

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Required Report - public distribution

Date: 10/4/2018

GAIN Report Number: FR1823

France

Agricultural Biotechnology Annual

2018

Approved By:

Kate Snipes

Prepared By:

FAS Paris

Report Highlights:

France has no commercial production or field trials of genetically engineered (GE) crops. Some fundamental research is being conducted in labs. The French livestock industry is dependent upon imported GE products to meet its feed needs. Public opinion is generally opposed to using biotechnology for agriculture and food production while most scientists and farmers are supportive of the technology. Some in the French administration and anti-biotech activists welcomed the July 2018 judgment of the European Court of Justice that organisms created through genome editing techniques are to be regulated as GE organisms. Scientists and the main farm organizations warn that it could harm research and agriculture in the EU. Animal biotechnology is primarily used in medical research.

Executive Summary:

France conducts some basic research and uses both genetic engineering and innovative biotechnologies in labs. 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 coming years.

France does not produce any agricultural goods derived from biotechnology for commercial purposes. However, the country imports GE feed, mainly soybeans and soybean meal from South America and rapeseed (canola) from Canada. French imports from the United States consist of soybeans and soybean meal. The French Government, the main farm organizations, and anti-biotech activists are all opposed to the European Commission's proposal that would allow member states to ban the use of EU-authorized GE products. This proposal is contrary to single market principles and incompatible with international obligations of the EU.

Agricultural biotechnology is a very controversial subject in France. Biotech opponents actively campaign against it and they have a strong influence on public opinion, which is generally opposed to using biotechnology for agriculture and food production. There is better acceptance among grain producers, animal feed compounders, the livestock industry, and scientists.

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 GE organisms in the EU. Some in the French administration and anti-biotech activists welcomed this decision whereas many scientists warned that it could put an end to a promising field of research in the EU. The main farm organizations said that it was a bad decision for farmers and consumers because it would limit the ability of French agriculture to reduce its environmental impact and to fight crop pests and diseases in the future. Public awareness of the ECJ's judgment is very limited.

As for animal biotechnology, it is mainly used for medical research purposes. The French administration is opposed to using biotechnology in animal breeding due to animal welfare concerns. Animal rights activists are becoming increasingly vocal in France. Debates among the general public and in the media are about whether or not it is morally acceptable to raise animals for food production and to eat meat; animal biotechnology for food production is out of the scope of the debate.

The French administration authorizes imports of GE products but restricts research and bans cultivation of GE crops. The current situation with imports but no cultivation and limited research is unlikely to change in the short term.

Acronyms used in this report are the following:

ANSES	Agency for Food, Environmental and Occupational Health and Safety
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
EFSA	European Food Safety Authority
EU	European Union
GE	Genetically Engineered
HCB	High Council for Biotechnology
MT	Metric Ton
NGOs	Non-Governmental Organizations

Glossary:

“Genetic Engineering” means transgenesis.

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

Note: The mention “in French” after a link means that this link returns a page that is only available in French.

Table of Contents:

CHAPTER 1 – PLANT BIOTECHNOLOGY	4
PART A – PRODUCTION AND TRADE	4
a) PRODUCT DEVELOPMENT	4
b) COMMERCIAL PRODUCTION	5
c) EXPORTS	6
d) IMPORTS	6
e) FOOD AID	10
f) TRADE BARRIERS	10
PART B - POLICY	11
a) REGULATORY FRAMEWORK	11
b) APPROVALS	13
c) STACKED EVENT APPROVALS	13
d) FIELD TESTING	13
e) INNOVATIVE BIOTECHNOLOGIES	14
f) COEXISTENCE	15
g) LABELING	16
h) MONITORING AND TESTING	17
i) LOW LEVEL PRESENCE POLICY	17
j) ADDITIONAL REGULATORY REQUIREMENTS	17
k) INTELLECTUAL PROPERTY RIGHTS (IPR)	17
l) CARTAGENA PROTOCOL RATIFICATION	18
m) INTERNATIONAL TREATIES AND FORUMS	18
PART C - MARKETING	19

