

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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Required Report - public distribution

Date: 10/19/2016

GAIN Report Number: FR1614

France

Agricultural Biotechnology Annual

2016

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Report Highlights:

Although public opinion in France is generally opposed to products derived from biotechnology, the livestock industry is dependent upon imported genetically engineered (GE) products to meet its feed needs. France has no commercial production or field trials of GE crops, but some laboratory research is being conducted in the country. The French administration has no official position yet on the way innovative biotechnologies should be regulated but they are active on this subject. The seed industry and the main farm organizations have developed a detailed position in favor of innovative biotechnologies, while anti-biotech groups have conducted a few actions against them. Public awareness is low. As for animal biotechnology, it is mainly used for medical research purposes.

Executive Summary

Despite difficulties in conducting their work, basic and applied research in plant and animal biotechnology by French research institutions continues, as well as involvement in a variety of international programs. No field trials of genetically engineered (GE) products are being carried out in France, due to the destruction of test plots by activists. Some institutions develop partnerships in order to conduct field experiments in other countries.

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 from Canada. French imports from the United States consist of soybean and soybean meal. Domestic non-GE soybean production remains marginal relative to imports but is expected to increase in the coming years.

France's agricultural biotechnology policies are part of the European Union's (EU) policy and regulatory framework. National legislation is more restrictive than EU legislation and includes a compulsory field register for GE crop fields and voluntary non-biotech labeling on food products. Regarding intellectual property, France supports the plant certificate system rather than the patent system. The government is opposed to using biotechnology in animal breeding, due to ethical and animal welfare concerns.

The French Government, the main farm union, 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 crops or products. This proposal is contrary to single market principles and incompatible with international obligations of the EU. Moreover, it would be very difficult and costly for the already stressed French livestock and poultry sectors to source sufficient non-GE feed ingredients to meet their needs.

Overall, agricultural biotechnology is a very sensitive and controversial subject in France. Anti-biotech groups actively campaign against it and they have a strong influence on public opinion, which is generally opposed to products derived from biotechnology. There is better acceptance among grain producers, animal feed compounders, and scientists.

The French administration has no official position yet on the way innovative biotechnologies should be regulated. The Ministry of Agriculture and the Ministry of Environment have conflicting views. Both are waiting for the answers of the European Court of Justice to the questions asked by the French Supreme Court in October 2016. The French biosafety authority (the High Council for Biotechnology) has released two reports on innovative biotechnologies and keeps working on this subject. The seed industry and the main farm organizations have developed a detailed position in favor of these technologies, while anti-biotech groups have conducted a few actions against them. Public awareness of the agricultural applications of innovative biotechnologies is low. France is conducting some research on this subject but constrained by the absence of field trials.

Acronyms used in this report are the following:

| | |
|--------|---|
| ANSES | Agency for Food, Environmental and Occupational Health and Safety |
| CIRAD | French Agricultural Research Centre for International Development |
| CNRS | National Center for Science Research |
| CRISPR | Clustered Regularly Interspaced Short Palindromic Repeats |
| EFSA | European Food Safety Authority |
| EU | European Union |
| GE | Genetically Engineered |
| HCB | High Council for Biotechnology |
| INRA | French National Institute for Agricultural Research |
| LLP | Low Level Presence |
| MT | Metric Ton |
| NGOs | Non-Governmental Organizations |
| ODM | Oligonucleotide-Directed Mutagenesis |
| SDN | Site-Directed Nuclease |
| TALEN | Transcription Activator-Like Effector Nuclease |
| ZFN | Zinc-Finger Nuclease |

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

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CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A – PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

- **Laboratory research for agricultural applications**

The actions of the **French National Institute for Agricultural Research (INRA)** are summarized in the report “Green Biotechnologies: Paving New Paths for Agriculture,” available [in English](#). It provides information on INRA’s partnerships and programs, and gives a brief history of biotechnology.

INRA coordinates France’s [Green Biotechnology](#) group (“green biotechnology” being defined as agricultural biotechnology), which brings together players from all over the agricultural sector, in order to launch research projects in plant genetics. More than 300 researchers are involved. This group contributes to the development of public-private partnerships.

INRA is involved in the national program called [Investments for the Future \(in French\)](#) with a total budget of 35 billion euros.¹ Within this framework, INRA pilots the following research projects, which involve both public and private organizations:

- [Amaizing](#): identifying markers and candidate genes of corn responsible for traits of agronomic interest such as yield, quality and tolerance to abiotic stress
- [AKER](#): creating new varieties of sugar beets to increase yields
- [Biomass for the Future](#): developing new varieties of miscanthus and sorghum to produce lignocellulosic biomass for biofuels and chemicals
- [Breedwheat](#): identifying markers and candidate genes for yield and quality traits of wheat under abiotic and biotic stress; developing new breeding methods
- [Peamust](#): developing new varieties of peas to stabilize the yields and the quality of seeds
- [Pro-bio3](#): developing innovative bioprocesses to produce lipids from renewable raw materials
- [Rapsodyn](#): improving the oil yield of rapeseed and reducing nitrogen inputs
- [Sunrise](#): optimizing the oil yield stability of sunflower under water constraints

Moreover, INRA participates in [the Wheat Initiative](#), an international consortium that gathers public institutions and private companies to coordinate global research on wheat.²

The **French Crop Research Institute** (Arvalis - Institut du Végétal), funded by farmers, is involved in research on GE grains. For more details on these projects, see the presentation of its [biotech laboratory \(in French\)](#).

