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France

Agricultural Biotechnology Annual

Significant Research and Imports - No Production

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Report Highlights:

The Government of France is strongly opposed to the use of agricultural biotechnology and no biotech plants or animals are commercially produced currently. Other tools are promoted as a means to make French agriculture more economical and environmentally sustainable. In the case of retail food products, there are various voluntary labeling systems used, mainly as a marketing tool, to make clear that products do not have genetically engineered content. However, France is a net importer of feed ingredients and large quantities of soybean and corn products continue to be imported annually, mostly from the world's leading biotech producing countries. Despite major 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.

Section I: EXECUTIVE SUMMARY

France is a major importer of agricultural products derived from biotechnology, mainly for animal consumption. These include soybean meal (with annual imports of approximately \$1.5 billion in the past decade), soybeans (\$300 million), dried distillers grains, or DDGs (\$20 million), and cattle semen (\$10 million). France's leading suppliers for soybean products are also the world's largest producers of biotech crops, i.e., the United States, Brazil, Argentina, and Paraguay. The United States is France's leading supplier of cattle semen, with 50 percent market share.

France's imports from the United States mainly include soybeans (\$50 million), soybean meal (\$20 million), and DDGs (up to \$18 million in 2010/11). U.S. exports of corn and soybean products to France vary not only upon economic market conditions, but also on the level France's biotech acceptance. For example, France imports of corn seeds for planting amounts to \$160 million per year, but U.S. products market share has declined from 20 percent to 3 percent in the past decade. At the same time, France's imports of canned sweet corn have boomed from \$6 million to \$51 million, while the U.S. market share collapsed from 50 percent to 3 percent. Finally, France imports of DDGs from the United States rose sharply in 2010/11, but have been zero since then.

There is no production of agricultural products derived from biotechnology in France, which nevertheless remains a leading agricultural producer and exporter in the European Union (EU), with an intensive and productive agriculture system. This contradiction is due to the narrow range of biotech crops approved in the EU for cultivation (only two products approved), and France's national ban since 2008 on the Bt corn trait approved and grown in other EU countries. No genetically engineered animal is commercialized, and cloned sport horses produced are not for the food industry.

Despite this absence of production, France remains a country where confined research in plant and animal biotechnology is intense. Public research institutes are involved in international projects like the G20 Wheat Initiative, the International Barley Sequencing Consortium, the International Swine Genome Sequencing Consortium, and the EU Pegasus project on GE animals. A wide range of national research projects continue to be conducted in laboratories, as well as by public research organizations.

France's agricultural biotechnology policies are part of the European Union's policy and regulation framework. National legislation is more restrictive than EU legislation on plant biotechnology, with the national ban on Bt corn, a compulsory field register for GE crop fields, a significant consideration of socio-economic criteria in GE product risk assessment, and national and voluntary non-biotech labeling in place on food products. France's government is not in favor of animal biotechnology, mainly due to ethical and animal welfare concerns. France favors a moratorium on clones and their products and labeling of products derived from clones' offspring.

France's hostility towards the adoption of biotechnology in agriculture has increased in the past years, since the Ministry of Environment took over the lead on these dossiers from the Ministry of Agriculture, and with environmental Non-Government Organizations becoming increasingly vocal against the technology. Current polls indicate that French consumers reject agricultural biotech products, given they have been significantly more informed on their risks than on their benefits.

The Government of France, whatever its political majority, is sensitive to combining the environmental

and economic sustainability of agriculture, and is taking a series of measures to make its agriculture systems more sustainable. To date, biotechnology has been ignored among the various tools in the sustainability toolbox in this country, and it remains to be seen whether stagnating yields and high chemical uses can sustain in the next decades, without the use of plant and animal biotechnology to address national and international food security and reduce the environmental footprint of agricultural practices.

Acronyms used in this report are the following:

ANSES: Agency for Food, Environment, and Work Safety CEA: Center for Nuclear and Alternative Energies

CIRAD: Center for Agricultural Research for Development

CNRS: National Center for Science Research

DDGs: Dried Distillers Grains

EFSA: European Food Safety Agency

GE: Genetically Engineered

HCB: High Council on Biotechnology

INRA: National Institute of Research in Agriculture

LLP: Low Level Presence

MT: Metric Ton

MMT: Million Metric Tons

NGOs: Non-Governmental Organizations

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SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1 – PLANT BIOTECHNOLOGY

PART A - PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

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

There is a historical tradition of plant breeding in France, the leading producer of planting seeds in the EU, with annual sales of 2.9 billion euros in 2011/12, and the second world largest exporter, with exports at 1.2 billion euros. France has a positive trade balance for seeds. It amounted to 666 million euros in 2010/11 (for more information on France's seed market and trade, see http://www.gnis.fr/index/action/page/id/25).

• Open Field Testing

Once the country with the highest number of open field test plots for transgenic plants in Europe, there has been only one trial in France since 2010 when the field trials being conducted by France's National Institute of Research in Agriculture (INRA) on fanleaf resistant grape varieties were destroyed by activists. Continued destruction of test plots have discouraged both public and private research organizations from conducting research in open fields. Many stakeholders regretted the absence of dissuasive action by national authorities against the authors of the vandalism. For more details on these destructions, see 2003-2010 reports FR3052, FR4041, FR5041, FR5045, FR5088, FR6040, FR9025, and

FR9046.

