

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: 6/15/2012 GAIN Report Number: FR9096

France

Agricultural Biotechnology Annual

Annual

Approved By: Lashonda McLeod Prepared By: Marie-Cecile Henard

Report Highlights:

This report describes the trade, production, research, policy, and marketing issues of genetically engineered plant and animal products in France. Hostility remains towards biotechnology among policy makers, the public opinion, and non-governmental organizations. Farming groups and scientists are increasingly vocal about the need to adopt the technology to make French agriculture both more productive and sustainable. Reported stagnation of crop yields, combined with massive use of crop protection chemicals, high costs of production, and reduced exports, all converge to a more sustainable intensification of agriculture. Biotechnology is part of the answer to meeting both domestic demand and export needs in an ever-growing world population.

Section I. Executive Summary

As a leading agricultural producer and exporter in the European Union (EU), France remains highly influential in agricultural policy both within the EU and globally, including francophone countries, and major trading partners. The seminars sponsored by FAS/Paris have conveyed to French policy makers, industry stakeholders and education and research institutions that biotechnology can help address global food security while increasing agricultural sustainability.

French agriculture is competitive and intensive, compared to the EU average, and would logically adopt biotechnology in the same line. Many experts, however, point that agriculture's competitiveness is in jeopardy as long as biotechnology is not adopted. For example, wheat yields are reportedly stagnating and corn yields marginally increasing. While France is increasingly sensitive to sustainability, and is taking a series of measures to make its agriculture systems more sustainable, plant biotechnology is not a tool considered by the government to address this issue.

France adopted biotech products whenever they presented economic advantage- Bt corn cultivation boomed in the years it was allowed. Millions of metric tons (MT) of soybean products are imported from the Americas every year and dozens of MT of Dried Distillers Grains (DDGs) were imported from the United States last year. In each case, the adoption of biotech products was countered by regulatory constraints, not economic factors: The 2008 national ban on MON810 stopped Bt corn cultivation. The animal feed industry stopped importing DDGs from the United States in 2012, due to the potential presence of a biotech event not approved in the European Union. France's imports of U.S. soybeans have significantly declined in the first quarter of 2012, as a result of the implementation of the EU's Renewable Energy Directive restricting soybean oil used to process biodiesel.

Despite regulatory hostility and pressure by environmentalists, France's research in plant biotechnology remains active. The National Research Institute in Agriculture (INRA) plays a key role in EU research projects. INRA uses a number of New Plant Breeding Techniques that belong to plant biotechnology but differ from transgenesis. In addition, the farmers-funded applied research institute, Arvalis, coordinates several programs involving biotechnology. France is the leading producer of plantings seeds in the EU, with a strong, diverse and active seed industry which continues to invest in the technology.

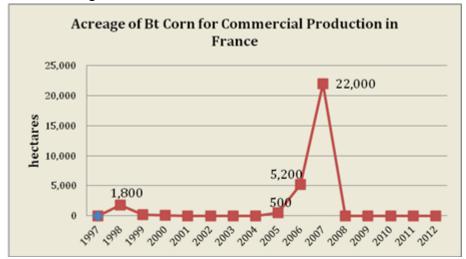
GE animals are used in public research, mainly for veterinary applications. No biotech animal is commercialized.

Sectio	on II. Plant Biotechnology Trade and Production	3
a)	Commercial Production of Biotechnology Crops	4
b)	Biotechnology Crops Under Development	
c)	Imports	6
d)	Food Aid	10
e)	Production of Biotechnology Crop Developed outside of the United States	10
Sectio	on III. Plant Biotechnology Policy	10
a)	Regulatory Framework	
b)	Biotechnology Crops Approved for Commercial Use	12
c)	Field Testing of biotechnology Crops	13
d)	Regulatory Treatment of multi-trait "stacked" events	13
e)	Additional Product Registration Prior to Use	13
f)	Coexistence Policy	13
g)	Labeling for Packaged Food or Feed	
h)	United Nations Cartagena Protocol on Biosafety under the UN Convention on Biolo	gical
Div	versity	16
i)	Position in Other International Treaties, Conventions or International For a	16
j)	Trade Barriers Negatively Impacting U.S. Exports	167
k)	Legislation in Place Addressing Intellectual Property Rights Issues in Case of Com	mercially
Pla	nted Biotechnology Crops	
1)	Agenda on Biotechnology Issues: France Specific Legislation/Registration Requirements	
Sectio	on IV. Plant Biotechnology Marketing Issues	
a)	Market Acceptance	
b)	Country-Specific Studies on the Marketing of Biotechnology Products	
Sectio	on V. Plant Biotechnology Capacity Building and Outreach	
a)	U.S. Government, USDA funded and Private Sector Capacity Building / Outreach A	Activities
	19	
	France-Specific Needs or Strategies	
Sectio	on VI. Animal Biotechnology	21
I.	Development and Use	
a)	Use of Animal Biotechnology	
	b) Commercial Production	
II.	Regulation	
III.	1	
IV.	$\partial \partial $	
V.	Outreach, Needs and Strategies	
Sectio	on VII. Annex - Related Reports	234

Section II. Plant Biotechnology Trade and Production

a) Commercial Production of Biotechnology Crops

There are only two transgenic plants approved for cultivation in the European Union: MON810 Bt corn and the Amflora potato, and neither commercially grown in France. There has been no commercial production of GE crops since 2008. There were 1,800 hectares (ha) of biotech corn planted in 1998, then none during the European *de facto* moratorium in 1999-2004. Cultivation was reinitiated and in fact, booming, from 2004 to 2007.



