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Spain

Agricultural Biotechnology Annual

2012

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Report Highlights:

This report offers an outlook of the situation of agricultural and animal biotechnology with regard to cultivation, research, policy and the marketing environment in Spain. Spain is the EU's largest biotech crop grower, and it imports a large quantity of feed products to meet the needs of its robust livestock industry. Field trials are permitted, although they are subject to prior notification and public information.

Disclaimer: Spain, as a member of the European Union (EU), conforms to EU directives and regulations on biotechnology. It is therefore recommended that this report be read in conjunction with the EU-27 consolidated report.

Abbreviations used in this report:

EC European Commission
EU European Union
FAS Foreign Agricultural Service
MS Member State(s)
MT Metric ton (1,000 kg)
Ha Hectares
GMO Genetically Modified Organism
N/A: Not available

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Section I. Executive Summary:

As a member of the European Union, Spain fully applies EU regulations on biotechnology. In terms of cultivation, Spain is the largest grower of GE corn within the European Union (EU), representing approximately 80 percent of total MON810 planted in the EU. MON810 corn has been commercially grown in Spain since 1998. Total area planted to corn varies every year based on water availability, prices paid to farmers and competition from alternative crops. Since 2006, GE corn area has varied following the fluctuations of total corn in Spain (**Graph 1**).

There is currently no commercial GE crop plot register implemented. To date, coexistence has been managed following the good agriculture practices promoted by ANOVE, the National Association of Seed Breeders. Field trials are also permitted in Spain, and they are authorized on a case by case basis. About 28 field trials to be carried out throughout 2011 were notified to the Ministry of Agriculture, Food and Environment (MAGRAMA) for its approval up to July 2011. For 2012, 39 field trials have been notified so far.

Most of Spain's farmers associations are also in favor of planting biotech crops. The use of agricultural technologies such as biotechnology or irrigation systems to improve competitiveness and obtain consistent output levels are positively perceived and defended by a large majority of the farming sector.

As it pertains to imports, as a result of the combination of a robust livestock and meat processing industry and the limited availability of domestically grown feed grains and oilseeds, Spain is among the largest EU Member States (MS) in terms of grain and oilseeds imports.

Spain's structural grain shortfall varies every year depending on the size of the domestic crop, but it is estimated to be on average between 9 and 12 million MT. Domestic oilseed crops consist primarily of sunflower and rapeseed to a lesser extent. Soybean production in Spain is virtually zero, other than a few acres planted for food purposes. As a consequence annual imports of soybean products, the largest oilseed traded, amount to over 3 million MT of soybeans and nearly 2.5 million of soybean meal.

Due to its strong dependency on imported feed grains, Spain has traditionally maintained a science based approach to biotechnology with regards to cultivation and imports, which ultimately favors the competitiveness of its robust livestock sector.

As far as the biotech decision making is concerned, there are two relevant Authorities that weight-in on Spain's biotechnology decision making process, which are the National Biosafety Commission (CNB) and the Inter-ministerial Council for GMOs (CIOMG). The CNB takes a scientific approach, whereas CIOMG's approach is technical.

According to Eurobarometer 2010, Spain's index of optimism for biotechnology/genetic engineering remains among the highest within the EU (74 percent) and so too remains Spain's support for GM food (35 percent of respondents agreed or totally agreed that GM food should be encouraged).