To date, the only transgenic plant tested in open fields in France is poplar as biomass for bioenergy. Renewal of the multi-year approval for open-field testing is currently pending. In April 2013, the High Council on Biotechnology's (HCB) committees disagreed on the recommendation on whether to continue (science committee), or to stop (socio-economic and ethical committee) the trial. Decision by the ministry of Agriculture to renew the trial's approval or not will be based on HCB's recommendations and public comments.

• International Projects:

G20 International Wheat Initiative:

During France's Presidency of the G20 in 2011, the action plan of the G20 Agricultural Ministries created the Wheat Initiative (http://www.wheatinitiative.org). The Wheat Initiative is an international consortium gathering public institutions and private companies to coordinate global wheat research. The Wheat Initiative "aims to reinforce synergies between bread and durum wheat national and international research programmes to increase food security, nutritional value and safety while taking into account societal demands for sustainable and resilient agricultural production systems." The International Scientific Coordinator of the Wheat Initiative is in INRA.

On May 15, 2013, the Wheat Initiative issued a <u>vision document</u>, paving the way for action. This document specifically indicates the use of biotechnology: "Increasing wheat production without agricultural expansion implies that we must increase wheat production on existing agricultural lands. This could be achieved partly by improving wheat yield genetic potential through a better understanding of the physiological traits involved and their interactions with the environment, and via their complementary introduction into new varieties by breeding and/or genetic manipulation." INRA's press release is available here (in English).

International Barley Sequencing Consortium:

INRA's Genomic Resource Center is part of the <u>International Barley Sequencing Consortium</u> (IBSC), which objective is to physically map and sequence the barley gene space. In October 2012, IBSC published "<u>A physical, genetic, and functional sequence assembly of the barley genome</u>" in the journal *Nature*. See INRA's press release here.

• National Projects:

France's research Center of Atomic and Alternative Energy (CEA) has a Life Science Division (in French, 'Division des Sciences du Vivant', or <u>DSV</u>) which combines basic research and applied technology research to provide key insights in two major community challenges: energy and healthcare. Within this Division, the Institute of Life Sciences Research and Technologies (<u>iRSTV</u>) research contributes to more finalized work that is carried out in biotechnologies and in technologies for

life science and health.

The Center for Agricultural Research for Development (CIRAD) uses a number of tools including molecular biology and biotechnology. For example, CIRAD is involved in a regional genotyping, sequencing and cloning platform, together with INRA, Universities, CNRS and the Research Institute for Development (IRD). Another example is the RicE Functional Genomics platform (REFUGE). Also, CIRAD has a research unit on genetic improvement and adaptation of Mediterranean and Tropical Plants (AGAP), with INRA and Montpellier University.

INRA's news and actions in plant biotechnology are summarized in a report named "Green Biotechnologies: Paving New Paths for Agriculture," available at http://www.inra.fr/en/Scientists-Students/Biotechnologies (in English). It includes association genetics and marker-assisted selection, mutations, transgenesis and homologous recombination, the impacts of genetically modified plants, in vitro culture methods, partnerships and programs, and a brief history of biotechnologies at INRA and elsewhere.

France's public/private partnership research program created in 1999 under the name "Genoplante" and now called "Green Biotechnology" is principally involved in crop genomics. It includes more than 300 researchers from the public (INRA, National center for Scientific Research - CNRS, Center for Agricultural Research for Development - CIRAD, and the Research Institute for Development - IRD) and private sectors (Biogemma and associate seed providers, Vilmorin &Cie, Euralis,&RAGT, Sofiprotéol, Arvalis grains extension institute).

INRA is 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 stresstolerant 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, http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=4959 and including other types of biotechnology techniques than transgenesis. These include cisgenesis, as well as agro-infiltration, and reverse breeding.

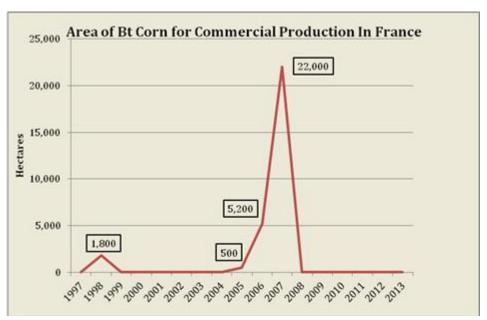
The Crop Research Institute (<u>Arvalis-Institut du Vegetal</u>), funded by farmers, is involved in research in biotechnology for grains. For example, Arvalis is involved in the BREEDWHEAT project with INRA, characterizing genes of interest for their environmental footprint; in the PHENOBLE project for high throughput phenotyping; in developing PCR and qPCR methods to identify wheat fungi. For more details on these projects, see here, and on Arvalis biotech laboratory, click here.