a)	PUBLIC/PRIVATE OPINIONS	19
a)	MARKET ACCEPTANCE/STUDIES.....	20

CHAPTER 2 – ANIMAL BIOTECHNOLOGY21

PART D – PRODUCTION AND TRADE.....		21
a)	PRODUCT DEVELOPMENT	21
b)	COMMERCIAL PRODUCTION	21
c)	EXPORTS	21
d)	IMPORTS.....	22
e)	TRADE BARRIERS	22
PART E – POLICY		22
a)	REGULATORY FRAMEWORK	22
b)	APPROVALS.....	23
c)	INNOVATIVE BIOTECHNOLOGIES	23
d)	LABELING AND TRACEABILITY	24
e)	INTELLECTUAL PROPERTY RIGHTS.....	24
f)	INTERNATIONAL TREATIES AND FORUMS	24
PART F – MARKETING.....		24
a)	PUBLIC/PRIVATE OPINIONS	24
b)	MARKET ACCEPTANCE/STUDIES.....	25

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 coming 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 coming 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.
- 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.

- **Regulatory constraints hinder the development of innovative biotechnologies.**

France has one research project in agricultural biotechnology that involves innovative techniques, the Genius project, launched in 2012 for eight years. It is a public-private partnership that aims at demonstrating the feasibility of genome editing in various plant species (corn, wheat, rice, rapeseed, tomato, potato, apple tree, poplar tree, rose tree). Some of the traits concerned are resistance to pathogens, salinity tolerance, and increased biomass production. The budget of this project is 21.3 million euros. The project managers published an update on their website on July 31, 2018.¹ They 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.”

- **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 and both public labs and private seed companies. 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 and commercialize them outside Europe; their biotech research facilities are based outside of Europe. For instance, Calyxt, the U.S. subsidiary of a French company, developed a soybean variety with improved nutritional properties (it contains less of the fats that raise bad cholesterol) that is being tested on 17,000 acres of farmland in the United States at the moment. This product was the first of the 23 gene-edited varieties that the U.S. Department of Agriculture (USDA) has recognized as safe to use to date.

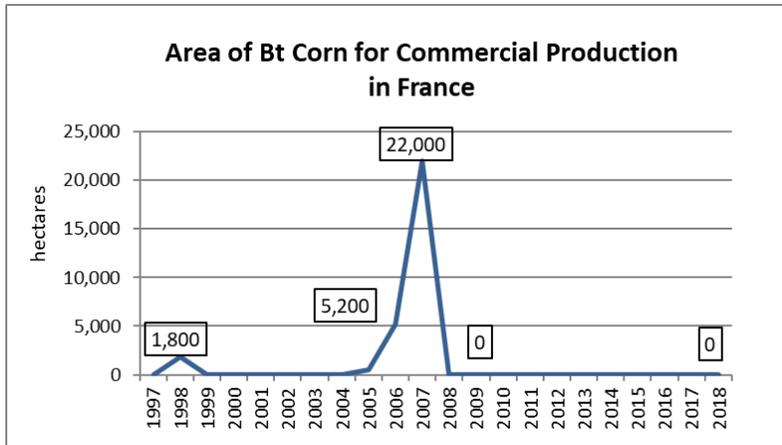
- **France conducts laboratory research for medical applications.**

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.