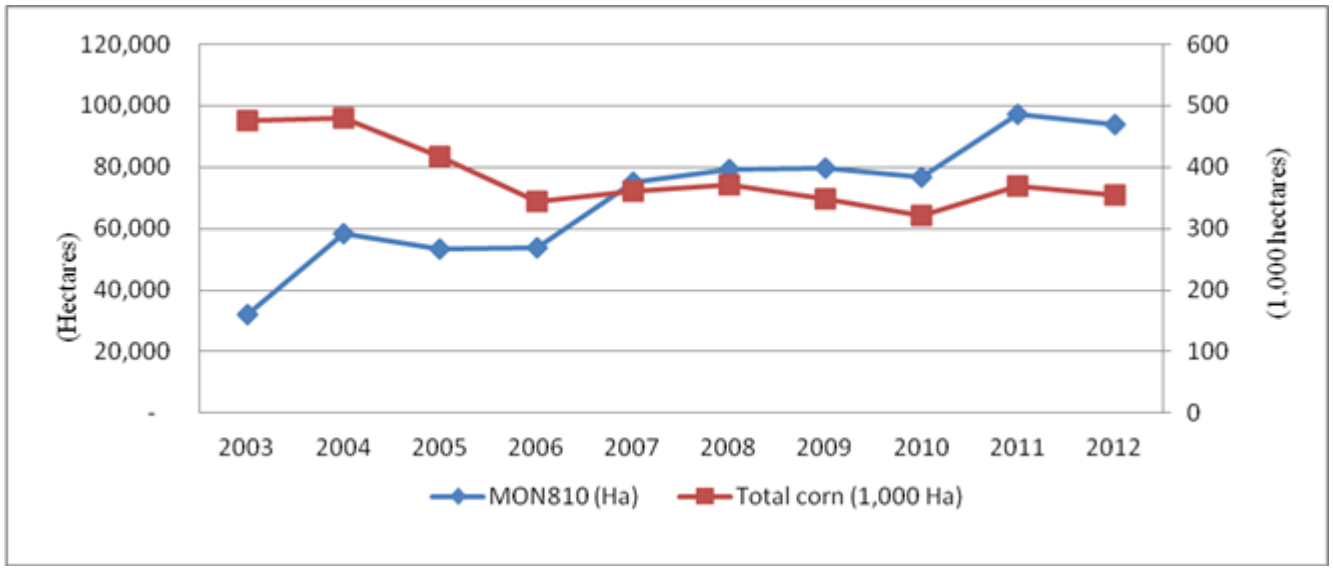
Regarding to animal biotechnology, there is no known research or development of GE animals for the food market.

Section II. Plant Biotechnology Trade and Production:

Commercial Cultivation

While in the EU there are two biotech events approved for cultivation, only MON810 corn is cultivated in Spain. MON810 corn has been commercially grown in Spain since 1998 - the longest practical experience in cultivating biotech events in the EU. Spain has the largest area planted to GM crops within the EU, representing approximately 80 percent of total MON810 planted in the European Union.

Graph 1. Total corn and MON 810 corn area on Spain.



Source: FAS Madrid based on Ministry of Agriculture, Food and Environment data and estimates.

Note: Since 2009, the Spanish Ministry of Agriculture, Food and Environment (MAGRAMA) publishes GM crop area including not only corn varieties in the national register in the EU common catalogue, but also those varieties granted with a provisional authorization. Figures from 2009 up to present in the chart above have been updated accordingly.

For 2012 a reduction in total area planted to corn due to the lower water supplies will likely result in

lower area planted to Bt corn, however the share of GE corn is expected to remain at similar level.

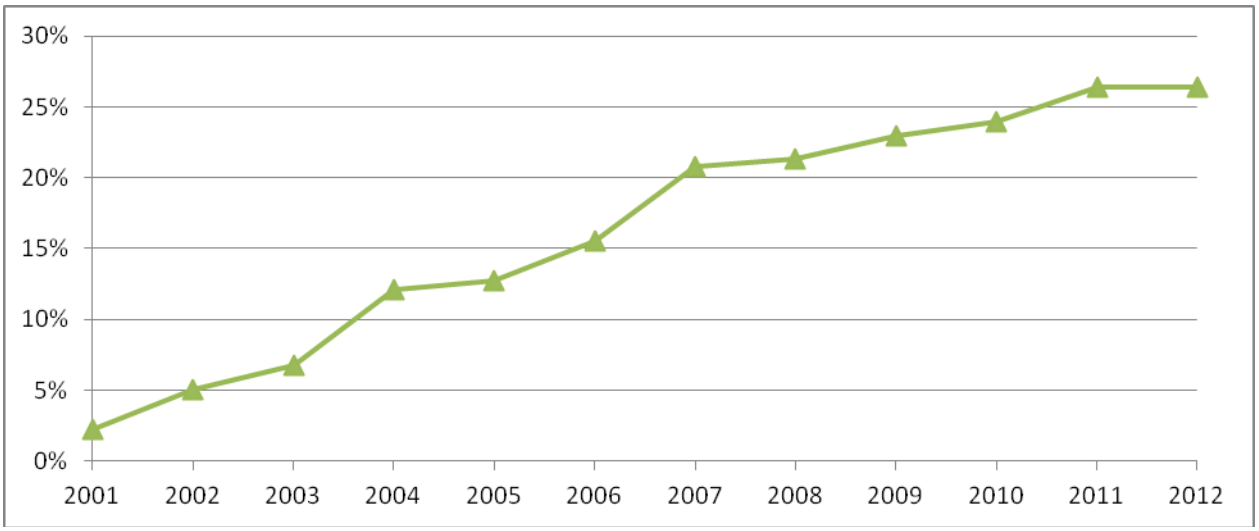
Table 1. Area of GM corn by Region (Hectares)