The **French Agricultural Research Centre for International Development** ([CIRAD](#)) uses a

¹ *Investissements d’Avenir*

² for more information, see the Wheat Initiative’s [vision document](#)

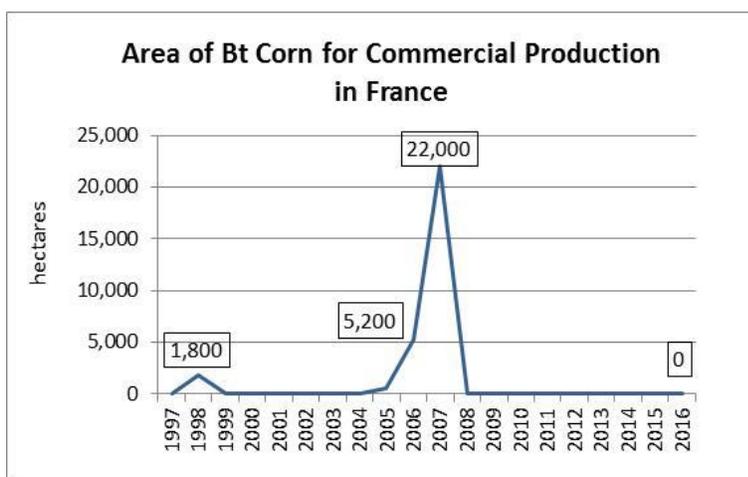
number of tools including molecular biology and biotechnology in its research. For example, CIRAD is involved in the Rice Functional Genomics Platform ([REFUGE](#)) and the research unit on genetic improvement and adaptation of Mediterranean and tropical plants ([AGAP](#)).

Several **French private companies** in the seed sector conduct laboratory research on plant biotechnology. The GE seeds they develop are intended for non-European markets.

- **Laboratory research for medical applications**

GE plants and plant cells are used to develop proteins of pharmaceutical interest in-lab. Proteins whose structure is simple, such as insulin and growth hormone, can be produced by GE microorganisms and some of them are commercialized. GE plants and plant cells are used to develop more complex molecules for research purposes (vaccines, antibodies, enzymes).

b) COMMERCIAL PRODUCTION



France does not produce any GE crops for commercial purposes. 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.

The technical results obtained by corn growers in 2006, with significantly higher yields and lower mycotoxin content than conventional corn, explain the rapid expansion of the planted area between 2005 and 2007.

c) EXPORTS

France does not export any GE products.

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 more than 80 percent. French non-GE soybean production is expected to increase in the coming years but it remains marginal relative to imports. France also imports GE

rapeseed.

Trade data do not differentiate between conventional and GE varieties. The graphs presented in this section therefore include both categories. The table below gives the share of GE crops in total soy and rapeseed production in France's main supplier countries.

Share of GE Crops in Total Production in 2015

| Soy | |
|---------------|------|
| Argentina | 99 % |
| Brazil | 93 % |
| Canada | 62 % |
| Paraguay | 96 % |
| United States | 94 % |
| Rapeseed | |
| Canada | 95 % |
| Australia | 17 % |

Source: USDA FAS GAIN reports

- **France imports around 4 million metric tons of soybean products per year.³**

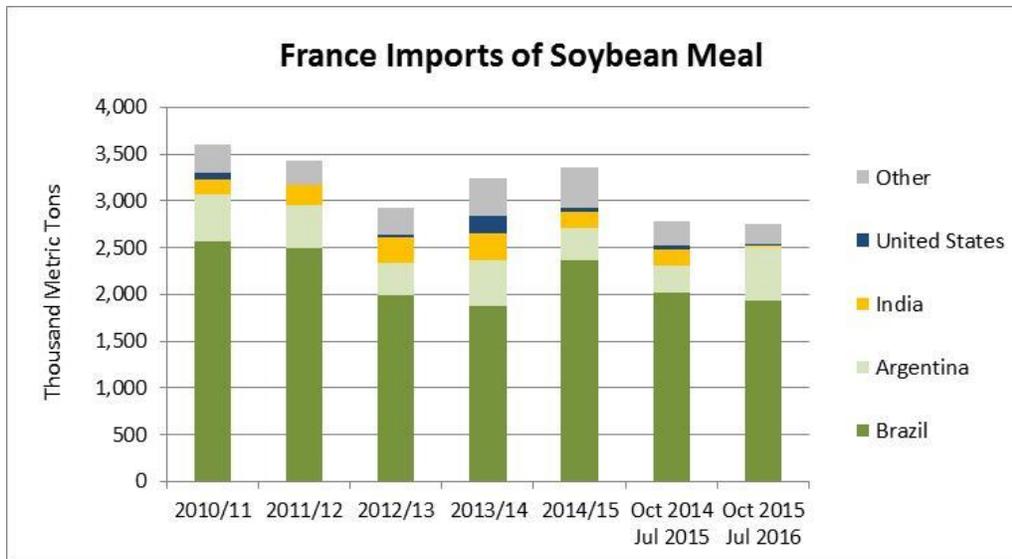
France is a major importer of soybean products to feed animals in its livestock and poultry sectors. Domestic production of soybeans and substitutes is limited, and there is a strong demand for protein to meet basic requirements of compound feed formulations. The decision of French importers on where to source soybean products from year to year is primarily based on price.

In the last five years, France imported 3.5 million metric tons (MT) of soybean meal per year on average. The chart below gives the evolution of French imports between 2010/11 and the first ten months of 2015/16. Brazil remains the leading supplier with a 70 percent market share in 2014/15.

Soybean meal imported in France includes on average:

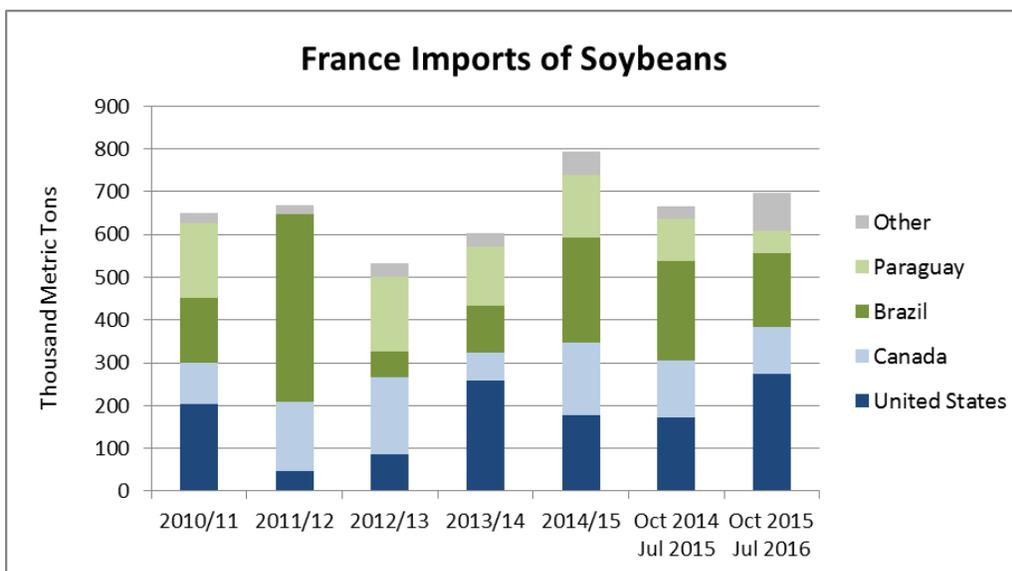
- 75 percent of standard product, not tested, and labeled as GE;
- 5 percent of Hard Identity Preserved product, traced back from the field to guarantee that it is not GE;
- the 20 percent remaining products include three categories:
 - product labeled as GE and that contain less than 0.9 percent of GE soy (when PCR-tested);
 - product not labeled as GE and that contain less than 0.9 percent of GE soy (when PCR-tested);
 - Soft Identity Preserved product, traced back from the crushing plant.

³ 2014/15 marketing year for soybeans: October 2014 to September 2015



Source: Global Trade Atlas

In the last five years, France imported on average 650,000 metric tons (MT) of soybean per year (see graph below). The U.S., Brazil, Canada, and Paraguay are France's leading suppliers.



Source: Global Trade Atlas

Soybean meal is the main oilseed meal for feed in France. Soybean meal and rapeseed meal accounted for 45 and 35 percent of total meal consumption, respectively, in 2014/15. The consumption of sunflower meal has increased in recent years due to its improved digestibility and supply availabilities from the Black Sea area (Ukraine and Russia). In MY 2014/15, it accounted for 20 percent of vegetable meals consumed in animal feed.

The demand for non-biotech soybean meal is estimated at 20 percent of the total market in France. It is mainly supplied by domestically-grown soybeans and imports of soybean products from Brazil and India. It has become increasingly difficult to source non-biotech soybeans

during the last ten years, because available supplies are small and it is costly to avoid the mixing of GE and non-GE products during transportation and storage. As a consequence, there is a premium for non-biotech soybeans, which varies between 60 and 100 euros per MT.

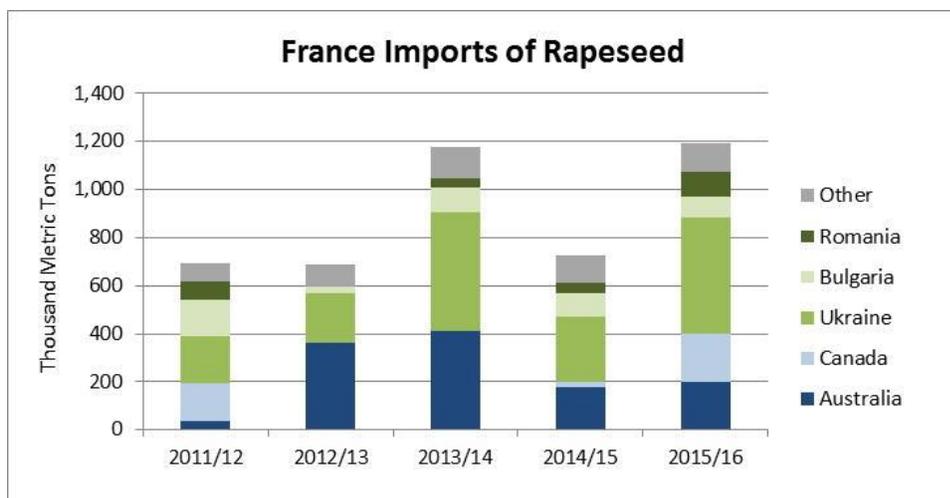
- **France is trying to reduce its dependence on imported proteins.**

French soybean production remains marginal relative to imports but it is expected to increase in the coming years, from 112,000 MT in 2013/14 to more than 350,000 MT in 2016/17 according to USDA’s outlook. Domestic production is 100 percent non-GE as no GE soybean is allowed for cultivation in the EU. Several reasons explain the rise in the planted area:

- The 2014-2020 Common Agricultural Policy (CAP) gives incentives to produce soybeans and protein crops. Under the CAP, France has chosen to give farmers coupled supports for soybeans from 2014 (100 euros per hectare for 12.5 hectares per farm at the most in 2015). Moreover, in France, soy areas can be considered as Ecological Focus Areas (EFAs) under the CAP, and farmers that have a certain amount of EFAs receive higher direct payments.
- Several French regions subsidize local production of soy and protein crops.
- Production costs are usually higher for corn, because it needs more inputs than soy. Moreover, there is a premium for non-GE soy that varies between 60 and 100 euros per MT.

- **France imports GE rapeseed from Canada.⁴**

In the last five years, France imported between 680,000 and 1,200,000 MT of rapeseed per year. In 2015/16, 17 percent of France’s imports came from Canada, where 95 percent of rapeseed is GE; and 16 percent came from Australia, where 17 percent of rapeseed is GE.



Source: Global Trade Atlas

⁴ 2015/16 marketing year for rapeseed: July 2015 to June 2016

e) FOOD AID

France is not a food aid recipient country.

France provides food aid in the form of food, money, equipment, seeds, or veterinary services. The country provides both planned aid (*Aide alimentaire programmée*) and emergency aid (*Fonds humanitaire d'urgence*) 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).

This aid does not include GE products.

In 2013, the total budget of French food aid was 35 million euros. It was delivered to Africa (Burkina Faso, Central African Republic, Chad, Congo, Ethiopia, Kenya, Madagascar, Mali, Mauritania, Niger, Somalia, South Sudan, Sudan), the Middle East (Afghanistan, Iran, Iraq, Jordan, Lebanon, Palestine, Syria, Turkey, Yemen), Haiti, Myanmar and North Korea. A map that provides the budget by country is available on the website of the [French Ministry of Foreign Affairs \(in French\)](#).

f) TRADE BARRIERS

• Cultivation Ban

Cultivation of GE corn has been banned in France since 2008. Three decrees were successively released by the Government and cancelled by the Supreme Court between 2007 and 2014; then [a law \(in French\)](#) was passed in June 2014.