¹ Link to the [July 31 update \(in French\)](#)



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

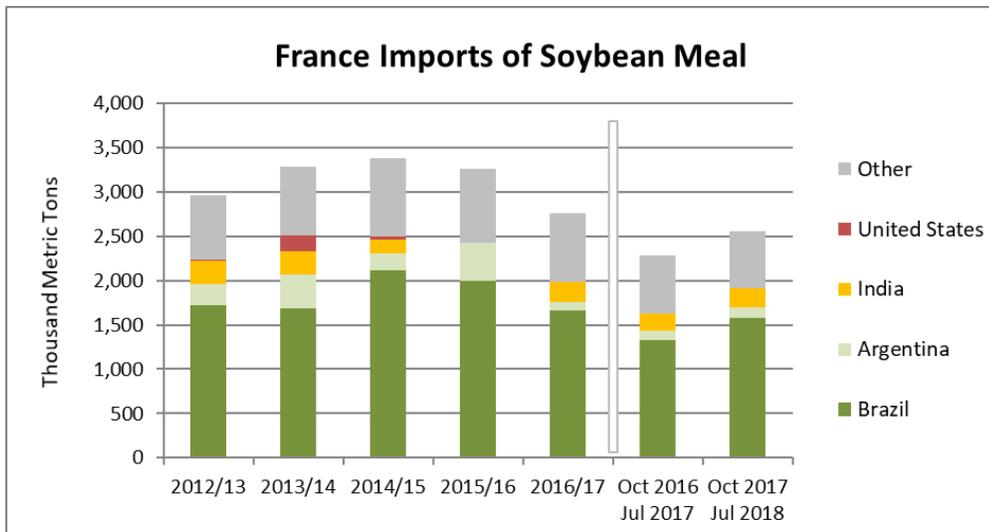
The bulk of France's imports of biotech products consist of soybeans and soybean meal from the Americas, used as animal feed ingredients. The share of GE products out of total imports is estimated at 80 percent. France also imports GE rapeseed from Canada and small quantities of GE corn and corn processing 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 in total production in France's main supplier countries.

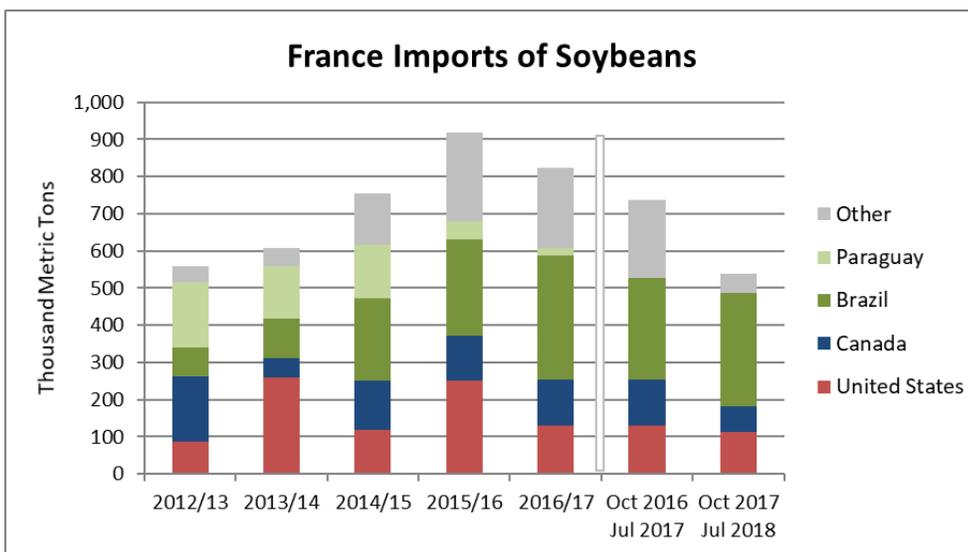
- **France imports around 4 million metric tons of soybean products per year, of which 80 percent are GE.**

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

- 3.1 million metric tons (MT) of soybean meal per year. The share of GE soybean meal out of France's total imports is estimated at 75 percent.
- 730 thousand MT of soybeans per year. The share of GE soybeans out of total imports is estimated at more than 90 percent.



Source: Global Trade Atlas



Source: Global Trade Atlas

France needs 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 taken into account only when prices of the different origins are close to one another.

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 and in the EU and imports from Brazil and India. There is a premium for non-biotech soybeans, which varies between 60 and 100 euros per MT, because available supplies are small and it is costly to avoid the mixing of GE and 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 2017/18 as a result of subsidies and incentives

from the Common Agricultural Policy (CAP) and some French regions.