There is a historical tradition of plant breeding in France, it is the leading producer of planting seeds in the EU with annual sales of 2.7 billion euros, and is the second largest world exporter with exports at

one billion euros. France has a positive trade balance for seeds. It amounted to 600 million euros in 2010/11, http://www.gnis.fr/index/action/page/id/25.

b) COMMERCIAL PRODUCTION

There are only two transgenic plants approved for cultivation in the European Union: MON810 Bt corn and Amflora potato. None is commercially grown in France. Looking back, there were 1,800 hectares 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.



When cultivated in France, 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 hectares of corn (see <u>FR7013</u>) in France. Many corn growers resent not being allowed to plant this crop (see report <u>FR8008</u>), but use other tools to fight against pest damage, including crop rotation and insecticides.

c) EXPORTS

France does not export GE crops/products.

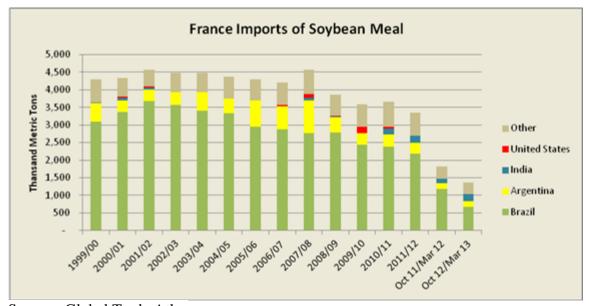
d) IMPORTS

Most of France's imports of biotech products consist of animal feed ingredients, mainly soybean meal and soybeans.

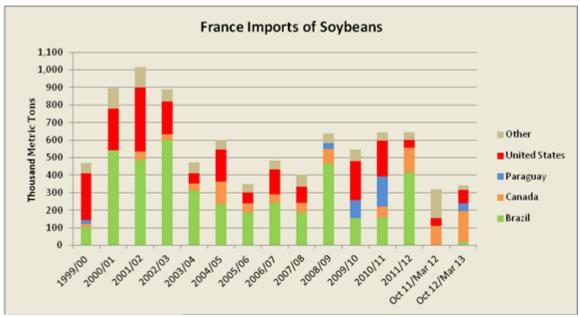
• Soybean Products

France is and will remain a major importer of soybean products to feed its livestock, dairy and poultry herds (see report FR9089). The major drivers in favor of soybean products imports and use in animal feed in France are the following: high demand of the livestock, dairy, and poultry industries; grains and soybean meal basic formulation of compound feed; the 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.

Soybean meal currently dominates the protein market for feed in France, with 4 million MT consumed annually. The large majority of it is imported as such (3.5 to 4 million MT imported annually), mainly from Brazil (70 percent), and 80 percent consists of biotech products, and 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.



Source: Global Trade Atlas



Source: Global Trade Atlas

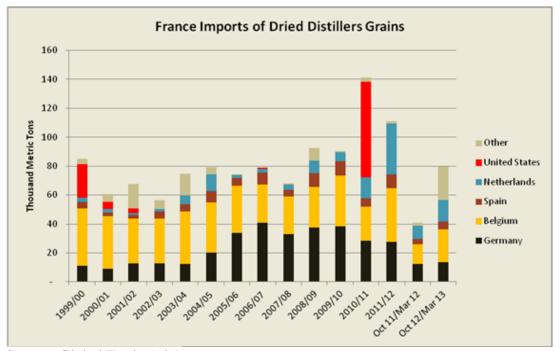
The French Government favors reducing imported protein-rich animal feed and seeks to promote domestic sources of protein feed, including domestically-grown rapeseed meal and field pea production. Nevertheless, domestically-grown soybeans remain marginal relative to imported products, with 100,000 MT produced per year. Domestically-sourced rapeseed meal has increasingly replaced soybean meal in animal feed. Overall, soybean meal and rapeseed meal accounted for 54 and 30 percent of total meal consumption in MY 2011/12, respectively. Interestingly, France's exports of rapeseed meal (mainly to Spain and Morocco) are significant and account for approximately 15 percent of the production. Finally, sunflower meal has become a direct competitor of soybean meal in recent years in animal feed rations, given its improved digestibility and world supply from the Black Sea area (Ukraine and Russia), which reduced prices. In MY 2011/12, sunflower seed meal accounted for 16 percent of vegetable meals consumed in animal feed in France.

In addition to economic factors, the non-biotech nature of rapeseed meal produced in Europe and the limited share of soybean meal has favored the diversification of protein sources from strictly soybean meal imported from the Americas in the past decade. The demand for non-biotech soybean meal is estimated at 20 percent in France and is mainly supplied by domestically-grown soybean and imports from Brazil and India.