Region	2007	2008	2009	2010	2011	2012e
Aragon	35,860	31,857	31,397	28,652	41,368	N/A
Catalonia	23,013	25,298	29,218	28,258	29,632	N/A
Extremadura	6,460	10,416	8,730	7,770	10,567	N/A
Navarra	5,327	5,150	4,691	4,477	4,096	N/A
Castile-La Mancha	3,659	4,739	3,417	3,187	5,816	N/A
Others	805	1,823	2,252	4,230	5,867	N/A
Total	**75,124**	**79,283**	**79,705**	**76,574**	**97,346**	**93,700**

Source: Ministry of Agriculture, Food and Environment and FAS estimates.

MON 810 is resistant to infestations of the European corn borer, which are a problem for corn plantations mainly located in the Ebro River Basin in Northeastern Spain, as well as areas in the regions of Castile-La Mancha, and in second crop or late plantings in Andalusia. Aragon and Catalonia, both crossed by the Ebro River, are the primary GM corn growing regions in Spain representing about 75 percent of total Bt corn area.

Graph 2. MON 810 Area Share in Spain (%)



Source: FAS Madrid based on Ministry of Agriculture, Food and Environment data.

Feedstuffs Trade

Spain boasts of one of the EU's largest livestock sectors but it suffers at the same time from a structural shortfall of feed grains and oilseeds meals. Though it varies depending on the size of the domestic crop, on average Spain has to import every year between 9 and 12 million MT of grains, over 3 million MT of soybeans and nearly 2.5 million MT of soybean meal. This strong dependency has

lead to a steady defense of biotech by the large majority of the agricultural community.

Section III. Plant Biotechnology Policy:

Spain's has traditionally taken a science-based approach biotech regulatory process. With the EU policy agenda and rules being set in Brussels, Spain works hard to ensure that science is an important ingredient in the process, but in the end, Spain must abide by the EU-wide legislation.

While EU regulations directly apply in all EU member States, directives have to be transposed into national laws and they provide the opportunity for Member States governments to exercise some discretion without altering the basic scope of the EU directive.

The European Directive 2001/18 regarding GMOs was transposed to national regulation by Law 9/2003 on confined use and voluntary release of genetically modified organisms. For EU-27 Biotech Regulatory Framework please see EU-27 report.

National Law 9/2003 created and defined the responsibilities of the two relevant Authorities that weight-in on Spain's biotechnology decision making process, which are the National Biosafety Commission (CNB) and the Inter-ministerial Council for GMOs (CIOMG).

National Biosafety Commission (CNB)

The CNB is an advisory body whose role is to assess the requests for cultivation, confined use and marketing of GMOs submitted at either the national or regional level. The CNB is comprised by representatives of different ministerial departments, representatives of the autonomous regions and experts in biotechnology. This Commission is chaired by the Director General of Environmental Quality and Assessment and Natural Environment. The current composition of the CNB is pending to be published.

Inter-ministerial Council for GMOs (CIOMG)

The CIOMG takes a technical approach, and it is the competent authority to grant nationwide authorizations for confined use, voluntary release and marketing of Genetically Modified Organisms. This Council is chaired by the Secretary General for Agriculture and it is comprised by representatives of the Ministries that are somehow related to biotechnology and it includes representatives from the Ministry of Agriculture, Food and Environment (MAGRAMA), the Ministry of Health, Social Services and Gender Equality, Minister for Economic Affairs and Competitiveness and the Ministry of Internal Affairs. The current composition of the CIOMG after the government re-shuffle is pending to be published

The CIOMG coordinates its work with the CNB and is responsible for the exchange of information with the European Commission and with the Autonomous Communities. Spain has one of the most decentralized governments in Europe. It is made up of 17 autonomous communities and each community has considerable legislative authority. That is particularly true in the field of agriculture.

As far as the GMO policy is concerned, the national government is responsible for the marketing authorization for GMO and products containing GMO. It is also responsible for authorizing confined use and deliberate release of GMOs for research and development carried out under national programs as well as for the authorization of pharmaceutical products for humans or animals containing GMOs, and for the monitoring and control of field trials previous to the registration in the Commercial Varieties Catalogue.

The Autonomous Communities governments are responsible for authorizing confined use and deliberate release of GMOs for research and development and for the monitoring and control of these activities, with the exception of those belonging to the national government portfolio. The National Government has exclusive responsibilities over the marketing authorization for GMOs and products containing GMOs.