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

Under Article 26c of the Directive – transitional measures – France demanded in September 2015 that the French territory be excluded from the geographical scope of the authorizations of cultivation for eight GE corn varieties.⁵ The companies that developed these varieties did not oppose this decision within the legal delay of 30 days and the geographical scopes of the authorizations were adjusted accordingly.

⁵ The notifications are available on the [European Commission's website](#)

The transcription of Directive (EU) 2015/412 into French Law was then released in December 2015.⁶

- **Imports Ban**

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

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 very uncomfortable position of facing great pressure to ban the use of GE products from anti-biotech groups. Such a ban would be devastating 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 GE products or not.

The main farm union in France (FNSEA) openly opposes the proposal, saying that “the European Union is a common market so we need common rules.” Anti-biotech activists criticize the proposal too, 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.

- **Reformulation**

Since the European regulation on biotech traceability and labeling for food and feed has been implemented in France, the French food industry and supermarket chains have reformulated to exclude potential GE ingredients, such as corn starch, soy lecithin, and soy oil.

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.

⁶ Only available in French - [Loi n° 2015-1567 du 2 décembre 2015](#) portant diverses dispositions d'adaptation au droit de l'Union européenne dans le domaine de la prévention des risques, Titre IV

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

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

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

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

ii. Role and membership of the biosafety authority

The High Council for Biotechnology ([HCB](#)) was established by the Biotech Bill of 2008. Its composition and functions were modified in September 2014.⁷

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.

It 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 the European Food Safety Authority (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.⁸ 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 – b. 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 1990's, France has

⁷ See [decree \(in French\)](#), September 2014

⁸ See ANSES [website](#) dedicated to agricultural biotech products (in English)

authorized biotech imports (due to the need for protein-rich ingredients in animal feeds), but restricted research and banned cultivation of biotech crops.

The process for approval of biotech products is carried out at the EU level, but the French Government has some latitude to implement its own regulations 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 corn 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

• **Food, feed, processing**

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](#).

In 2016, the European Commission adopted 14 new authorizations for GE crops for food or feed use:

- On September 16, 2016, the European Commission authorized [eleven corn varieties](#),⁹ [all of which are stacks from previously approved singles](#).
- On July 22, 2016, the European Commission authorized three soybean varieties.¹⁰

• **Cultivation**

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](#).

⁹ GE corn Bt11 x MIR162 x MIR604 x GA21; four related GE corn varieties combining three different single GE events (Bt11 x MIR162 x MIR604, Bt11 x MIR162 x GA21, Bt11 x MIR604 x GA21, MIR162 x MIR604 x GA21); six related GE corn varieties combining two different single GE events (Bt11 x MIR162, Bt11 x MIR604, Bt11 x GA21, MIR162 x MIR604, MIR162 x GA21 and MIR604 x GA21)

¹⁰ MON87705xMON89788, MON87708xMON89788, and Bayer FG72

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 government, usually through the Ministry of Environment.¹¹ The government must consider the opinion of the HCB regarding possible risks for public health and the environment before granting an authorization. The government 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.

- **Open-field testing**

No open-field testing is currently conducted in the country due to repeated destruction of test plots by activists. France used to have the highest number of open-field test plots for GE plants in Europe, but continued destruction of these plots by activists has discouraged both public and private organizations from conducting research in open fields. Some of the labs that develop biotech plants in France conduct field tests in other countries.

The last experimental plot in France was a GE Poplar tree being tested by INRA. Their multi-year permit for open-field testing was not renewed by the Ministry of Agriculture and all the trees were destroyed in 2013. The Ministry of Agriculture was supposed to make its decision based on the advice of the HCB. However, the HCB struggled in giving a clear opinion on the renewal of the permit, since its two committees disagreed:

- The **science committee**, made up of 40 scientists, concluded that there was “no risk for human or animal health or the environment,” and proposed to continue the experiment.
- The **socio-economic and ethical committee**, which gathers jurists, farmers, representatives of the seed industry, consumer associations, and environmental NGOs, opined that the objectives of the research were too vague and that it raised “many socio-economic and ethical questions.” This committee consequently proposed to put an end to the test.

Despite the destruction of its last remaining open-field test plot, INRA expressed its wish to continue research on GE crops.¹²

¹¹ Environmental Code [art. L533-3 \(in French\)](#)

¹² More information available in French on [INRA website](#)

e) INNOVATIVE BIOTECHNOLOGIES

The HCB has released two reports on innovative biotechnologies and keeps working on this subject. The French administration has no official position yet on the way these technologies should be regulated; they are waiting for the answer of the European Court of Justice. The seed industry and the main farm organizations have developed a detailed position in favor of innovative biotechnologies, while anti-biotech groups have conducted several actions against these technologies. Public awareness of the agricultural applications of innovative biotechnologies is low; medical applications are much more publicized to the general public. France is active in research but constrained by the absence of field trials.

- **The High Council for Biotechnology (HCB) is working on innovative biotechnologies.**

In January 2016, the HCB released its first two reports on innovative biotechnologies:

- A [scientific report \(see pages 95 to 107 in English\)](#) that gives a description of each technique and of its possible applications; explains what is at stake regarding the regulation of innovative biotechnologies; analyses the questions raised, technique by technique (for instance the ability to detect the genetic modification or the possible agronomic applications of innovative biotechnologies); and answers the question “Should the resulting organisms be regulated as ‘GMOs’ under Directive 2001/18/EC?,” technique by technique (see the table below).
- An [economic, ethical and social report \(see pages 106 to 117 in English\)](#) that presents the different and sometimes opposite points of view of farm unions, the seed industry, retailers, and NGOs. This report also provides two legal analyses that reach opposite conclusions. It concludes that the way to regulate the organisms produced through innovative biotechnologies “will be dictated essentially by policy considerations, in accordance with a set of criteria that are yet to be determined. The European Commission has pointed out, however, that without a legal amendment to the texts, which is clearly a policy matter, only the European Court of Justice has the power to issue a ruling.”

