on whether the ingredients are of plant, animal, or bee origin.

- Ingredients of plant origin (e.g., flour, starch, or lecithin) can be able labeled "GMO-free" if they are derived from raw materials that incidentally contain a maximum of 0.1% GMOs;
- Manufacturers of ingredients of animal origin (e.g., milk, meat, fish, or eggs) may be labelled "from animals fed without GMOs (<0.1%)" or "from animals fed without GMOs (<0.9%)";
- Ingredients of beekeeping origin may be labeled "GMO-free within a radius of 3 km" provided that this distance between the hives and the genetically modified fields is respected.

Reference to the absence of GMOs will appear most often in the list of ingredients; however, GE free labels can also be printed on the main visual of the packaging should the GE-free ingredient represent more than 95 % of the food item.

ii. Voluntary Private Initiatives

Food products from animals fed with GMOs (such as meat, milk, and eggs) are not labelled to reflect their GE status. To meet consumer demand for more sustainability and transparency, there is a growing interest in non-GMO labelling initiatives from private companies that communicate about new integrated supply chains, selecting organic, local, non-GMO characteristics.

h) MONITORING AND TESTING

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

In January 2021, the Fraud Control Office (DGCCRF - Ministry for economy and finance) published a report on GE products, French regulation, and monitoring strategies. The latest reported GE incident in France occurred in 2018 when a batch of unauthorized transgenic rapeseed was identified and destroyed.

The report specifies that around a hundred authorized imported GE products (including seeds) can be found in France, mainly corn, rapeseed, soy, and sugar beet.

i) LOW LEVEL PRESENCE POLICY
In 2011, the European Commission put in place a "technical zero" tolerance of 0.1 percent for unauthorized GE products in feed. This tolerance applies to only GE products authorized for commercialization in a non-EU country and for which an EU authorization request has been presented to the European Food Safety Authority (EFSA). This tolerance does not apply to food and seeds.

j) ADDITIONAL REGULATORY REQUIREMENTS
French legislation imposes transparency rules on the cultivation of GE crops. A GE farmer is required to notify farmers in the surrounding area of the intention to plant GE crops prior to sowing. The location where GE crops are grown must also be declared to the government and this information is entered into a national register, which is available online. This rule has been very controversial since the public register has been used by activists to commit illegal acts of sabotage of open-field trials. French lawmakers have established a penalty system whereby not declaring the location of GE crops is punishable by a 30,000 euro fine and six months of incarceration, while the destruction of authorized GE crops is punishable by a 75,000 euro fine and two years of incarceration. The destruction GE crop research purposes is punishable by a 150,000 euro fine and three years of incarceration. However, in practice, court decisions have varied widely, and actual penalties have not deterred activists from continuing acts of destruction of GE open-field trials.

k) INTELLECTUAL PROPERTY RIGHTS
France supports the plant certificate system 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.

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 "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 became a signatory in 2000 and ratified the CPB in 2003. Regulations implementing the CPB 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.

The French points of contact for the CPB are in the Ministry of Ecology and Sustainable Development (Biosafety Clearing House) and the Ministry of Foreign Affairs (Cartagena Protocol on Biosafety, Convention on Biological Diversity).
For more information, see the CBP website.

m) INTERNATIONAL TREATIES AND FORUMS
As a member state of the EU, the French position in international organizations is closely aligned with the EU.
France is a member of several international organizations that work with food and agriculture, 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 the Codex Alimentarius. In these fora, France takes a very active role in promoting its views on biotechnology.

In May 2018, the HCB released comments (see pages 17 to 25 in English) regarding the OECD's document on environmental risk assessment of GE plants. The HCB recommended that biodiversity and long-term effects of GE, including the possibility of horizontal gene transfer and the development of resistance in target organisms required more consideration.

PART C – MARKETING
a) PUBLIC/PRIVATE OPINIONS

Public awareness of agricultural biotechnology applications is limited. Since 2016, the French mainstream media has given a lot of coverage to actions of anti-biotech groups, while almost never explaining the scientific risks or how these innovations could benefit agriculture and food production. The gap between medical or "white" biotechnology and agricultural or "green" biotechnology is significant. Overall, the medical applications of DNA sequencing and genome editing receive much wider support and acceptance compared to agricultural applications. While risk and ethical questions are obviously relevant to both "white" and "green" biotechnology, few journalists seem willing to investigate the merits of green biotechnology with the same objectivity typically found in medical journalism.

When French microbiologist and biochemist Emmanuelle Charpentier and American biochemist Jennifer Doudna won the Nobel Prize for Chemistry in 2020 for their discovery of the CRISPR-Cas system, the French media celebrated their achievement. Yet, when CRISPR-Cas techniques are discussed in the context of agriculture and forestry, the French public shows little interest.
The French government differentiates between what it calls "first generation" and "second generation" GE plants. The "first generation" includes herbicide and insect resistant plants, which the government clearly opposes. The "second generation" consists of crops that could potentially bring direct consumer or environmental benefits, like for example enhanced nutritional value, reduced nitrogen use or

improved water efficiency. On "second generation" plants there is some openness to discussion, however, French authorities maintain stringent regulations.