India is a minor supplier of soybean meal to the EU and France compared to Brazil and Argentina. However, the EU has become one of India's top export destinations for soybean meal, with 13 percent market share in the first five months of MY 2012/13. France is now India's leading export market within the EU, with 36 percent market share in the first five months of MY 2012/13. This is mainly due to the high premium for non-biotech soybean meal, currently estimated at 60-70 euros per MT, or roughly a 13 percent premium to normal soybean meal prices. (see 2013 annual EU oilseeds report AU13002)

• Dried Distillers Grains (DDGs):

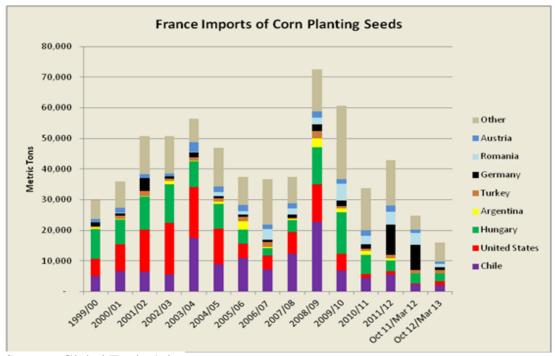
While the United States had become France's leading supplier of DDGs in MY 2010/11, U.S. exports to France have been zero in MY 2011/12 and MY 2012/13. This was due to both their potential content of biotech events unapproved in the EU (especially MIR 162 approved in the EU in October 2012) and to significantly higher prices for U.S. DDGs in 2012, as a result of the severe drought, which reduced their competitiveness with other feed ingredients.



Source: Global Trade Atlas

• Planting Seeds:

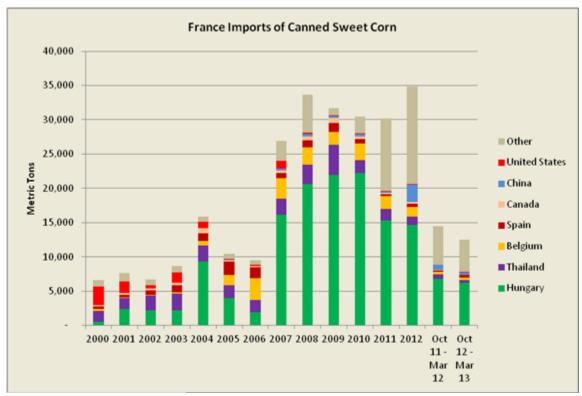
Although a net exporter to total destinations, France has a trade deficit in planting seeds with the United States. The United States is a leading supplier of corn seeds for planting for France, but its market share has declined in the past few years, while that of Romania and Germany has increased. France banned the cultivation of MON810 Bt corn in 2008 and no biotech seeds have been multiplied since then.



Source: Global Trade Atlas

• Sweet Corn:

The United States was a leading supplier of canned sweet corn to France until biotech corn was commercialized in the United States and non-biotech labeling was used in France on this product. Hungary, which is a "biotech-free country," has become France's leading supplier of canned sweet corn in the past five years.



Source: Global Trade Atlas

e) FOOD AID

France provides food aid to various countries, mainly to francophone West African countries where it is politically influential.

PART B - 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 2012 EU annual biotechnology report FR9105).

i. Responsible Government Ministries and role in the regulation of GE plants

There are several ministries involved in plant biotechnology in France. The Ministry of Environment

has the lead and principally focuses on environmental risks; the Ministry of Agriculture principally deals with cultivation and coexistence, as well as plant and animal health issues; the Ministry of Economy's Fraud Control Office (DDCCRF) controls imported products and is involved in low-level presence (LLP) issues; the Ministry of Research covers public research programs (for example, most of the National Institute of Research in Agriculture's budget is funded by the Ministry of Research); and the Ministry of Health is involved in impact of human health. These ministries have a joint website that communicates on biotechnology policies and regulations: http://ogm.gouv.fr/.

ii. Role and Membership of Biosafety Committee/Authority

The High Council on Biotechnology (HCB - http://www.hautconseildesbiotechnologies.fr) was established by the Biotech Bill of 2008. It has a unique composition of a science and socio-economic and ethics committees. Both committees review biotech dossiers and provide their respective conclusions and recommendations to France's government and to the European Food Safety Agency (EFSA) regarding environmental and health risks of biotech products under review for approval for cultivation or commercialization, as part of the European approval framework.

Despite the resignation of several members of the socio-economic and ethics committee in February 2012 (see FR9093), and the fact the Government did not seek the HCB's recommendation before reinitiating the safeguard clause on MON810 on March 18, 2012, there has been no reorganization of the HCB since then. France's current government, a coalition of socialist and ecologists, was formed in May 2012, and has not changed the functioning of HCB, to date.

France's National Agency for Health Safety of Food, Environment, and Work (ANSES) is in charge of reviewing the food safety of GE products and their derived products in food and feed, and transmits its conclusions and recommendations to EFSA, as part of the European approval framework. ANSES website dedicated to agricultural biotech products is: http://www.anses.fr/en/content/gmos (in English).

iii. Political factors influencing regulatory decisions related to plant biotechnologies

Overall, France's authorities consider that agricultural biotechnology is not necessary in French agriculture, since farmers have access to other tools with lower risks for health and the environment to fight against diseases and pests and produce high yields. France's overall approach of agricultural biotechnology has changed since the lead on this issue moved from Agriculture to Environment in 2007. While the Ministry of Agriculture had historically given priority to production and farmers, the Ministry of Environment has a wider approach than just agriculture and is primarily focused on environmental impact. The combination of these upstream and downstream approaches has stimulated dialogue among stakeholders, but often agriculture took a defensive posture when stigmatized by environmentalist Non-Governmental Organizations (NGOs) about its environmental footprint.