HCB Scientific Report on Innovative Biotechnologies, January 2016 - Should the organisms produced through innovative biotechnologies be regulated as “GMOs?”

| Technique | Should the resulting organisms be regulated as “GMOs” under Directive 2001/18/EC? | Why? |
|-----------------------|--|--|
| SDN-1 SDN-2 ODM | No | These techniques generate modifications and products identical to those obtained by conventional mutagenesis. They should be |

| | | |
|--|---|---|
| | | classified the same way as mutagenesis (Annex 1B of Directive 2001/18/EC). |
| SDN-3 | Yes if the sequence introduced is exogenous to the plant, otherwise no | If the sequence introduced is not exogenous, the modification is similar to naturally occurring duplication. |
| Grafting: (a) non-GE graft on GM rootstock, or (b) non-GE graft on a rootstock produced through innovative biotechnologies | Differentiated assessment for graft and rootstock | Fruit and seed of non-GE plants derived from GE rootstock do not require specific environmental or health assessment; the rootstock should be regulated on the basis of the technique used to produce it. |
| RNA-directed DNA methylation (RdDM) | No if they contain no transgenes | Epigenetic changes are observed in nature. RdDM is intended to guide such changes, but the mechanism is not different from those found in nature. If they contain no transgenes, plants with epigenetic modifications should not be subject to systematic assessment. |
| Agro-infiltration | No | Agro-infiltration in the narrow sense used by the European Commission does not include transformation of germ tissue and is not intended to produce GE offspring. The agrobacteria used are genetically modified micro-organisms and are therefore regulated as such. |
| Cisgenesis and intragenesis | No if modifications could be obtained by conventional breeding, otherwise yes | Specific molecular analysis is required. If the modification could be obtained by conventional breeding, the resulting organism should not be regulated as a GE organism. |
| Null segregants | No | After molecular confirmation that the modification has been removed, the resulting plant should be exempt from risk assessment and could be considered to be a plant obtained by conventional breeding. |

The position of the seed industry and of the main farm unions is available in French in the economic, ethical and social report. They state that:

- Innovative biotechnologies could address a number of issues in the agricultural sector, i.e., using less fertilizer, pesticides, and water; increasing the stability of production and adapting to a changing climate; increasing production to meet rising demand; improving food quality, addressing food safety and food preservation; diversifying crops; and answering specific needs (producing drugs, biomass, cosmetics, fibers).
- Innovative biotechnologies complement and follow on from previous breeding techniques.
- Innovative biotechnologies will lead to innovations only if regulatory costs are acceptable, considering the size of target markets.
- Regulations should be based on science.

- The organisms developed using innovative biotechnologies should not be considered as GE under Directive 2001/18/EC if: (a) they could have been developed through crosses; (b) they could have been developed through mutagenesis; or (c) no exogenous heritable material is inserted in their progeny.

On April 20, 2016, the Minister of Agriculture and the Minister of Environment sent an official request to the HCB. They asked the HCB to work on the techniques that do not produce “GMOs” according to the definition set out in Directive 2001/18/EC (see table above). For these techniques, the HCB is asked to release an opinion on the following subjects:

- detection and traceability of the plants and products;
- coexistence between biotech and non-biotech plants and products;
- direct risks to health and the environment linked to novel characteristics of the final products and measures that could be implemented to manage possible risks;
- impact of the development of innovative biotechnologies on the ability of the private sector to innovate;
- innovative biotechnologies and intellectual property;
- an analysis of the legal interpretation of the European Commission as soon as it is available;
- recommendations about the way innovative biotechnologies should be regulated; the proposals should be between those of the European catalogue (no risk evaluation, no labeling) and those of Directive 2001/18/EC (risk evaluation and labeling). Socio-economic issues should be taken into account.

The HCB is working on these subjects at the moment. Its opinion is expected to be released at the beginning of 2017 at the earliest.

- **The French administration has no official position yet; the French Supreme Court has questioned the European Court of Justice.**

On October 3, 2016, the French Supreme Court (Conseil d’Etat) referred four interlocutory questions about innovative biotechnologies and mutagenesis to the European Court of Justice. In these questions, the term “mutagenesis” includes chemical and radiation mutagenesis, which have been practiced for decades, as well as innovative biotechnologies, such as oligonucleotide-directed mutagenesis and site-directed nucleases.¹³

- Are the organisms produced through mutagenesis “GMOs” under Directive 2001/18/EC? Which of these organisms are regulated as “GMOs” under Directive 2001/18/EC?
- Are the organisms produced through mutagenesis “GMOs” under Directive 2002/53/CE?
- If organisms produced through mutagenesis are not regulated as “GMOs” under Directive 2001/18/EC, does it mean that the member states are not allowed to set their own regulations for these organisms?

¹³ The [decision \(in French\)](#) is available on the website of the Conseil d’Etat.

- Is the exclusion of mutagenesis from Directive 2001/18/EC consistent with the precautionary principle?

It takes on average between one year and a half and two years for the Court of Justice to answer member states' questions. Depending on the answers, the European Commission may have to amend Directive 2001/18/EC.

The French administration has no official position yet on the way innovative biotechnologies should be regulated. The Ministry of Agriculture and the Ministry of Environment have conflicting views on biotechnology. Both of them are waiting for the conclusion of the European Court of Justice. However, it is worth noting that there is a shift in French policy makers' minds from technique-based regulation to trait-based regulation; and that anti-biotech groups focus attention on herbicide-resistant plants.

The decision to ask the European Court of Justice's opinion is due to the fact that nine anti-biotech groups submitted a complaint with the Conseil d'Etat in March 2015.¹⁴ These groups contest the fact that under an article of the French Environment Code, plants produced through traditional mutagenesis are not considered as GE.¹⁵ This article is a transposition of Directive 2001/18/EC. These groups also ask for a moratorium on cultivation and sales of herbicide-resistant plants produced through mutagenesis (herbicide-tolerant rapeseed and sunflower produced through mutagenesis are grown in France). Before submitting a complaint with the Conseil d'Etat, these groups had asked the Prime Minister to change the law so that plants produced through mutagenesis are considered as GE. He had not answered.