Bt corn, self-protected against major pests (the European corn borer and sesamia) had significant economic and agronomic benefits for farmers, as these pests are estimated to infect at least 500,000 ha of corn. Most corn growers resent not being allowed to use this crop anymore.

b) Biotechnology Crops Under Development

Once the country with the highest number of open field test plots for biotech crops in Europe until the early 1990's, there has been none in France since 2010. The last field trials conducted by INRA on fanleaf resistant vine, were destroyed. Since then, both public and private research organizations have stopped conducting research in open fields, due to repetitive destructions by activists. Many stakeholders regretted the absence of dissuasive action by national authorities against the authors of the vandalism.

Note: For detailed information on destructions, see GAIN reports <u>FR3052</u> dated September 2003, <u>FR4041</u> dated August 2004, <u>FR5041</u> dated August 2005, <u>FR5045</u> dated June 2005, <u>FR5088</u> dated December 2005, <u>FR6040</u> dated July 2006, <u>FR9025</u>, dated September 2009, and <u>FR9046</u>, dated August 2010.

Despite the vocal pressure of anti-biotech activists against transgenic plant development, France remains a country where major stakeholders are involved in plant biotechnology research programs.

These include INRA, agricultural research entities with research and extension services, in addition to private companies.

• INRA:

There is no herbicide-tolerant (HT) biotech crop currently approved in the European Union for cultivation. In November 2011, the conclusions of a joint INRA/National Center for Scientific Research (CNRS) survey (Herbicide Tolerant Plant Varieties: Agronomic, Environmental, and Socio-Economic Impact) were released. According to this survey, there are several non-transgenic (obtained by selection of spontaneous variability or by mutagenesis) HT crops cultivated in France. There was approximately 10 percent of the sunflower acreage planted to HT crops, i.e., 80,000 ha in 2011. The survey expressed concern about the risk of weed resistance when HT crop are cultivated on large acreage, and recommended HT crop production in "limited in time and space," which "respects best agronomic practices, integrates mechanical methods of weed management and maintains diversified rotations."

On May 31, 2012, the genome of tomato was announced to be fully sequenced by an international consortium of 300 researchers and 14 countries (<u>http://solgenomics.net/</u>). INRA coordinated France's contribution, and researchers sequenced tomato's chromosome 7 (<u>http://www.inra.fr/presse/sequencage_genome_tomate</u>).

The public/private partnership research program created ten years ago under the name "Genoplante" and now called "<u>Green Biotechnology</u>" is principally involved in crop genomics. INRA belongs to its major stakeholders.

INRA is strongly involved in the national program for research and higher education called "Invest for the Future" ("Investissements d'Avenir"), and with a total budget of 35 billion euros. The programs lead by INRA include the following: <u>BREEDWHEAT</u> (selecting corn varieties with high yields and reduced needs in water supply and chemical inputs), <u>AMAIZING</u> (selecting high yield, high quality, and stress-tolerant wheat varieties, for a more sustainable production), <u>Rapsodyn</u> (optimizing rapeseed yields with reduced nitrogen input), <u>Sunrise</u> (increasing the oil content of sunflowerseed varieties in conditions of water shortage), <u>PeaMust</u> (optimizing pea yields and quality), <u>Aker</u> (increasing the sugar content of sugarbeet), <u>Genius</u> (developing plant breeding new technologies for varieties more resistant, less polluting, and more adapted to consumer needs), <u>BFF</u> (developing miscanthus and sorghum plants for advanced biofuels), and <u>Probio3</u> (developing aircraft biofuels).

INRA conducts research programs involving several of the New Plant Breeding Techniques (NPBTs) listed by the European Union Joint Research Center (JRC)'s Institute for Prospective Technological Studies, <u>http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=4959</u> and including other types of biotechnology techniques than transgenesis. These include cisgenesis, used on apple trees to fight against fire blight, as well as agro-infiltration, and reverse breeding.

• Agricultural Research Entity:

The Crop Research Institute (Arvalis-Institut du Vegetal), funded by farmers, also conducts research in plant biotechnology (mainly in grain crops phenotyping, DNA chips detecting fusarium and septorium diseases, drought tolerant varieties, and nitrogen use). The objectives of Arvalis research include supplying makers and phenotyping technology to contribute to plant breeding; identifying wheat, barley and durum varieties; identifying mechanisms of nitrogen utilization by plants; and characterizing varieties with the interaction of genes (mapping) with the environment (more specifically, water, and temperature).

• Private and Cooperative Seed Industry:

There is a historical tradition of plant breeding in France, the leading producer of planting seeds in the EU, with annual sales of 2.7 billion euros, and the second world largest exporter, with exports at one billion euros. France has a positive trade balance for seeds. It amounted to 600 million euros in 2010/11 <u>http://www.gnis.fr/index/action/page/id/25</u>.