While there is evidence of a number of environmental, economic, and social benefits of growing GE crops, France has not selected the technology as one of the tools in the toolbox to make agriculture more sustainable. In fact, France's Government has taken to direction of reducing the role of inputs, sometimes at the price of lower resulting outputs, in its "Let's Produce Differently" (in French – "Produisons Autrement") initiative launched in December 2012, which favors an agro-ecological

approach of agriculture (see report FR9129).

Environmental NGOs have gained credibility with the environmental legislation adopted in France (the "Grenelle for the Environment") under the former government (2007-2012), where they were fully involved. Although biotech opponents are usually considered small in number, their communication skills are top notch and amplified by the media to a public already sensitized to fears about GE foods. 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

Since the beginning of the commercialization of biotech plants in the 1990's, France has stuck to the inconsistent position of authorizing biotech imports (due to the high domestic demand for protein-rich ingredients in animal feed), while restricting research and banning cultivation of biotech crops.

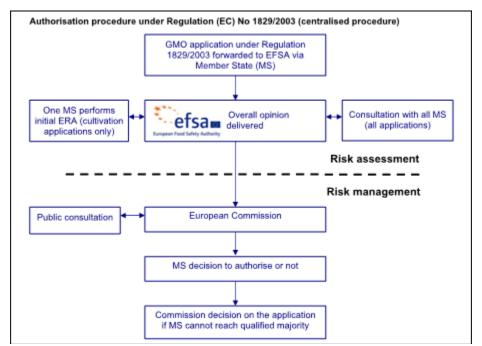
The approval of biotech products in France is subject to approval by European authorities. A wide number of biotech events has been approved for feed and food at the European level and not questioned by national authorities. On the other hand, only two biotech events have been approved for cultivation by EU authorities (MON810 corn and Amflora potato), but none is commercially grown in France. The MON810 Bt corn cultivation has faced national ban since 2008, and there has been no attempt to grow the Amflora potato.

v. Legislations and Regulations with the Potential to Affect U.S. Exports

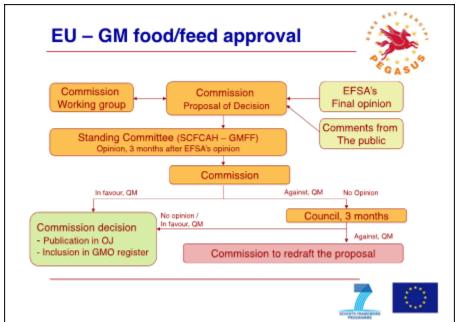
Legislations and regulations with the potential to affect U.S. trade include the national ban on MON810 cultivation and the non-biotech labeling system implemented at the national level one year ago.

vi. Timeline Followed for Approvals

The EU-wide authorization procedure is described in the graphs below. French authorities (HCB and ANSES) intervention on this graph are at the Member State (MS) level (top center and left).



Source: EFSA (http://www.efsa.europa.eu/fr/gmotopics/docs/gmoauthorisation.pdf)



Source: http://www.wageningenur.nl/en/project/Pegasus.htm European Pegasus research project, Work Package 6

b) APPROVALS

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) website.

Environmental Release:

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

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

c) FIELD TESTING

The regulation in place is that 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 authorisation 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 authorisation 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."

Field tests of GE crops can be conducted legally in France, based on risk assessment conducted by the HCB and public consultation. However, there has only been one field test in recent years, due to opposition by activist groups. Please see page 5 for further information on field testing.

d) STACKED EVENT APPROVALS

In the European Union, the risk assessment of stacked events should follow the principles provided in EFSA's Guidance Document, 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 REQUIREMENTS

France's 2008 Biotech Bill (described in FR8008) imposed a compulsory public field register for GE

crop fields. This measure is suspected to discourage farmers from growing GE crops, since it allows fields to be easily identified by protestors.

f) COEXISTENCE

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 (see FR9091).

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 (see report FR5084):

- 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:

SIGMEA (2004-2007) focused on the sustainable introduction of biotech crops into European agriculture and proposed a toolbox for managing crop systems

COEXTRA (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

• European Positive labeling:

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 (see report FR4062) 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 here.

• France National Negative Labeling:

A biotech-free labeling system has been in place at the national level since July 1, 2012 (see explanations by the Ministry of Environment <u>here</u>. The system is based on <u>decree</u> number 2012-128 relative to voluntary "GMO-free" labeling published in France's Official Journal dated January 31, 2012 (see <u>FR9091</u>), and on the HCB's recommendation of the definition of "GMO-free" labeling in 2009 (see <u>FR9032</u>).

The January 2012 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.

Private Labels – Voluntary Negative Labeling Initiatives:

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.



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.

The following market segments among the poultry, beef, pork, and goat cheese industry have committed themselves to use biotech-free feed and label their end products. They have a collective website: http://www.sans-ogm.org



NOURRI SANS OGM DES FILIÈRES S'ENGAGENT





















"Fed without GMOs – Industries Commitments"



The poultry company Loué uses this logo "Fed without the use of GMOs – minimum 99.1%" on ready-to-cook chicken and eggs.