Anti-biotech activists continue actions against research and imports. In France, different civil society organizations have fought against agricultural biotechnology ever since it was first introduced in the 1990s. Many of these groups are also opposed to economic growth and globalization. They see more risks than opportunities in technical progress, and so they actively campaign for the broadest application of the precautionary principle. Some may support scientific inquiry but reject the idea of business applications. Biotech opponents are deeply skeptical of new technologies and in general, believe that biotechnology is dangerous, is of little public benefit, and is only developed by large companies that seek to profit at the expense of the common good. Many groups are also deeply suspicious of independent experts that work for regulatory authorities. These groups often look for any linkages that might suggest a conflict of interest to discredit expertise and credibility. Ironically, they don't always apply the same standards of transparency to their own political lobbying and media campaigns. Some groups are suspected to have even broken the law in committing or condoning acts of violence to further their cause. Public opinion generally favors anti-biotech groups, seeing them as crusaders for the public good against the evils of large corporations. In the court of public opinion, anything but strong opposition to agricultural biotechnology can be a political liability. Politicians that are generally progressive on matters of technology prefer to maintain a neutral or non-committal position for fear of the political consequences.

Since 2013, anti-biotech activists have repeatedly destroyed imported products, including seeds and conventional crops. In 2019, a group of activists blocked a shipment of 50,000 tons of GE soy from Brazil arriving at the Port of Sète. Protestors against GE also made a direct reference to Brazilian soy cultivation and the deforestation in the Amazon. The latest incident involving the "voluntary reapers", took place in November 2021 when they destroyed bags of herbicide tolerant sunflower seeds. In April 2021, the European Commission published a study on new genomic techniques, concluding that the "GMO Directive" was not appropriate for New Breeding Techniques (NBTs). The European Commission study received mixed reviews by agricultural stakeholders and environmental groups. Many were not even aware of NBTs and attempted to brand them as the "New GMOs." French opponents to NBTs claim that the European Commission is not doing enough to respect the precautionary principle and is opening the doors to new risks for plants, animals, and humans. French Minister of Agriculture Julien Denormandie has been a vocal supporter of NBTs, while French Minister of Ecological Transition Barbara Pompili is in opposition.

b) MARKET ACCEPTANCE/STUDIES

Acceptance of GE crops in France varies within and across groups of consumers, retailers, the food industry, and farmers.

- **Consumers**: Consumer attitudes towards GE products are primarily negative in France. However, a Eurobarometer survey on food safety released in 2019 indicates 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 in recent years. The French media does not report on the fact that biotechnology could potentially help reduce the use of pesticides.

- **Retailers**: Because consumer perceptions are primarily negative, food retailers, especially major supermarkets, often promote their non-GE credentials. They fear that any visibility of GE products could attract unwelcome attention, generating negative publicity with their customer base. Some stores are going further in announcing that are taking steps to decrease the share of meat derived from animals fed with GE products.
- **Food Industry**: Since implementation of European regulations on mandatory biotech labeling, the French food industry has reformulated many 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.
- **Farmers**: The animal production sectors, and their feed supply chains (importers; animal feed compounders; poultry, swine, and cattle farmers) depend heavily on imported soybean products for animal feed. Market acceptance of GE products is rather high in these sectors. Feed grain producers in France also generally support the use of GE varieties, as they understand proven yield gains and lower production costs. French farmers cultivated Bt corn between 2005 and 2007, and most of them welcomed this technology. However, due to negative consumer perceptions, acceptance of biotech cultivation is much lower among producers in the fruit and vegetable sector, and other sectors that have a much more direct link to customers. Organic farmers across the political spectrum are generally very opposed to GE as they look for opportunities to strengthen the presence of organics in the market.

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 was active in exporting cloned horses, but this company has ceased operations.

d) IMPORTS
It is widely believed that France has imported semen and embryos from cloned animals or their offspring. The specific quantity of these imports is not available. In 2015, an expert report submitted to the European Commission admits that there is a "possibility" that food from clone offspring may be found on the plates of European consumers. This is due to imports of meat and milk from third countries, but also because of imports of live animals and genetic material used for animal reproduction. Pauline Constant, a spokesperson for BEUC (a European Consumer Organization) notes that "Europeans are undoubtedly unknowingly eating meat from the descendants of clones in the absence of traceability and labeling."

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 EU biotechnology regulatory framework. For more information, please refer to USDA EU-28 Agricultural Biotechnology Annual report.

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

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

ii. Political factors influencing regulatory decisions
In analysis conducted by ANSES, there are no food safety concerns regarding cloning. The French government is opposed to using biotechnology and cloning in animal breeding for food production. 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. This report recommends 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 in line with EU regulations on GE and cloned animals (see the EU-28 Agricultural Biotechnology Annual report).

b) APPROVALS
As no applications have been submitted, no biotech animals are approved for feed or food use in the EU because no such application has been submitted. Food from cloned animals 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 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 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 and legal framework would need to be clarified.