The table below gives the share of GE soybeans in total soybean production in France’s main supplier countries.

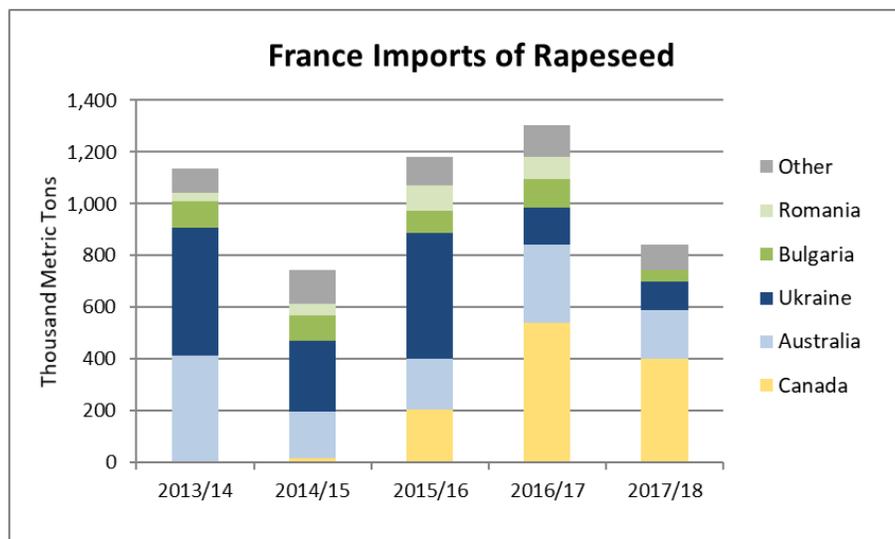
Share of GE Soybeans in Total Soybean Production

Argentina	100%
Brazil	97%
Canada	85%
Paraguay	96%
United States	94%

Source: [ISAAA](#) (2017)

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

In the last five years, France imported between 730,000 and 1,300,000 MT of rapeseed per year. In 2017/18, 46 percent of France’s imports came from Canada, where 95 percent of rapeseed is GE; and 22 percent came from Australia, where 24 percent of rapeseed is GE.²



Source: Global Trade Atlas

The table below gives the share of GE rapeseed in total rapeseed production in France’s main supplier countries.

Share of GE Rapeseed in Total Rapeseed Production

Australia	24%
Bulgaria	0%
Canada	95%
Romania	0%

² 2017/18 marketing year for rapeseed is July 2017 to June 2018

Ukraine	0%
---------	----

Source: FAS GAIN reports (2017)

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

In the last six years, France imported 300 to 600 thousand MT of corn per year. The tables below shows that:

- Less than three percent of these imports were from countries that produce GE corn except in MY 2012/13 and in MY 2013/14 (see “potentially GE” line in the table).
- Less than 3 percent of imports were from extra-EU countries that do not produce GE corn (“non-GE extra-EU” line)
- More than 95 percent of imports were from EU countries that do not produce GE corn (“non-GE EU-28” line)

Origin of France’s Imports of Corn

	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17
Potentially GE	1%	22%	20%	2%	3%	2%
Non-GE extra-EU	1%	1%	3%	2%	2%	2%
Non-GE EU-28	98%	77%	77%	95%	95%	96%
TOTAL	98%	77%	77%	95%	95%	96%

Source: Global Trade Atlas

Origin of France’s Imports of Potentially GE Corn in MTs

	2012/13	2013/14
Spain	9,000	9,000
United States	2,000	2,000
Ukraine	100,000	92,000

Source: Global Trade Atlas

The table below gives the share of GE corn in total corn production in France’s main supplier countries for GE corn.

Share of GE Corn in Total Corn Production

Spain	36%
Ukraine	estimated at 5%
United States	92%

Source: FAS GAIN reports (2017)

- **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.