The leading French seed producer, <u>Limagrain</u>, is internationally based and is investing through partnerships in biotech research and development. Limagrain's subsidiary Vilmorin, which is the second largest producer of fruits and vegetable seeds in the world, has established a partnership with the University of California Davis and conducts work on plant genome sequencing, uses marker assisted selection, and performs plant breeding. Limagrain uses biotechnology for selecting wheat varieties in the United States and in Australia, where a partnership with the Commonwealth Scientific and Industrial Research Organization (CSIRO) was recently established.

c) Imports

Most of France's imports of biotech products consist of animal feed ingredients, mainly including soybean meal, soybeans, and dried distillers grains (DDGs).

Soybean Products

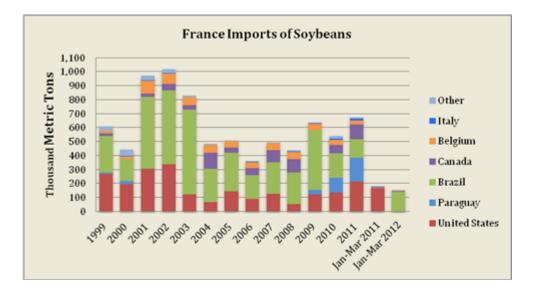
France is and will remain a major importer of soybean products to feed its livestock, dairy and poultry herds. The major drivers in favor of soybean products imports and use in animal feed in are the following: high demand of the livestock, dairy, and poultry industries; grains and meal basic formulation of compound feed; ban of meat and bone meals in animal feed in place since the bovine spongiform encephalopathy (BSE) crisis in 1996; and limited domestic production of soybean products and substitutes.

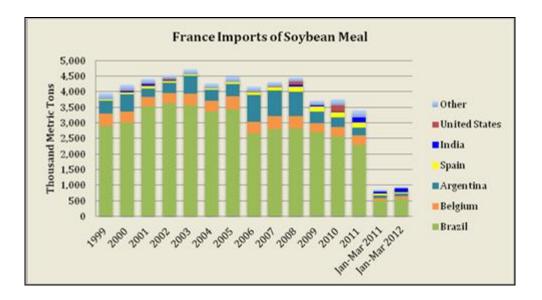
Domestically-sourced rapeseed meal has increasingly, but still partially, replaced soybean meal in animal feed. Overall, soybean meal and rapeseed meal accounted for 55 and 33 percent of total meal consumption in MY 2010/11, respectively.

Soybean meal currently dominates the protein market for feed in France, with 4 million MT consumed annually. The large majority of it is imported (3.5 to 4 million MT annually), mainly from Brazil (70 percent), and 80 to 90 percent consists of biotech products, and is labeled as such. France's imports of soybeans are relatively low (500,000 to 800,000 MT per year), and the leading supplier is the United States, with a 30 percent market share.

Domestically grown soybeans are marginal relative to imported products, with 100,000 MT produced per year. Domestic production is non-biotech and more than half is for the food market.

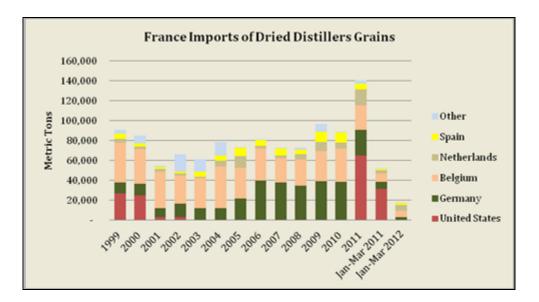
France's crushing industry changed from imported soybeans ten years ago to domestically grown rapeseed and sunflower seed. Imports of U.S. soybeans were null during the first quarter of 2012. This can be explained by the implementation of the European Renewable Energy Directive, which imposes certain sustainability criteria on raw materials (such as soybean oil) used to process biofuels.





• Dried Distillers Grains (DDGs):

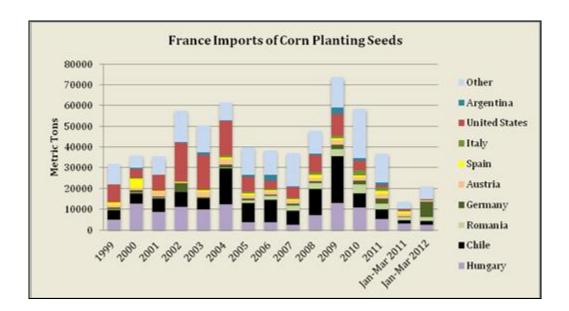
The decline from DDG imports from the United States is attributed to the asynchronous approval of the MIR162 biotech event between the EU and the United States. It seems that increasing quantities of domestically produced DDGs and grains have been incorporated by feed compounders since the beginning of 2012 to replace U.S. DDGs in animal feed rations.



• Planting Seeds:

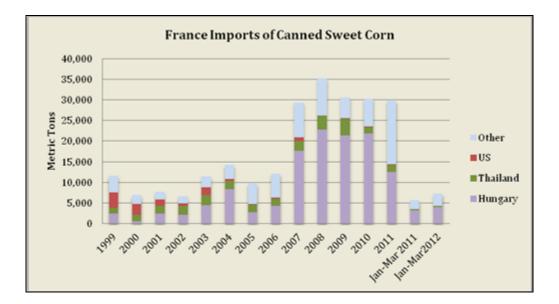
Although a net exporter to total destinations, France has a trade deficit in planting seeds with the United States. In 2010/11, France exported USD19.5 million to the United States but imported USD 42.4 million. More specifically, the United States is a leading supplier of corn seeds and oilseeds for

planting for France. France banned the cultivation of MON810 Bt corn in 2008 and no biotech seeds have been multiplied since then.