Other Ministerial departments involved

The Spanish Office of Vegetal Varieties, belonging to the Directorate General for Agricultural Productions and Markets, is responsible for registering and monitoring GM seed for planting. Information on the corn varieties registered for planting in Spain is available in the link.

The EU is a signatory to the Cartagena's Biosafety Protocol, and Spain is an EU Member State. At national level, the Protocol is followed by the Ministry of Agriculture, Food and Environment being the Subdirectorate General for Support and Coordination ascribed to the Directorate General for Agricultural Production and Markets the focal point. Additional information on the Cartagena's Biosafety Protocol can be found in its official website.

Within the MAGRAMA, the Sub directorate General for Animal Feed and Resources Preservation coordinates the National plan in feedstuffs whereas AESAN, the Spanish Food Safety and Nutrition Agency, ascribed to the Ministry of Health, Social Services and Equality is in charge of the food chain control.

Other Ministerial Departments weigh in to the GM decision process through the Inter-ministerial Council for GMOs (CIOGM) or the National Biosafety Commission (CNB).

Consultative Committee for GMO

While the cultivation of GM crops is permitted, Spain is also strengthening public information and participation. The Consultative Committee for GMO (CPOGM) ascribed to the Inter-ministerial Council was created in October 2010 by Ministerial Order 2616/2010. This participation body's main objective is to reassure public participation in GMO issues so that the Inter-Ministerial Council obtains first hand information of civil society representatives. The CPOGM can express its opinion on decisions to be taken and it is entitled to prepare proposals to be examined by the CIOMG.

The CPOGM is comprised by representatives of farmers' unions, agricultural cooperatives, consumers' organizations, labor unions, conservation NGOs, food industry, pharmaceutical industry, the entrepreneurial organization and the national network for rural development.

GM Crops Field Register and Coexistence

Despite the ongoing internal discussions there is no commercial GM fields register or coexistence regulation enforced yet in Spain. Thus far, despite the fact that public field registers with the location of commercially grown biotech crops are regulated in most MS, the only information available about commercial GE crops planting in Spain was the total area at the regional and national level, which was calculated based on GM seed sales records and it is publicly available at the Ministry of Agriculture, Food and Environment website.

There are no EU-wide rules on coexistence and there is not coexistence regulation enforced in Spain either. A first draft of a coexistence decree was made public in 2004. The lack of consensus among the interested parties halted the implementation of a government-imposed national coexistence decree. Nevertheless, Spanish farmers continue to grow biotech corn without any incident between farmers.

To date, coexistence has been managed following the good agriculture practices promoted by ANOVE, the National Association of Seed Breeders. ANOVE publishes on a yearly basis a guide containing good agricultural practices for Bt corn cultivation. This guide includes practical tips to facilitate production traceability, labeling and coexistence. Hard copies of these guidelines are handed out along with seed sacs by seed distributors and its latest electronic version is available on line at http://www.anove.es/docs/maizbt_2012.pdf**.**

Cultivation opt out based on socioeconomic criteria

The nationalization of cultivation decision has been debated since July 2010, when the EU Commission launched a proposal under which, EU members would be allowed to decide individually whether or not they would permit the cultivation approved biotech crops in their territory.

Back in 2010 Spain reacted cautiously to the Commission proposal to allow EU MS governments to ban the cultivation of approved genetically modified organisms on grounds other that scientific safety assessments. At that time, Spain's main concerns regarding cultivation opt out, were the compatibility with the common internal market and the compliance with WTO rules.

Spain's current Minister of Agriculture, Food and Environment has publicly stated that the EU is lagging behind in the use of biotech crops – for cultivation and imports - and this has a significant impact on farms profitability. It is our understanding that Spain's Agricultural Administration, as a part of the EU decision-making, will intend to move forward in terms of biotech crops cultivation.

GM-free Zones

Aside from the commercial production and research areas for GE crops, some municipalities/ provinces have declared themselves GM free zones. These zones are formed by the voluntary agreement of farmers to not plant GE crops in the particular area. Most of these areas are located in regions where the type of agricultural production cannot benefit from the current GM events approved for cultivation in the EU. It is our understanding that there is no legal enforcement mechanism connected to this declaration that would prevent a farmer from growing GE plants.