- **The French Parliament is working on medical and agronomical applications of innovative biotechnologies.**

The French Parliamentary Office for the Evaluation of Scientific and Technological Choices is working on innovative biotechnologies, with a focus on CRISPR-Cas9.¹⁶ This office is common to the National Assembly and the Senate, and is in charge of keeping the French Parliament informed on scientific issues by assessing the consequences of emerging scientific progress, monitoring the implementation of new technologies, and reviewing topical and controversial subjects.

They have conducted hearings¹⁷ and two parliamentarians have traveled to a number of countries, including the United States, to assess the potential medical and agronomical applications of the technologies as well as their economic, environmental, and ethical impact and the way they could possibly be regulated. Their report is expected to be released by the end of 2016.

¹⁴ 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

¹⁵ French Environment Code, [Article D531-2 \(in French\)](#)

¹⁶ Office parlementaire d'évaluation des choix scientifiques et technologiques (OPECST)

¹⁷ The filmed hearings are available [here](#), in French. The [program](#) of the hearing is also available, in French.

- **The Academy of Agriculture and the Academy of Technologies have released a position paper on genome editing.**

The position of the Academies of Agriculture and Technologies on genome editing (meganucleases, ODM, ZFN, TALEN, CRISPR) is that “the administration should support the development of experiments, including field trials, and use the results of these experiments to build a legislative framework that includes monitoring and allows the technical advances that these techniques provide to be used. (...) These techniques can be excluded from the scope of Directive 2001/18/EC, in accordance with Annex I B.”¹⁸

- **Anti-biotech groups have conducted several actions against innovative biotechnologies.**

Small groups of people conduct actions that aim at turning public opinion against innovative biotechnologies and influencing policy-makers.

They call the plants produced through innovative biotechnologies “new GMOs” or “hidden GMOs” and want all of them, as well as the plants produced through classical mutagenesis, to be regulated as GE plants under Directive 2001/18/EC. As a result of their actions, the terms “new GMOs” and “hidden GMOs” have become widely used by the media.

They have conducted several actions since the beginning of 2016. In April 2016, seven anti-biotech organizations that are represented at the socio-economic council of the HCB organized a protest before the General Assembly of the HCB, which was cancelled, and then they resigned from the HCB. These resignations were widely covered by the media. In May, a few dozen people of the minority farm-union *Confédération paysanne* protested on a site owned by the main French seed company.

- **France is active in research on innovative biotechnologies but constrained by the absence of field trials.**

Public institutions are conducting some research and seed companies know that it is vital for them to master these techniques. However, both face regulatory uncertainty and deplore the absence of field trials.

The [Genius project](#) is a public-private partnership that aims at demonstrating the feasibility of genome editing (meganucleases, TALENs, CRISPR-Cas9) in various plant species (corn, wheat, rice, rapeseed tomato, potato, apple tree, poplar tree, rose tree). The traits concerned are resistance to pathogens, salinity tolerance, and increased biomass production.

Moreover, in October 2015, the French Minister of Agriculture presented an “Innovation Plan for 2025,” which includes a research project aiming at mastering innovative biotechnologies.¹⁹ This project would be launched in 2018 and last until 2021. It would bring together public

¹⁸ Their position paper is available on the [website of the Academy of Agriculture \(in French\)](#).

¹⁹ See the [Innovation Plan for 2025](#) in French

research institutes and private companies. The plants developed would have better resistance to diseases, water or nitrogen efficiency, or tolerance to climate change. The expected output is:

- A strong knowledge of innovative biotechnologies, especially gene editing and meiotic recombination, when applied to the main crops. This would include phenotypic analysis in the fields.
- Strategies to improve the efficiency of innovative biotechnologies;
- Cost benefit analyses of innovative biotechnologies and of the plants produced through innovative biotechnologies;
- A knowledge of the expected performance of the plants produced through innovative biotechnologies when cultivated in the fields.

The project includes field trials. If it is launched, it remains to be seen how the risk of destruction of field trials by anti-biotech groups will be managed.

f) COEXISTENCE

French legislation requires that GE plants only be grown, sold, or used “in a manner that respects the environment and public health, agricultural structures, local ecosystems, production and commercial channels labeled as ‘without GE plants,’ and with full transparency.”²⁰ It also guarantees the “freedom to consume and produce with or without GE plants.” In order to promote these goals, 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 are subject to certain technical rules established by the Minister of Agriculture, after consultation with the HCB and the Minister of the Environment.²¹ Rules governing distances between GE crops and other fields are highlighted as being important to avoid the accidental presence of GE plants in other crops. Violations of these technical rules on separation distances can be punished by a fine of 75,000 euros and two years of incarceration.²²

In addition to the rules discussed above, French 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.²³ 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.²⁴ 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 automatically liable when the accidental spread of his plants causes economic harm to a non-GE crops cultivator.²⁵ If a non-GE crop cultivator ends up having to label his or her crops as GE, because of spread from a nearby field, he can seek compensation for the resulting depreciation of his crop’s value. It is

²⁰ Environmental Code [art. L531-2-1 \(in French\)](#)

²¹ Rural Code [art. L663-2 \(in French\)](#)

²² Rural Code [art. L671-15 \(in French\)](#)

²³ Rural Code [art. L251-1 \(in French\)](#)

²⁴ [Comité de surveillance biologique du territoire \(in French\)](#)

²⁵ Rural Code [art. L663-4 \(in French\)](#)

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.

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. The coexistence research programs in place in France, conducted by Arvalis-Institut du Végétal and the French Corn Growers Association (AGPM), included the following:

- The POECB (Programme opérationnel d'évaluation des cultures issues des biotechnologies, 2002-2004) studied the feasibility of coexistence in real field conditions (from seed to storage facilities), assessing risks based on the results of pollen dispersion studies;
- The PACB (Programme d'accompagnement des cultures issues des biotechnologies, 2005-2006) developed and implemented a guide for GE corn cultivation, focusing on risk management;
- A 2007 study surveyed fields commercially planted to GE corn to test the efficiency of strengthened coexistence rules.