• <u>Sweet Corn:</u>

France was an importer of U.S. canned sweet corn until biotech corn was commercialized in the United States. Since compulsory biotech labeling on food was implemented in the European Union, sales dramatically shrank and haven't recovered. Although France is a major producer and exporter of canned sweet corn in the European Union and exports have significantly increased in the past decade, imports have also expanded.



d) Food Aid

France is not a recipient of food aid, but does provide food aid to various countries, including mainly Western francophone African countries, where its political line is influential.

e) Production of Biotechnology Crop Developed outside of the United States None.

Section III. Plant Biotechnology Policy

a) Regulatory Framework

As a Member State of the European Union, the biotechnology regulatory framework implemented in France is that of the EU. The European Directive 2001/18 provides the framework for the deliberate release into the environment of biotech events, the Regulation (EC) 1829/2003 covers the authorization for placing biotech events on the market for food and feed. (For more information, please see the 2011 <u>EU annual biotechnology report FR9074</u>).

i. Responsible Government Ministries

There are several ministries involved in plant biotechnology in France. The Ministry of Environment has the lead, followed by the Ministries of Agriculture, Economy (Fraud Control Office), Research, and Health. These ministries have a joint website that communicates on biotechnology-related issues to the public: <u>http://ogm.gouv.fr/</u>.

ii. Role and Membership of Biosafety Committee

• High Council on Biotechnology

The High Council on Biotechnology (HCB), established by the Biotech Bill of 2008, has a unique composition of a science and socio-economic and ethics committees. Both committees review biotech issues, and provide their own conclusions and recommendations to France's government, which makes decisions based on the <u>HCB's recommendations</u>.

The difficulty for these committees to reconcile their conclusions and recommendations reached its paroxysm in February 2012 (see <u>FR9093</u>), when several members (representing the leading farmers unions, the food industry, and the seeds inter-branch organization) resigned. Moreover, the media related that the Government did not seek the HCB's recommendation before reinitiating the safeguard

clause on MON810 on March 18, 2012. This ban had been lifted only a few months earlier (in November 2011) by the Highest Administrative Court "Conseil d'Etat" based on the conclusions of the European Court of Justice.

A new government was formed after the Presidential elections in May 2012, and it is likely to review the functioning of the HCB.

• National Agency for Health Safety of Food, Environment, and Work (ANSES)

<u>ANSES</u> is in charge of reviewing the food safety of GE products in food, and some of its work overlaps with the HCB's. Both organizations provide their expertise to France's government, which takes decisions based on the recommendations of the HCB and ANSES.

iii. Political factors influencing regulatory decisions

In France, policy makers generally follow the public opinion on biotechnology matters, mainly dictated by environmentalist non government organizations (NGOs), and therefore considered hostile to biotechnology, rather than take the lead with clear science-based political decisions. According to surveys, food and health safety issues (including mainly the bovine spongiform encephalopathy, dioxin contamination and HIV-tainted blood) have significantly weakened and reduced the credibility of the French Government since the early 1990's. They have considerably increased consumers' fears and concerns, especially for food, which plays a significant role in the cultural identity of French citizens. Policy makers addressed these anxieties by extreme decisions, such as the introduction of the precautionary principle in the Constitution since 2004.

Note: Please see Section III. 1). Agenda on Biotechnology Issues: France Specific Legislation/Registration Requirements on recent national political developments relative to biotechnology.

Environmental NGOs have gained credibility with the environmental legislation recently adopted in France ("Grenelle for the Environment"), where they were fully involved in the past few years. Although biotech opponents are usually considered marginal in number, their communication is top flight and well-transmitted by the media to a public overall receptive to fears culturally and traditionally associated with food. The following pictures illustrate some of the recent anti-biotech propaganda conducted by activists.



("GMOs: I don't want it")



("It is not dangerous")

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

The approval of biotech products in France is subject to approval by European authorities. A wide number of biotech events has been approved for feed and food at the European level and not questioned by national authorities. On the other hand, none of the two biotech events approved for cultivation by the EU authorities (MON810 corn and Amflora potato) is commercially grown in France.

Since the beginning of the commercialization of biotech plants in the 1990's, France has stuck to the inconsistent position of authorizing biotech while banning biotech plant cultivation (except in 2005-2007 for corn), and significantly restricting research on biotech plants.

b) Biotechnology Crops Approved for Commercial Use

i. Food, Feed, Processing

A variety of biotech events are approved in the European Union for feed and food use under Regulation EC 1829/2003. The full list of approved products is available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

The list of biotech products pending renewal authorization under Regulation EC 1829/2003 is available on the European Food Safety Agency's (EFSA) <u>website</u>.

ii. Environmental Release

The full list of approved products is available on the European Commission's website at <u>http://ec.europa.eu/food/dyna/gm_register/index_en.cfm</u>

For the list of pending authorizations for environmental release under Directive 2001/18, see EFSA's <u>website</u>.

c) Field Testing of biotechnology Crops

The regulation in place is the one of the European Union. The <u>European Commission website</u> states that:

"A person or a company who wishes to introduce GMOs into the environment for experimental purposes must first obtain written authorization from the competent national authority of the Member State within whose territory the experimental release is to take place.