Origin of France's Imports of DDGs³

	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17
Potentially GE (Spain)	11%	12%	11%	17%	17%	15%
Non-GE extra-EU	0%	3%	0%	0%	0%	0%
Non-GE EU-28	89%	85%	89%	83%	83%	84%
TOTAL	100%	100%	100%	100%	100%	100%

Source: Global Trade Atlas

In the last six years, France imported 100 to 250 thousand MT of Corn Gluten Feed and Meal (CGFM) per year.

Origin of France's Imports of CGFM⁴

	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17
Potentially GE (Spain)	9%	7%	4%	4%	6%	3%
Non-GE extra-EU	0%	0%	1%	0%	0%	0%
Non-GE EU-28	91%	92%	96%	95%	94%	97%
TOTAL	100%	100%	100%	100%	100%	100%

Source: Global Trade Atlas

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 aid⁵ and emergency aid⁶ 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).

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

³ DDGS are a corn by-product of distillation

⁴ CGFM is a corn by-product of wet-milling

⁵ Aide alimentaire programmée

⁶ Fonds humanitaire d'urgence

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 2014.⁷ 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.⁸

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.⁹ 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 2015.¹⁰

- ***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.¹¹

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.

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 USDA [EU-28 Agricultural Biotechnology Annual](#) report.

⁷ [LOI n° 2014-567 du 2 juin 2014 \(in French\)](#)

⁸ For more information, please see USDA [EU-28 Agricultural Biotechnology Annual](#) report.

⁹ The notifications are available on the [European Commission's website](#)

¹⁰ 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 »

¹¹ For more information, please see USDA [EU-28 Agricultural Biotechnology Annual](#) report.

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

Several ministries are involved in oversight of GE plants in France:¹²

- 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.¹³ Its composition and functions were modified in September 2014.¹⁴ 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.¹⁵ 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

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 (see [Part C. Marketing – a. Public / Private 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

¹² These ministries have a [joint website \(in French\)](#) to communicate on biotechnology policies and regulations.

¹³ Loi n° 2008-595 du 25 juin 2008

¹⁴ See [decree \(in French\)](#), September 2014

¹⁵ See ANSES [website](#) dedicated to agricultural biotech products (in English)

has some latitude to implement its own regulations as long as they comply with EU regulations. A large number of biotech 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 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. For more information, please refer to USDA [EU-28 Agricultural Biotechnology Annual](#) report.

b) APPROVALS

All of 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 EVENT APPROVALS

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.¹⁶ 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

¹⁶ Environmental Code [art. L533-3 \(in French\)](#)

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 issued its judgment that organisms created through genome editing techniques are to be regulated as “genetically modified organisms (GMOs)” in the EU.¹⁷ Reactions of French stakeholders are summarized below.

The **Ministers of Agriculture, Economy, Environment, and Research** released a joint statement in which they “welcome this long-awaited clarification” that will “enable courts and the competent authorities to have a harmonised framework at European level to protect consumers and the environment while respecting the precautionary principle.”

Many **scientists** warn that this decision could put an end to a promising field of research in the EU:

- The Association for Plant Biotechnologies (AFBV) call the decision "staggering," as it is up to "scientific groups to rule on scientific facts." ECJ states that plants produced through mutagenesis should be regulated like GE plants because the risks linked to mutagenesis might prove to be similar. AFBV underlines that it is a scientific statement and that it is not the role of ECJ to make scientific statements; AFBV adds that the ECJ did not take into account the fact that the risks linked to GE crops are not higher than those associated with plants developed through traditional breeding techniques. AFBV also anticipates that non-EU countries will use innovative biotechnologies in agriculture and that the EU will be unable to compete.
- The managers of France’s only agricultural research project on innovative biotechnologies (Genius) 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.”
- Several scientists released similar statements in the media.¹⁸

The anti-biotech activists that initiated this legal procedure in 2015 welcome the ECJ judgment as a victory.¹⁹ They 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. On August 3, 2018, they wrote an open letter to rapeseed producers, warning them that planting herbicide-tolerant crops could have “serious consequences” because they would soon be regulated as “GMOs.” In August, they destroyed several sunflower fields of the French seed company RAGT; some were dedicated to the production of seeds, others were part of an experiment that aims at producing disease-tolerant varieties (activists thought these varieties were herbicide-tolerant but they were not).