According to the largest consumer association UFC-Que Choisir, the "fed without GMO" logo has been marginally used by the French food industry. In January 2013, the association surveyed food products labeled with the logo in more than 300 supermarkets and concluded that the "fed without GMO" logo has limited availability and lacks visibility. For more information, click here.

h) TRADE BARRIERS

Agricultural biotechnology is expected to be a key issue in the Transatlantic Trade and Investment Partnership (TTIP) negotiations that will begin this year between the United States and the European Union. This results from the slow approval process of new GE products by European authorities and associated asynchronous authorizations and Low Level Presence issues. France is one of the most opposed European Member States against the use of biotechnology in agriculture and is expected to play a major role in this topic in the TTIP negotiations.

• 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 and could be provisionally restricted or prohibited on its territory. This reduces U.S. export sales of corn seeds to France and to other EU member states, as France's domestic policy is influential on other member state policies.

In France, a safeguard clause was initiated on three biotech events: Bayer's Topas 19/2 rapeseed in 1998; Bayer's MS1XRf1 in 2008; and MON810 in 2008 and 2012. Since it was first imposed in 2008, 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. The ban is very unlikely to be lifted by the current government.

• 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, food, and commercially grown products. The slow pace of approvals restricts the right for the industry to use the technology and 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. It would show wider possibilities for use of the technology on a range of species other than just corn, provide a wider range of characteristics than just insect resistance, and involve companies other than just Monsanto, as well as 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). 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 the reviewing process significantly.

i) INTELLECTUAL PROPERTY RIGHTS

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 the International Union for the Protection of new Varieties of Plants (<u>UPOV</u>), rather than the patent system. Some in France feel that the cultivation of biotech plants in France will never occur if the IP issue remains unsolved globally.

j) CARTAGENA PROTOCOL RATIFICATION

The sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 6) took place on October 1-5, 2012 in Hyderabad, India. 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).

k) INTERNATIONAL TREATIES/FORA

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

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 introduced 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 (for more details, see FR9072).

The 2011 action plan of the G20 Agricultural Ministries created the Wheat Initiative, an international consortium gathering public institutions and private companies to coordinate global wheat research. For more details, see Part A – Production and Trade a) Product Development.

I) RELATED ISSUES

Under the new French government formed in May 2012, the Ministry of Agriculture has launched an initiative to make agriculture more sustainable, which aims to make France a champion of agro-ecology. Under this initiative, the Ministry puts forward practices that are environment-friendly and increase farm autonomy. The government's focus is on the environmental and social legs of sustainability in agriculture. Unsurprisingly, agricultural biotechnology is not included as a way to address agricultural sustainability. For more information, see FR9129.

In 2007-2012, environment was put at the center of France's former President Sarkozy government. Key actions were taken in a "mega" Environment Ministry with significantly wider responsibilities on two environmental laws following broad-based discussions of environment-related topics by 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:

A national ban on MON810 Bt corn cultivation in October 2007,

A biotech bill adopted in 2008 that imposed a public field register for plots where GE crops are grown for commercial and research purposes, and 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).

A 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 commercial production of GE crops is widely documented, biotechnology is not considered in this action plan as a tool to reduce pesticide use.

m) MONITORING AND TESTING

The inter-ministerial website dedicated to biotech products regulation indicates that "Monitoring and testing is performed 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 linked to GMOs." For more information, click here.

n) LOW LEVEL PRESENCE POLICY

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). A technical solution for food is still pending.

PART C - MARKETING

a) MARKET ACCEPTANCE

Market acceptance of plant biotech products is high among stakeholders that need the products, i.e., importers, animal feed compounders, as well as poultry/swine/cattle ranchers who all depend upon

largely imported soybean products.

French crop growers were allowed to cultivate biotech Bt corn in 2005, 2006 and 2007, and benefitted from it both agronomically and economically. Most of them welcome the technology to boost their economic and environmental sustainability, but do not push the Government for authorizing GE crop cultivation, as they benefit for other technologies, and lack the possibility of expanding the scope of GE crops approved for cultivation in the EU. In addition, farmers fear that growing biotech crops would damage their image among urban consumers.

Driven by consumer fears and threats by environmental NGOs, retailers reject biotech products and either avoid labeling through reformulation with biotech-free ingredients or push labeling of products certified as biotech-free, including organic, high-end products with Protected Geographical Indications (PGIs) such as Label Rouge, and specific non-biotech labels (see labeling section above).

b) PUBLIC/PRIVATE OPINIONS

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 "pro and con" sources. The public opinion generally expresses distrust of private international biotech companies that are the most visible. On the other hand, academic and public research exists, but is less visible to the public, although they would be perceived as more credible and neutral as non-profit organizations.

Below are examples of anti-biotech logos and pictures highly visible to the public:







"GMOs: I don't want it" "It is not harmful - On GMOs, we still don't know enough

c) MARKETING STUDIES

On May 22, 2013, the daily newspaper Le Monde published a study that had been carried out by the science magazine La Recherche, Le Monde, and the Ministry of Research and Higher Education. It concludes that, while a majority of French polled trust that scientists say the truth about their results and the consequences of their work on new sources of energy (71 percent), stem cells (61 percent), neurosciences (57 percent) and climate change (54 percent), a minority trusts scientists on nuclear energy (39 percent) and on biotech products (25 percent). More information is available here.