The decision on the experimental release is made on the basis of an evaluation of the risks presented by the GMO – or GMOs – for the environment and human health. The authorization process is through a purely national procedure as it is only applicable in the Member State where the notification was submitted. Nevertheless, the other Member States and the European Commission may make observations to be examined by the competent national authority."

The HCB and ANSES are the French competent authorities in charge of assessing the risks of biotech products prior to their release in the environment for research purposes.

d) Regulatory Treatment of multi-trait "stacked" events

In the European Union, the risk assessment of stacked events should follow the principles provided in <u>EFSA's Guidance Document</u>, which stipulates that "where all single events have been assessed, the risk assessment of stacked events should focus mainly on issues related to a) stability, b) expression of the events, and c) potential interactions between the events."

e) Additional Product Registration Prior to Use

The 2008 Biotech Bill imposed a compulsory public field register for GE crop fields. This measure was estimated to discourage farmers from growing GE crops, making fields easily accessible by protestors.

f) Coexistence Policy

The HCB released its conclusions regarding biotech and non-biotech coexistence in December 2011. A draft decree signed by the French Ministries of Economy, Environment, and Agriculture was transmitted to the European Commission in January 2012. To date, no reaction has been recorded from the European authorities as to validate the decree or not.

There are records of many years of research on the conditions of biotech and non-biotech coexistence in France, which were the basis for the commercial cultivation of Bt corn until 2007. At that time, a buffer zone of 24 rows of 50 meters was put in place around the fields commercially planted with Bt corn.

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

- POECB (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;
- PACB (2005-2006) developed and implemented a Good Agricultural Guide for GE corn cultivation, focusing on risk management
- OECB (2007) surveyed fields commercially planted to GE corn to test the efficiency of strengthened coexistence rules.

In addition, several French research institutes (including INRA and Arvalis-Institut du Vegetal) have been involved in European coexistence research programs including:

- <u>SIGMEA</u> (2004-2007) focused on the sustainable introduction of biotech crops into European agriculture and proposed a toolbox for managing crop systems
- <u>COEXTRA</u> (2005-2009) studied the coexistence and traceability of GE and non GE supply chains and was a decision support system for the feed and food chains.

g) Labeling for Packaged Food or Feed

Under the Regulations 1829/2003 and 1830/2003 on biotech traceability and labeling, the European policy set standards for positive (sourced from biotech), but not for negative labeling (not sourced from biotech). Each Member State can, however, put in place specific national requirements for biotech-free labeling. France implemented the 1829/2003 and 1830/2003 Regulations in April 2004. The Fraud Control Office of the Ministry of Economy, Finance and Industry (DGCCRF) is the authority enforcing compliance with the regulation and sets general rules for negative labeling.

An explanation on biotech labeling regulation by the Fraud Control Office of the Ministry of Economy (DGCCRF) is available <u>here</u>.

There have been several voluntary initiatives put in place by the food industry and supermarket chains using "biotech-free" labeling, including Carrefour-branded products, and the Loué free range poultry industry. In both cases, animal products concerned are sourced from animals fed on less than 0.9 percent biotech feed. However, these represent minor market shares in the total French food market.



Canned sweet corn has been sold with a specific "biotech-free" logo since 2004, when the European traceability and labeling regulation for biotech products in food was implemented, in order to prevent sales from declining.



The supermarket chain Carrefour puts a "fed without GMO" logo on animal products sold under the Carrefour-branded name and using a 0.9 percent threshold. Opposed is the logo.

The Government of France has worked for several years on national rules for non-biotech labeling, so that it would inform rather than disorient consumers, when based on specific rules for all products, as part of the implementation of the national biotech law of 2008. More than two years after the High Council for Biotechnology (HCB) released its recommendation of the definition of "GMO-free" labeling, a <u>decree</u> number 2012-128 relative to voluntary "GMO-free" labeling was published in the Official Journal dated January 31, 2012.

This decree describes the requirements for "GMO-free" labeling for products produced in France, but does not apply to imported products from the European Union or from the Economic European Area. Nothing in the decree mentions application to imported products from the rest of the world. In the decree, the threshold of 0.1 percent was used for plant products under which they can be labeled as "GMO-free." For animal products, two thresholds are set in the decree: 0.1 percent and 0.9 percent, to be indicated on the label, under which "fed without GMOs" or "Sourced from animals fed without GMOs" can be labeled. For apiculture products, the decree stipulates that there shouldn't be biotech plants closer to the apiary than three kilometers. "GMO-free" labeling is not permitted to catch the

attention of consumers more than the regular list of ingredients.

h) United Nations Cartagena Protocol on Biosafety under the UN Convention on Biological Diversity

The sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (MOP 6) will take place on October 1-5, 2012 in Hyderabad, India. See http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4715. France is one of the 163 Parties of the Protocol and the national competent authorities are the Ministry of Higher Education and Research; the Ministry of Ecology and Sustainable Development; the Ministry of Economy, Finance and Industry; National Agency for Health Safety of Food, Environment, and Work (ANSES); and the Ministry of Agriculture and Food.