The main farm organizations²⁰ say that this decision is:

¹⁷ For more information, see GAIN report [EU Court Extends GMO Directive to New Plant Breeding Techniques](#)

¹⁸ Only available in French, see for example the article “[L’Europe a tort d’interdire l’agriculture CRISPR](#)” published in Les Echos newspaper on September 8, 2018

¹⁹ 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

²⁰ FNSEA, AGPB, AGPM, CGB, FOP

- bad for consumers because biotechnology is a useful tool to produce healthy food, use less pesticides and reduce the environmental impact of agriculture.
- bad for French agriculture because farmers need innovations to fight crop pests and diseases.

The seed industry²¹ released public statements emphasizing that if the ECJ judgment is implemented, there will be no public or private research on agricultural applications of genome editing in the EU. The EU will 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.

Media coverage of the ECJ decision remained limited and **public awareness** is 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.²²

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.²³ 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 French territory, to observe the health of plant life and watch for possible unforeseen consequences of agricultural practices, including the use of GE plants.²⁴ 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.²⁵ This body submits an annual report to both 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 will be liable when there is an accidental spread of GE plants causing economic harm to a non-GE crop cultivator.²⁶ If a non-GE crop cultivator ends up needing a GE label because the GE crop spread from a nearby field, the injured party can seek compensation for the resulting 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.

²¹ The French Seed Industry Association (UFS) and the Seed Inter-Branch Organization (GNIS)

²² 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

²³ Rural Code [art. L663-2 \(in French\)](#)

²⁴ Rural Code [art. L251-1 \(in French\)](#)

²⁵ [Comité de surveillance biologique du territoire \(in French\)](#)

²⁶ Rural Code [art. L663-4 \(in French\)](#)

g) LABELING

- **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. 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.²⁷

- **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.²⁸ It only applies to food produced in France, not to imported products. It states that:

- Plant products can be labelled 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 labelled 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 labelled as "sourced from animals fed without GE plants (0.1 or 0.9 percent)," for animals fed with GE feed under those limits.
- For apiculture products, biotech plants should be no closer than three kilometers to an 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.

²⁷ An explanation on biotech labeling regulation is available on the Fraud Control Office's [website \(in French\)](#).

²⁸ See the 2012 [decree \(in French\)](#)

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.²⁹

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 being grown must be declared to the government and this information is entered into a national register, available online.³⁰ 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.³¹ 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.³²

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

France supports the plant certificate system³³ under the International Union for the Protection of new Varieties of Plants ([UPOV](#)), rather than the patent system.

The bill on biodiversity adopted in 2016 limits the patentability of living organisms in France:

- [Article L611-19 \(in French\)](#) of the Code of Intellectual Property states that “products obtained

²⁹ For more information, see the interministerial [website \(in French\)](#) dedicated to biotech products regulation

³⁰ Rural Code [art. L663-1 \(in French\)](#)

³¹ Rural Code [art. L671-14](#) and [L671-15 \(in French\)](#)

³² Rural Code [art. L663-1 \(in French\)](#)

³³ In French: *Certificat d'Obtention Végétale (COV)*

exclusively through essentially biological processes, the elements that compose them and the genetic information they contain” are not patentable.

- [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.³⁴

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

In July 2017, the European Patent Office ([EPO](#)) amended the Implementing Regulations to the European Patent Convention, establishing that European patents shall not be granted for plants or animals exclusively obtained by means of “essentially biological processes.” The French seed industry welcomed this decision. “Essentially biological processes” means naturally occurring processes such as the crossing of whole genomes and the subsequent selection of plants or animals.

l) CARTAGENA PROTOCOL RATIFICATION

The 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).