PART D - CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES

Since 2006, FAS/Paris has published a multi-year newsletter of the United States and Agricultural Biotechnology, disseminated to approximately 600 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. The most recent newsletter is dated May 2013.

FAS/Paris organizes visits of U.S. Government officials, scientists, farmers and industry representatives including topics related to agricultural biotechnology. More information is available at http://www.usda-france.fr/biotechnology-437263-en.htm.

b) STRATEGIES AND NEEDS

• Plant Biotechnology to Boost Agricultural Economic Sustainability:

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, and the G20 Wheat Initiative, an international consortium gathering public institutions and private companies to coordinate global wheat research, includes biotechnology as a way to boost wheat economics and environmental sustainability (see page 6)

• Plant Biotechnology to Address Agriculture Environmental 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 by the government or the public to address this issue. See reports FR9129 and FR9121. 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 The use of Plant Protection Products in the European Union). With the growing market share of organic agriculture and increasing need for environmentally friendly practices, sustainable agriculture appears a logical combination of the good agricultural practices and reduced pesticide use. This would encompass reduced pesticide use with organic and biotech practices, and increasing productivity with biotech crop production.

Plant Biotechnology to Address World Food Security:

A large portion of the French scientific community is aware of the importance of using biotechnology to address world food security. However, the French Government maintains its strong opposition to the

technology and continues to use its influence with former French colonies to convince them to avoid it.

CHAPTER 2 – ANIMAL BIOTECHNOLOGY

PART E - PRODUCTION AND TRADE

a) BIOTECHNOLOGY PRODUCT DEVELOPMENT

Transgenic animals are mainly used in basic and medical research to study human diseases (rodents, rabbits, pigs,); to produce organs and therapeutic proteins (from milk and eggs); and to improve animal production (animal breeding).

France's National Institute of Research in Agriculture (INRA) conducts research programs on animal genomics to improve animal breeding. For INRA, "animal genomics is considered to have tremendous potential in the livestock sector as evidenced by recent research on the identification of several genomic zones (Quantitative Trait Loci - QTL) responsible for a decline in the fertility of dairy cows. Likewise, genomic research on sheep has led to the identification of the mutation and unique processes that spur the production of muscle tissue, ultimately producing an animal that yields high-quality meat." For more information, see INRA's website on animal genomics here.

A map of France with INRA's research programs and laboratories in animal genomics are available <u>here</u>. They include a Biological Resources Centre dedicated to livestock genomics, two genotyping platforms, and a bioinformatics platform for the analysis of breeding animal genome.

The International Swine Genome Sequencing Consortium, launched in 2003 in France and led by American and European researchers conducted a thorough genomic study of the domestic pig and its wild boar counterparts. A new genomic analysis reveals some new, unexpected and potentially beneficial similarities between pigs and humans, along with a few distinct differences. A report of the study appears in the journal *Nature* on 15 November 2012. For more details, see INRA's press release here.

b) COMMERCIAL PRODUCTION

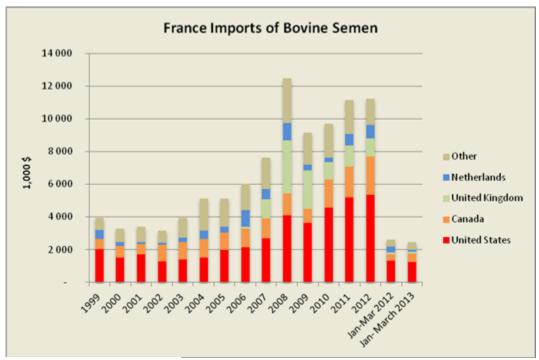
There are no GE animals for food use commercialized in France. A French company does clone sport horses, in collaboration with Italian industry.

c) BIOTECHNOLOGY EXPORTS

n/a

d) BIOTECHNOLOGY IMPORTS

The United States is France's leading supplier of bovine semen, with more than a 50-percent share the market. For this reason, stakeholders in France may be concerned by the origin of U.S. semen, potentially GE or cloned animal or their offspring.



Source: Global Trade Atlas

PART F - POLICY

a) REGULATION

Under the 7th Framework Program (FP), the European Commission has funded an integrated project, titled Pegasus, providing 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: http://www.pegasus.wur.nl/UK/. France's National Research Institute in Agriculture (INRA) was one of the participating research institutes in the project.

i. Responsible Government Ministries

As a Member State of the European Union, France implements the EU Regulation on animal biotechnology (see <u>FR9074</u>). As is the case for plant biotechnology, the European Food Safety Agency (EFSA) is in charge of risk assessment, while the European Commission's Directorate General for Consumers and Health (DG SANCO) is in charge of governance and risk management for animal biotechnology.