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).

i) Position in Other International Treaties, Conventions or International For a

As a Member State of the European Union, France's position in international organizations is generally expressed as similar to the European Union's position.

The Government of France had not considered food security as a strategic necessity until the G8 food security initiative in 2008. In 2011, France chaired the G20, and took the initiative to introduce agriculture among the top issues discussed at the ministerial level. A meeting of the agriculture ministers of the G20 countries took place in Paris in 2011, and their conclusions were taken into account in the final meeting of the heads of state in Cannes in November 2011. The ministerial declaration adopted unanimously by the ministers of agriculture of the G20 called for "improved agricultural technologies" and "innovation in plant breeding" to "increase the agricultural production and productivity." Although not specifically indicated, plant biotechnology is part of these tools.

j) Trade Barriers Negatively Impacting U.S. Exports

Safeguard Clause:

According to the Directive EC 2001/18, when a member state, as a result of new information, has detailed grounds for considering that an approved biotech event constitutes a risk to human health or the environment, the member state may invoke a safeguard clause on the biotech product; its use would be provisionally restricted or prohibited on its territory. This reduces U.S. export sales of corn seeds to

France, and also to other EU member states, as France's domestic policy is influential on member states policies.

A safeguard clause was initiated on three biotech events. In 1998, on Bayer rapeseed Topas 19/2 and Bayer rapeseed MS1XRf1 for imports and processing, and in 2008 and again in 2012 on Monsanto corn MON810. France's ban on MON810 has been challenged several times both by scientific (European Food Safety Agency - EFSA) and legal organizations (European Court of Justice).

In November 2011, the French high administrative authority Conseil d'Etat lifted the ban imposed in 2008, based on the conclusions of the European Court of Justice. Nevertheless, the Government of France reinitiated the ban in a decree March 2012, early enough to prevent farmers from planting, and only a few weeks before the presidential elections. Many farmers were disappointed by this decision, as they enjoyed both agronomic and economic benefits with this commercial production until 2007.

Delays in EU Approvals of New Events, Resulting Asynchronous Approvals:

Delays in EU approvals of new events restrict the scope of biotech events present in feed and food products, and commercially grown products. In 2012, U.S. exports of Dried Distillers Grains to France were stopped due to the potential presence of the MIR-162 biotech event in corn, unapproved in the European Union but commercially grown in the United States.

The slow pace of approvals restricts the right for the industry to use the technology, and only exacerbates the polarization on one single product, MON810 Bt corn, by the public.

Undoubtedly, a wider range of biotech events approved would reduce the pressure on this product, now outdated by more modern technology using stacked events for example. It would show wider possibilities of use of the technology on a wider range of species than just corn, providing a wider range of characteristics than just insect resistance, and created by other private companies than just Monsanto and also public research organizations.

Level of Tolerance of Unapproved Biotech Events by European Authorities:

In 2011, a technical solution was put in place by the European Regulation 619/2011 with a tolerance of 0.1 percent in feed GE feed material authorized for commercialization in a non-EU country and for which an EU authorization request has been lodged with the European Food Safety Agency (EFSA) for at least three months. A technical solution for food is still pending.

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 or soy lecithin or soy oil).

Consideration of Socio-Economic Criteria:

France's High Council on Biotechnology (HCB) includes two committees of equal importance when reviewing biotech products and issues: the socio-economic and ethics committee, and the scientific committee. This slows down significantly the reviewing process.

k) Legislation in Place Addressing Intellectual Property Rights Issues in Case of Commercially Planted Biotechnology Crops

This is a major issue in France, which, as a leading seed producer in the world, is supportive of the Plant Certificate system (Certificat d'Obtention Vegetale – COV) under UPOV, rather than the patent system. Some in France consider the cultivation of biotech plants in France cannot be solved if the IP issue remains unsolved globally.

l) Agenda on Biotechnology Issues: France Specific Legislation/ Registration Requirements

In 2007-2012, environment was put at the center of France's former President Sarkozy government and key actions were taken in a "mega" Environment Ministry with significantly wider responsibilities than usual, and measures taken in two environmental laws following broad-based discussions on all kinds of environment-related topics bringing together the government, businesses, farmers, NGOs and international environmental activists. This process was called "Grenelle for the Environment." Their objectives were to develop concrete measures to reduce greenhouse gases, preserve biodiversity and limit pollution.

For agriculture, the "Grenelle for the Environment" process resulted in the following:

- National ban on MON810 Bt corn cultivation in October 2007
- Biotech Bill adopted in 2008, imposed a public field register for plots where GE crops are grown for commercial and research purposes, changed the format of the past biotech authority from a purely scientific to a socio-economic and scientific body (see <u>FR8008</u>) called the High Council on Biotechnology (HCB).
- French action plan to reduce pesticide use, adopted in 2008 (Ecophyto 2018), aiming to reduce pesticide use by half by 2018. While the environmental benefits of the commercial production of GE crops are widely documented, biotechnology is not considered in this action plan as a tool to reduce pesticide use.

In May 2012, President Hollande was elected in France, and the Ministry of Environment doesn't seem to be as powerful as in the previous Government. However, the new Administration in place has not shown any sign of being more open than its predecessor to biotechnology.