Several French research institutes (including INRA and Arvalis-Institut du Végétal) have been involved in European coexistence research programs:

- [SIGMEA](#) (2004-2007) built a decision-making tool that helps minimize the risk of gene flow;
- [COEXTRA](#) (2005-2009) defined good harvesting and processing practices aimed at managing the coexistence of GE and non-GE sectors affordably.

In March 2015, the research project called “Practical Implementation of Coexistence in Europe” (PRICE), of which INRA is a partner, released its conclusions. The main results are the following:

- The current measures implemented to ensure coexistence of GE and non-GE crops in the EU are practically feasible, both at farm level and along the supply chain. However, they come with additional costs, which are partly paid by consumers and other supply chain stakeholders.
- During two years, field trials with GE corn were conducted in Spain, applying buffer zones or different sowing dates resulting in asynchrony in flowering. Researchers concluded that the current isolation distances set up by most member states were disproportionate and may lead to unnecessary costs and burden.
- Another team developed a decision-making tool that evaluates the effect of specific buffer zones or of a difference in flowering time on the probability of cross-pollination for corn. It thus makes it feasible to implement proportional coexistence measures.

g) LABELING

- **European Mandatory Labeling of GE Products**

Labeling in France complies with EU regulations (EC) [No 1829/2003](#) and (EC) [No 1830/2003](#). These regulations require food and feed produced from or containing GE products to be labeled as such. They apply to products originating in the EU and imported from third

countries. Bulk shipments and raw materials must be labeled, as well as packaged food and feed.

The products exempt from labeling obligations are:

- Animal products originating from animals fed with GE feed (meat, dairy products, eggs);
- Products that contain traces of authorized GE ingredients in a proportion no higher than 0.9 percent, provided that this presence is adventitious or technically unavoidable;
- Products that are not legally defined as ingredients according to Article 6.4 of Directive [2000/13/EC](#), such as processing aids (like food enzymes produced from GE microorganisms).

The French Fraud Control Office of the Ministry of Economy, Finance and Industry (DGCCRF) enforces compliance with the regulation. An explanation on biotech labeling regulation is available on the Fraud Control Office's [website \(in French\)](#).

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

A biotech-free labeling system has been in place at the national level since 2012 (see [explanations \(in French\)](#), by the Ministry of Environment). The system is based on the 2012 [decree \(in French\)](#) relative to voluntary GE-free labeling and on HCB's 2009 recommendation on the definition of GE-free labeling.

The 2012 decree only applies to food produced in France (it does not apply to imports). It states that:

- Plant products can be labelled as “GE Free” if they contain less than 0.1 percent GE plants. However, some companies could try to differentiate their products by putting “GE Free” labels on products that cannot be GE. Therefore, 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: 1) under 0.1 percent is labeled as “fed without GE plants (0.1 percent),” and 2) under 0.9 percent 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 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**

Several voluntary initiatives put in place by the food industry and supermarket chains use GE-free labeling. However, these represent a minor share of the total French food market. For instance:

- Canned sweet corn has been sold with a specific “GE-free” logo since 2004.
- Several supermarket chains put a “fed without GMO” logo on animal products sold under their brands.
- Several labels of origin among the poultry, beef, pork, and cheese industry have committed themselves to use biotech-free feed.
- Some salmon products are sold with a “GE Free” logo.

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 in order to detect any potential non-intentional effects.²⁶

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.²⁷ 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 euros fine and two years of incarceration.²⁸ The destruction or degradation of GE crops that were planted for research purposes is punished by a 150,000 euros 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.

²⁶ For more information, see the interministerial [website \(in French\)](#) dedicated to biotech products regulation

²⁷ Rural Code [art. L663-1 \(in French\)](#)

²⁸ Rural Code [art. L671-14 and L671-15 \(in French\)](#)

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.²⁹

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

France supports the plant certificate system³⁰ under the International Union for the Protection of new Varieties of Plants ([UPOV](#)), rather than the patent system.

On March 25, 2015, the Enlarged Board of Appeal of the European Patent Office ruled that plants or seeds obtained through conventional breeding methods were patentable.³¹ The French seed industry deplors this decision. They advocate that patents should only be allowed for biotechnological inventions. They state that “this decision allows patenting of native genes. Varieties that possess this characteristic will not be freely accessible. Genetic progress will be hindered.” They underline that this decision contradicts the breeder’s exemption, which allows free use of a protected variety for further breeding under the plant certificate system.

On July 20, 2016, the Parliament adopted a bill on biodiversity that limits the patentability of living organisms in France:

- [Article L611-19 \(in French\)](#) of the Code of Intellectual Property now states that “products obtained 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 now 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.³²

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

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 and Sustainable Development;

²⁹ Rural Code [art. L663-1 \(in French\)](#)

³⁰ In French: *Certificat d’Obtention Végétale (COV)*

³¹ European Patent Office’s [decision](#)

³² 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.”

- the Ministry of Economy, Finance and Industry;
- the National Agency for Health Safety of Food, Environment, and Work (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/FORA

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 Protection Organization (EPPO), and Codex Alimentarius. France takes an active role in these fora regarding biotechnology.

n) RELATED ISSUES

COP21 United Nations Conference on Climate Change was held in Paris in December 2015. In February 2015, France hosted an International Forum on Agriculture and Climate Change. During the closing speech, the President of France stated that progress in genetics was one of the four levers that could enable agriculture to face climate change: "It is about producing more with a reduced carbon footprint and developing new products adapted to new climate conditions, namely plants that resist to drought, animals that emit less greenhouse gases, it is also about using less water. (...) It is about using all the inventions related to biological pest control, information technology, biotechnology and agricultural equipment (...), inventing new plant breeding techniques."