In June 2019, the Veterinary Academy of France unanimously voted on 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, otherwise it will lead to detrimental delay."
- EU legislation adapted to the case of genetically modified domestic animals should rapidly be introduced 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, 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;
- 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 considering an analysis of the degree of acceptability by society."

In February 2021, the Veterinary Academy of France wrote to the President of the European Commission Ursula von der Leyen to denounce the obsolete intent of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms with regard to the development of new Genome Editing technologies such as those involving the use of programmable endonucleases (CRISPR-cas9 for example). The Academy urged the European Commission to allow this regulation to evolve, taking into account animal production to facilitate basic on animal genomic editing. The concern was that European research is at risk, compromising capabilities to improve animal and public health. The Veterinary Academy is particularly convinced that CRISPR-Cas9 tools could contribute to addressing urgent global challenges.
In April 2021, Stella Kyriakides, EU Commissioner for Health and Food Safety noted that the Commission was carrying out a study on the status of new genomic techniques. The "Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16" states that "future policy action would also need to address the knowledge gaps and limitations identified in this study. Safety data are mainly available for genome editing in plants, making it difficult to draw relevant conclusions on other techniques and applications in

animals and micro-organisms. It would be prudent to generate relevant information in these areas too. In addition, the effects of business models and the patenting system on NGTs and their users should be investigated further. Finally, more effort should be made to inform and engage with the public on NGTs and assess their views."

d) LABELING AND TRACEABILITY
Laboratory animals developed through biotechnology are all labeled and traced and are not released into the environment. Some cloned sport horses are released into the environment.

The last and one of only very few reported incidents dates back to2014. A genetically modified ewe lamb, developed by the INRAE, the French agricultural research institute, was sent to a slaughterhouse. While the release of the animal (modified using a jellyfish protein) was considered a malicious act, the meat itself was deemed to not present any health risks.

e) INTELLECTUAL PROPERTY RIGHTS
French regulations are in line with the European Union.

f) INTERNATIONAL TREATIES AND FORUMS
As a member state of the EU, the French position in international organizations is closely aligned with the EU. France is a member of several international organizations that work with animal food and agriculture, 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), and Codex Alimentarius. In these fora, France takes a very active role in promoting its views on animal 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. However, there is a strong interest in animal genomics and marker assisted selection for animal breeding.

Animal cloning could gain wider acceptance in France, especially in the following two areas: the cloning of endangered species to safeguard future populations, and the cloning of family pets. The French pet animal market has grown 150 percent over the last 10 years, reaching a turnover of more than 5 billion euros in 2020. France has approximately 76.4 million pets, including 14 million cats and nearly 8 million dogs. However, for now, French legislation continues to prohibit animal cloning.

Animal rights activism first appeared in France in the 1980s. Since then, animal rights activists have become more assertive in their acts of sabotage and protest.
Actions often target research facilities, farms, and slaughterhouses and increasingly hunting facilities and animal parks. Since 2018, dozens of butcher shops have been damaged by vegan activists. Growing tension between the farming community and militant groups led to the October 2019 creation of "Demeter," a special division in the national police force (Gendarmerie Nationale). Demeter focuses on

illegal actions and violence against farms and farmers. In 2019, attacks against the agricultural community increased by 1.5 percent. [3]

One of France's leading animal rights groups is called L214. This group often places hidden cameras in slaughterhouses to later broadcast shocking images. The long-term objective of L214 is to abolish livestock farming. The funding and origins of L214 are unclear. Some have suggested an American connection because the group has received funding from a U.S. organization called "Open Philanthropy Project" which supports research of cultured meat (i.e., meat produced by in vitro cultivation of animal cells). On November 30, 2021, L214 was sentenced by the Court of Appeal of Rennes for property violation after the shooting of a video in a rabbit farm in France. While L214 has been ordered to remove the videos from its websites and social networks, the group has vowed to appeal this decision.

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 to entrap them with hidden cameras. DxE released a map with 5,000 "industrial" farm locations. The group encouraged journalists to report on the "decline" of industrial farming. Five percent of the French population now identifies with vegetarian or vegan lifestyles. While extreme activists are small in number, they exert a large influence on public opinion. Public opinion is heavily weighted against "industrial farming" and this continues to affect debate on animal biotechnology. Any research involving animals carries a real risk of becoming a target for activists. As a result, farmers and researchers are very constrained even if new technology could offer some societal benefits, including improved animal welfare. While biotechnology for human medicine is allowed to advance, biotechnology for animal medicine is significantly more constrained.

b) MARKET ACCEPTANCE/STUDIES

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

Attachments:

No Attachments

[3] Press briefing – Former Interior Minister Mr. Christophe Castaner – December 13th, 2019