Section IV. Plant Biotechnology Marketing Issues

a) Market Acceptance

There is overall reluctance within the public opinion regarding GE products in food, due to various factors including the lack of objective sources of information to the public, which mainly hears from two extreme "pros and cons" sources. The public opinion generally expresses distrust of private international biotech companies, which are the most visible. On the other hand, academic and public research exist, but is less visible to the public, while they would be perceived as more credible and neutral, as non-profit organizations.

b) Country-Specific Studies on the Marketing of Biotechnology Products

In 2011, France's Parliament Science Committee (Office Parlementaire des Choix Scientifques et Technologiques) conducted an in-depth review of the public perception of a variety of scientific innovations, including plant biotechnology. A report was released in January 2012: http://www.assemblee-nationale.fr/13/cr-oecst/synthese_innovation.pdf http://www.assemblee-nationale.fr/13/cr-oecst/synthese_innovation.pdf http://www.assemblee-nationale.fr/13/cr-oecst/synthese_innovation.pdf http://www.assemblee-nationale.fr/13/pdf/rap-off/i4214.pdf http://www.assemblee-nationale.fr/13/pdf/rap-off/i4214.pdf http://www.assemblee-nationale.fr/13/pdf/rap-off/i4214.pdf http://www.assemblee-nationale.fr/13/pdf/rap-off/i4214-tii.pdf

The main conclusions of the report are that in France, the lack of risk acceptance, pioneer spirit, and scientific education have resulted in the current situation of public fears for innovative technology, including biotechnology. The main recommendations of the report include acting on the perception of innovation by the public, reducing the impact of the precautionary principle, and creating a watchdog on scientific innovation.

Section V. Plant Biotechnology Capacity Building and Outreach

a) U.S. Government, USDA funded and Private Sector Capacity Building / Outreach Activities

Preparing and Disseminating Multiyear Newsletter:

Since 2006, FAS/Paris has published a multi-year newsletter of the United States and Agricultural Biotechnology, disseminated to approximately 400 contacts in France and internationally. This newsletter focuses on U.S. policy, economic studies, recent scientific progress made in this area http://www.usda-france.fr/biotechnology-437293-en.htm.

Organizing Official Visits:

FAS/Paris organizes a number of official visits (of U.S. Government officials, scientists, farmers and industry representatives) mainly illustrating the need to include biotechnology as a tool in the toolbox to address agricultural sustainability and food security. During these programs, large-scale seminars to one-on-one meetings with key stakeholders, interviews by the French media and video interviews on the Embassy website were organized for official visitors including USDA's Chief Scientist, policy makers, researchers and farmers.

In 2011, these visits were of special interest in France, which held the presidency of the G20, and where the G20 agriculture ministerial meeting was held. In this special context, FAS/Paris coordinated the visit of three speakers to participate in OECD Agricultural Knowledge System (AKS) meeting held in Paris in June 2011 and the annual conference of the plant biotechnology organization (AFBV) in September 2011 (http://www.usda-france.fr/biotechnology-437263-en.htm).

b) France-Specific Needs or Strategies

Plant Biotechnology to Boost Agricultural Productivity:

Plant biotechnology is generally perceived by scientists, farmers and the farm industry as a tool to increase productivity of the farm sector. There are many who point that the competitiveness of agriculture in this country is in jeopardy as long as biotechnology is not adopted. Wheat yields are reportedly stagnating.

An umbrella organization for French crop growers, <u>Passion Céréales</u>, recently published a report "<u>Feeding Nine billion in 2050 – World Strategy and France's Challenges</u>," including the recommendation to boost France's grains productivity, and pointing the stagnating yields in wheat observed since 1996.

Plant Biotechnology to Address Agriculture Sustainability:

While France is increasingly sensitive to sustainability, and is taking measures to make its agriculture more sustainable (including good agricultural practices, reduced pesticide use, reduced pollution and green house gas emissions, renewable energies, organic), plant biotechnology is not a tool usually considered neither by the government nor by the public to address this issue.

Reducing pesticide use is key for France, as it is the EU's largest consumer of crop protection chemicals, which is not sustainable (see Eurostat report <u>The use of Plant Protection Products in the European Union</u>). With the growing market share of organic agriculture and increasing need for

environmental-friendly practices, sustainable agriculture appears a logical combination of the good agricultural practices and reduced pesticide use included in organic agriculture with reduced pesticide use and increased productivity included in biotech crop production.

Recently, Passion Céréales published a white paper on a study they sponsored and conducted by the Economist Intelligence Unit of The Economist, called "Agriculture in High-Growth Markets – Securing Global Food Supplies." One of the key findings of this study is, "Agriculture will increasingly be ecologically sustainable, technologically driven, and inclusive of small suppliers. Food production will have a lesser environmental impact; it will be driven by plant breeding technologies, including hybridization and genetic modification; and it will embrace smaller suppliers as well as larger ones" (full report).

Plant Biotechnology to Address Food Security:

The G20 conclusions in 2011 under France's presidency, as well as the commitment of the G8 in May 2012 on a "<u>New Alliance on Food Security and Nutrition</u>" may encourage France to incorporate agricultural biotechnology as a key research, development and innovation tool for achieving food security in the developing world.