PART C - MARKETING

a) PUBLIC/PRIVATE OPINIONS

- **Anti-Biotech activists focus on traits rather than on techniques.**

Anti-biotech groups have a long history of opposing the cultivation, importation, and consumption of GE crops and products in France. Their actions include the systematic destruction of test plots, the destruction of imported soybean products (in July 2016, they destroyed around 2,000 tons of GE soybean meal imported from Argentina that was stocked in a port), and regular communication campaigns. Many of these actions have led to arrests and criminal charges against them. Courts decisions have varied widely, with results ranging from acquittals to prison sentences.

Although biotech opponents are usually considered small in number, their communication skills are top-notch and amplified by the media. They strongly influence 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 used to destroy crops produced through transgenesis. Now that the area planted in GE crops has fallen to zero, they focus on herbicide-resistant plants produced through classical mutagenesis. They want them to be legally considered as GE and they ask for a moratorium on all herbicide-resistant crops, whatever the technique used to produce them. Herbicide-resistant rapeseed and sunflower produced through mutagenesis are currently being cultivated in France. In April 2015, activists destroyed a test plot of rapeseed. In August 2016, they destroyed three hectares of sunflower. Since the beginning of 2016, they have also conducted several actions against innovative biotechnologies (see Part B - Policy, e) Innovative Biotechnologies).

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

There is low awareness about possible agricultural applications of innovative biotechnologies (also called “new plant breeding techniques”) among the general public. In 2016, the mainstream media covered some actions of anti-biotech groups but did not explain the possible applications of innovative biotechnologies for agriculture and food production. Medical applications of genome editing and the ethical questions they raise are much more publicized than agricultural applications. 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.

In February 2015, during the closing speech of a Forum on Agriculture and Climate Change held in Paris, the President of France expressed his position as follows: “Consumers in France and in Europe are opposed to the cultivation of first generation GE plants. They see threats to health and to the environment without sufficient benefits to counterbalance the risks. That is why France and the European Union have adopted a clear and firm position, including in the negotiation of the Transatlantic Trade and Investment Partnership. It is a societal choice and a matter of food sovereignty. However, researchers in Europe and in France should be able to do their work and to advance science. Public research has to be free in Europe within the limits established by law and it should not fear intimidation, pressure and threats. We need research to feed the world, fight climate change, and produce better.” Both public and private researchers deplore the absence of field trials and the threats they face from anti-biotech activists.

a) MARKET ACCEPTANCE/STUDIES

Acceptance of GE crops in France must be looked at from the differing points of view of producers, retailers, and consumers.

Feed grain producers in France, especially corn producers, generally support the use of GE varieties, due to the proven yield gains and lower production costs. French farmers were allowed to cultivate Bt corn between 2005 and 2007, and most of them welcomed the technology. However, due to negative consumer perceptions, acceptance is lower among producers in other sectors where the products are consumed directly, such as vegetables and fruit.

Market acceptance of GE products is high in the animal production sectors and in their feed supply chains, including animal feed compounders, as well as poultry, swine and cattle farmers who depend on imported soybean products to make balanced animal feeds.

In France, consumer attitudes towards GE products are strongly negative, with concerns about the potential risks of cultivating and consuming them. In 2012, 79 percent of French people said they were “worried” about the presence of GE products in food, and 71 percent of them thought that they represented “a significant risk in terms of food safety.”³³ Most of them believe that continued research is needed on this subject.³⁴

As a consequence of consumers’ negative perceptions, food retailers, especially major supermarkets, market themselves as carrying only non-GE products. They also fear actions by activist organizations, such as protests and destruction of products in stores, which would generate negative publicity.

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 white produced by hens. Proteins can also be produced by animal cells in-lab.
- to improve animal breeding.

³³ Source: [IFOP \(in French\)](#)

³⁴ Source: [CSA \(in French\)](#)

b) COMMERCIAL PRODUCTION

No GE animals for food use are commercialized in France. A French company, [Cryozootech](#), clones sport horses, in collaboration with Italian industry.

c) EXPORTS

Cryozootech has exported some horse clones.

d) TRADE BARRIERS

Public and governmental opposition is a barrier to 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

At EU level, EFSA is in charge of risk assessment, while the European Commission's Directorate General for Health and Consumers (DG SANCO) is in charge of governance and risk management.³⁵

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 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.

Since October 2015, the HCB has been working on an evaluation of the risks and benefits of GE mosquitoes from scientific, technical, sanitary, environmental and socio-economic perspectives. GE mosquitoes could be used to prevent the transmission of human diseases.

³⁵ See EFSA's website on [GE animals](#) and on [animal cloning](#)

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 ethical and animal welfare concerns.

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

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

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 position of the European Parliament.

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.³⁶ This report recommended a ban on the marketing of food products derived from cloned animals or their offspring, cloning practices for breeding, and importing cloned animals and their offspring.

b) INNOVATIVE BIOTECHNOLOGIES

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

c) LABELING AND TRACEABILITY

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

Cloned sport horses are released into the environment.

d) INTELLECTUAL PROPERTY RIGHTS

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

e) INTERNATIONAL TREATIES/FORA

France hosts the Organization for Economic Cooperation and Development (OECD) and the World Organization for Animal Health (OIE). OECD and the Codex Alimentarius Commission (CAC) develop guidelines on biotech animals. For example, the CAC developed a "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals." OIE has guidelines on the use of cloned animals (no specific guidelines on GE animals).

³⁶ See the [summary of the report, in English](#) or the [full report, in French](#)

f) RELATED ISSUES

In 2014, meat from a GE lamb was put on the market. The lamb contained a gene for green fluorescent protein (GFP, from jelly fish), which poses no food safety risk. It was part of a medical research program at a public research center. It was sold to a slaughterhouse along with other non-GE animals, reportedly due to a conflict between two employees. The research center has taken the matter to court. This event was widely covered by the media under the title “a jellyfish lamb in the food chain” in the days that followed the press release.

PART F – MARKETING

a) PUBLIC/PRIVATE OPINIONS

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

b) MARKET ACCEPTANCE/STUDIES

Although GE animals and clones are not in commercial channels, the market acceptance is low among producers and consumers. The acceptance of clones offspring is low too.

There is low awareness of research on GE insects such as mosquitoes and GE olive flies among the general public.