For more information, see France’s [profile](#) on the CBP website.

m) INTERNATIONAL TREATIES AND FORUMS

As a member state of the EU, France’s position in international organizations is generally expressed as similar to that of the EU.

France is a member of several international organizations dealing with food and plants like most importantly the Organisation for Economic Cooperation and Development (OECD), the Food and Agriculture Organization of the United Nations (FAO), the European and Mediterranean Plant

³⁴ 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.”

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

- **Activists continue their actions against research and imports.**

In France, different types of civil society organizations have militated against agricultural biotechnology since it was first introduced in the 1990s. 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.

- Innovative biotechnologies (see [Part B - Policy, e\) Innovative Biotechnologies](#)).
- 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. Their political messages usually insist that there is a link between soy cultivation (most of which is GE) and deforestation in South America.
- **Some decision-makers are concerned with the precedence of politics over science.**

In 2017, the National Assembly (the lower house of the bicameral Parliament of France) voted on a “[Resolution on Science and Progress in the Republic \(in French\)](#).” The Assembly deplored that “scientific expertise is not enough taken into account in political decision-making” and ask the government to give more importance to the recommendations of scientific academies and the Parliamentary Office for the Evaluation of Scientific and Technological Choices. They advise decision-makers to look at the benefits and risks of both adopting a technology and rejecting it.

- **Public awareness of agricultural applications of innovative biotechnologies is low.**

There is low 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, the government welcomed the July 2018 ECJ ruling even if it is likely to put an end to research on second-generation biotech plants in the EU.

a) 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 strongly negative in France, with concerns about the potential risks of cultivating and consuming such products.

Retailers: Because of consumers' negative perceptions, 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.

Food Industry: Since the European regulation on mandatory biotech labeling has been implemented in France, the food industry has reformulated 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 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.

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. A French company, Cryozootech, clones sport horses. These animals are kept out of the food chain.

c) EXPORTS

Cryozootech has exported some horse clones.

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 [EU-28 Agricultural Biotechnology Annual](#) report.

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 animal welfare concerns and 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.³⁵ 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 that of the EU.

³⁵ See the [summary of the report \(in French\)](#) or the [full report \(in French\)](#)

France asked the European authorities to put in place a moratorium on clones and their products intended for food use and a system of traceability and labeling of the products derived from offspring of clones, in line with the positions of the French Advisory Committee on Food and of the European Parliament.

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:

- It is essential to explore techniques that can substitute for or complement existing vector control methods, which are not sufficient in metropolitan and overseas France.
- Only one technique has been developed to an operational level: Oxitec's RIDL technique.³⁶ 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.
- Employing the incompatible insect technique, the standard sterile insect technique or the release of insects carrying a dominant lethal gene on French territory 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.

³⁶ RIDL consists in repeated mass releases of sterilising GE males

- The legal framework needs to be clarified. Precise monitoring is needed, as well as strengthened assessments of the consequences of disseminating GE mosquitoes.

d) LABELING AND TRACEABILITY

Laboratory animals developed through biotechnology are all labeled and traced and are not released into the environment.³⁷

Cloned sport horses are released into the environment.

e) INTELLECTUAL PROPERTY RIGHTS

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

f) INTERNATIONAL TREATIES AND FORUMS

As a member state of the EU, France's position in international organizations is generally expressed as similar to that of the EU.

France is a member of several international organizations dealing with food and animals like most importantly the Organisation 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. 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. Another group regularly puts hidden cameras in slaughterhouses and broadcasts the most shocking images. Since the beginning of 2018, dozens of butcher shops have been damaged by vegans (broken windows, graffiti tags, false blood sprayed).

Activists are small in number but they have a strong influence on public opinion. Debates among the general public and in the media are about whether or not it is morally acceptable to raise animals for food production and to eat meat; animal biotechnology for food production is out of the scope of the debate.

³⁷ LOI n° 2008-595 du 25 juin 2008

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.