EFSA's website on GE animals is http://www.efsa.europa.eu/en/topics/topic/gmanimals.htm EFSA's website on animal cloning is http://www.efsa.europa.eu/en/topics/topic/cloning.htm

EFSA is pursuing two different approaches for the food and feed safety issues, animal health and welfare issues, as well as environmental safety issues, and two Working Groups (WG) within EFSA:

- WG of the biotech Panel that is developing guidance for (1) food and feed safety risk assessment of products derived from GE animals, and (2) environmental risk assessment for GE fish, insects, mammals and birds:
- WG from the Animal Health And Welfare (AHAW) Panel that is developing guidance for animal health and welfare aspects.

In July 2012, EFSA released an Update on the <u>State of play of Animal Health and Welfare and Environmental Impact of Animals derived from SCNT Cloning and their Offspring, and Food Safety of Products Obtained from those Animals, summarized here.</u>

In France, the High Council on Biotechnology (<u>HCB</u>) makes environmental risk assessment while the Agency for Food, Environment and Work Safety (<u>ANSES</u>) is in charge of food safety risk assessment of GE animals.

ii. Political Factors Influencing Regulatory Decisions

France's government is opposed to using biotechnology in animal breeding, mainly due to ethical and animal welfare concerns.

iii. Legislations and Regulations with the Potential to Affect U.S. Trade

Although France's Ministry of Agriculture recognizes that both ANSES and EFSA concluded on the absence of food risk for consumers, it underlines the animal welfare and ethics concerns of animal cloning. For more details, click here. Consequently, France asked the European Authorities to put in place a moratorium on clones and their products 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 2005, ANSES' predecessor Agency (French Food Safety Agency - AFSSA) released a risk/benefit assessment report of animal cloning (<u>summary</u>; <u>full report</u>). The report concluded that "the use of

cloning could have a significant and relative rapid economic impact." However, AFSSA considered it "necessary to carry out more in-depth evaluations, based on measurement of various biological parameters," and observed that "the detrimental effects of cloning within a species are reproducible and observed in all laboratories where these methods are used."

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, available here (summary in English). 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) LABELING AND TRACEABILITY

Laboratory animals developed are all labeled and traced and are not released into the environment. The exception is commercialized cloned sport horses. According to the company developing and commercializing cloned horses, the animals are traced and not destined for consumption.

c) TRADE BARRIERS

The main trade barrier is the political and societal hostility for animal biotechnology and cloning among France's government.

d) INTELLECTUAL PROPERTY RIGHTS

n/a

e) INTERNATIONAL TREATIES/FORA

As part of the Pegasus, research project, Vazquez-Salat N, et al, published The current state of GMO governance: Are we ready for GM animals? Biotechnol Adv (2012), available here. This paper describes international organization approaches to animal biotechnology as follows: the Organization for the Economic Cooperation and Development (OECD) and the Codex Alimentarius Commission (CAC) have working groups and develop guidelines on biotech animals. For example, the CAC developed a "Guideline for the Conduct for Food Safety Assessment of Foods Derived from Recombinant-DNA Animals." The World Organization for Animal Health (OIE) has no specific guidelines on GE animals, but on the use of cloned animals. France hosts both OECD and the OIE.

PART G - MARKETING

a) MARKET ACCEPTANCE

Market acceptance is low among consumers, industry, and policy makers.

b) PUBLIC/PRIVATE OPINIONS

France's livestock industry doesn't favor the commercialization of cloned or GE animals, but are interested in animal genomics and Marker Assisted Selection for animal breeding. There is little visibility of animal biotechnology in the public opinion, which is generally more hostile to it than to plant biotechnology, because of ethical concerns.

c) MARKET STUDIES

See same section in the plant biotechnology section.

PART H - CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES

Activities include meeting with French authorities and stakeholders to explain the status of animal biotechnology and cloning in the United States.

b) STRATEGIES AND NEEDS

Given the significant market share of U.S. genetics in France's imports of bovine semen, a number of policy makers and stakeholders in France would be interested in getting more up-to-date information regarding the status of regulation, research, and production of cloned animals and GE animals in the United States.

ANNEX – RELATED REPORTS

Since 2010, Foreign Agricultural Service in Paris prepared or coordinated the following reports for the

European Union and France:

Year	Date	Report Number	Title
2013	April 5	AU13002	Annual EU-27 Report – Oilseeds and Products Ample Soybean World Supplies to Boost EU-27 Soybean Meal Consumption
	April 19	FR9137	France and the Bioeconomy or Green Economy
	January 15	FR9129	France Chooses Agro-Ecology for a More Sustainable Agriculture
2012	December 17	FR9126	Ag Biotech Policy – Emotion Takes Precedence Over Science
	November 9	FR9121	France's Sustainable Initiatives
	October 25	FR9122	France Takes Tough Position on GE Crops Based on Flawed Study
	October 9	FR9119	International Scientists Respond to Uncritical Media
	June 15	FR9096	Agricultural Annual Biotechnology
	July 10	FR9102	Biotechnology – Food Security – Sustainability in the Americas
	March 30	FR9093	Farmers and Seed Industry Appeal National Biotech Corn Ban
	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
2011	November 29	FR9081	Biotech Outreach Program – Lessons Learned
	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

2010	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

All these reports are available on the USDA/ FAS website at http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx

And on the FAS/Paris website at:

 $\underline{http://www.usda-france.fr/biotechnology-437295-en.htm}$