Biotechnology to address world food security is an approach the French understand and are sensitive to. They are generally uninformed of the benefits of biotech crop production in emerging and developing countries and are eager to know more about it. Programs organized by FAS/Paris linking plant biotechnology and food security have been a success. This, however, remains a hot topic for the Government of France, given its overall hostility for the technology and strong influence on former French colonies.

Section VI. Animal Biotechnology

I. Development and Use

a) Use of Animal Biotechnology

Animal biotechnology is mainly used by INRA in its Animal Genetics unit. The programs are conducted on the following three main themes: study of the structure of the genome (including gene expression, mapping), analysis of the phenotypic variability (analysis of resistance to diseases, biomedical models), and methods of population management (including the conservation of genetic resources and the selection of animal population). INRA conducts research on the genetic resistance to infectious diseases in sheep. In 2010, INRA collaborated to the characterization of the gene and

mutation responsible for a hair character in rabbits, used high debit genome analysis to assess genetic potential of dairy bulls, and studied the genetic factor of some hereditary genetic disorder in dogs.

In January 2012, INRA published a <u>report</u> on its action on animal genetics improvement. This report describes the status of the current knowledge of animal genetic improvement on animals and its perspectives. In less than a decade, genetic animal breeding has significantly improved as a result of genomic selection. Conventional breeding estimates the genetic value of an animal based on its performance and these of its related animals, while genomic breeding measures the value of animals based on their genotypes in numerous genetic markers thanks to the fast development of sequencing and high speed genotyping technologies.

The Pasteur Institute, in collaboration with the University of California Irvine, created a genetically engineered model of the *Anopheles stephensi* mosquito (a major source of malaria in India and the Middle East) that impairs the development of the malaria parasite. These GE mosquitoes, in turn, cannot transmit the disease through their bites. In this model, antibodies are released in genetically engineered mosquitoes that render the malaria parasite harmless to others. The <u>announcement</u> of the outcome of this U.S./France collaboration was made in June 2012, after the <u>publication</u> of the scientific paper.

b) Commercial Production

There is no GE animal commercialized in France.

II. Regulation

As a Member State of the European Union, France implements the EU Regulation on animal biotechnology (see <u>FR9074</u>). EFSA is pursuing two different approaches for the food and feed safety issues, animal health and welfare issues, as well as environmental safety issues. The first approach includes creating two Working Groups (WG) within EFSA:

- WG of the Biotech Panel that is developing guidance for the molecular characterization and the food and feed safety assessment of products derived from GE animals, and

- WG of the AHAW Panel that is developing guidance for animal health and welfare aspects.

For the environmental safety issues, EFSA tendered third party expert reports to define the criteria to be considered for the environmental risk assessment (ERA) of GE fishes, insects, mammals, and birds. These reports will serve as a basis for the development of EFSA biotech Panel guidance on the ERA of GE animals. During 2010, separate final reports for GE fishes and GE insects were published on

EFSAs webpage, whereas work on the report for GE mammals and birds is still ongoing. EFSA has created webpage on Genetically Modified Animals that keeps track of the progress of the work on GE animals, as well as provides relevant documents and reports. To date, EFSA has not received any applications on GE animals.

Under the 7th Framework Program (FP), the European Commission is funding an integrated project, titled Pegasus, which aims to provide policy support regarding development, implementation, and commercialization of GE animals, derivative foods, and pharmaceutical products. The Pegasus project includes eight Work Packages. More information about the Pegasus project is available at: <u>http://www.pegasus.wur.nl/UK/</u>

III. Stakeholder/Public Opinion

There is little visibility of animal biotechnology in the public opinion, which generally considers it as a non-issue.

IV. International Organizations

N/A

V. Outreach, Needs and Strategies

There have been no recent activities conducted on animal biotechnology. Section VII. **Annex - Related Reports**

Since 2010, Foreign Agricultural Service in Paris prepared or coordinated the following reports for the European Union and France. These and related reports are available on the FAS/Paris website at: <u>http://www.usda-france.fr/biotechnology-437295-en.htm</u>.

Year	Date	Report	Title
		Number	
2012	February 10	FR9091	Non-Biotech Labeling Rules in Place and Proposed
			Rules on Coexistence
	February 3	FR9089	Incentives and Plant Breeding Breakthroughs to Reduce
			Soy Imports

January 12	FR9087	France Lifts Bt Corn Ban – Louder Voices in Favor of
		Ag Innovation
November	FR9081	Biotech Outreach Program – Lessons Learned
29		
July 29	FR9074	EU Annual Agricultural Biotechnology Report
July 15	FR9013	France Annual Agricultural Biotechnology Report
July 13	FR9072	Innovation and Plant Biotechnology to Address Food
		Security
May 17	FR9067	Chief USDA Scientist Gets Scientific View of
		Biotechnology
October 14	FR9050	Combining Sustainable Agriculture and Food Security
August 19	FR9046	France Approves New Biotech Corn, Biotech Vine
		Destructions Extremely Unpopular
June 17	FR9043	EU-27 Annual Biotechnology Report
	November 29 July 29 July 15 July 13 May 17 October 14 August 19	NovemberFR908129July 29July 29FR9074July 15FR9013July 13FR9072May 17FR9067October 14FR9050August 19FR9046