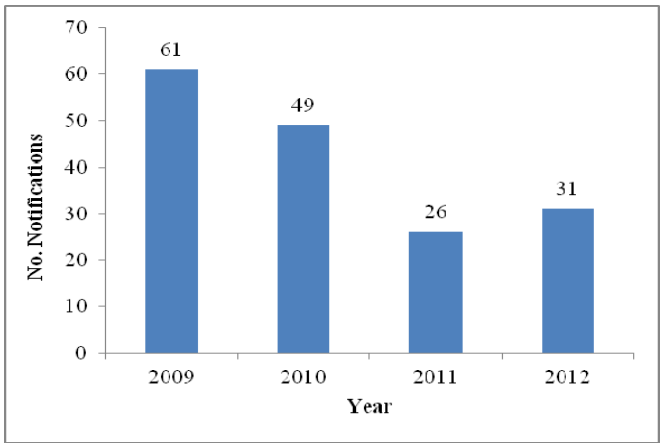
Biotechnology Research

For confined research and open field research prior notice and authorization are required. Other biotech techniques that do not imply transgenesis, such as mutagenesis or marker assisted selection, are not subject of authorization and do not need to be recorded. For instance, Biovegen's iStrategic Research priorities include solanaceae genomics-assisted breeding. More information on Spain's Strategic Research Agenda can be found in Biovegen's website.

Open field experimentation

Most of the open field trials in Spain are carried out by private companies. About 26 field trials of plant biotech to be carried out throughout 2011 under Part B of the Directive 2001/18 were notified to the Ministry of Agriculture, Food and Environment for its approval. Open field trials notification data for 2012 available to date add up to 31. Agricultural field trials consist mainly in corn plots. Permits to test sugar beets, cotton, tobacco and poplars have been requested. Herbicide tolerance and insect resistance are the main trait tested. Nevertheless, there are some other traits such as plant disease resistance (rhizomania in sugar beets), altered starch levels in tobacco and corn plants, higher biomass yield poplar trees or vitamin enriched corn.

Graph 3. Number of Notifications



Source: FAS Madrid based on Ministry of Agriculture, Food and Environment data.

Confined use

As set out in of Law 9/2003, confined use means any activity that modifies the genetic material conducted in such a way that the contact with the population and the environment is limited.

Notifications to Spanish Competent Authorities throughout 2011 include confined research on GE plants, animals, fungi, bacteria and virus. Some examples are listed below:

- Plants: tobacco
- Animals: mice, zebra fish for human health applications
- Bacteria: Saccaromyces cerevisiae bioethanol purposes and others
- Virus: Parapoxvirus ovis, Bovine diarrhea virus, Ankara virus (for animal health purposes), Citrus tristeza virus (for plant health purposes) among other intended for human health applications

Up to March 2012, public and private research centers have notified to the competent authorities that they are researching in confined conditions on various GE animals including but not limited to zebra fishes and mice as well as on GE plants such as potatoes and tobacco, poplars among other requests in which the species are not specified.

Section IV. Plant Biotechnology Marketing Issues:

The large majority of Spain's farmers associations are in favor of planting biotech crops as a tool to increase farms' competitiveness. Most farmers complain about the lack of events available, as they would benefit significantly from having access to herbicide tolerant varieties. Spain is one of the major livestock producers within the EU. Its structural shortfall of grains and oilseeds makes Spain's

trade, feed and livestock sectors traditional supporters of biotech. There is not a strong reaction from retailers or meat consumers.

Despite the fact that grain crops have the largest area cultivated in Spain, Spain's livestock industry is heavily dependent upon feed ingredient imports – which includes both GE and non-GE animal feed imports. Spain has a structural deficit of between 9 and 12 million MT tons of feed grains that varies every year depending on the demand of the feed sector, the domestic supply of grains and the availability of pastures. Regulatory constraints on biotech makes it increasingly difficult to import corn from Spain's traditional suppliers, namely the United States and Brazil, which has a direct impact on prices paid by end-users.

Soybean meal is the primary source of protein for livestock as domestic and European production of soybeans is marginal. Despite the availability of rapeseed meal produced in northern EU Member States, soybean meal remains the preferred protein ingredient both in terms of price and quality by feed compounders.

With a large trade deficit for soybean meal, used in animal feed rations, Spain imports large quantities of soybean meal and soybeans for crushing. The majority of the soybean products imported are GM, with the exception of those devoted to special markets niches.

Spain's soybean crushing industry is made up of four soybean crushing plants. Total soybean crushing in Spain capacity is over 3 million MT and expected to remain stable. Brazil followed by the United States is the main supplier of soybeans. In addition to the domestically produced soybean meal, Spain imports nearly 2.5 MT of soybean meal every year, with Argentina ranking as the largest supplier.

According to Eurobarometer 2010, Spain's index of optimism for biotechnology/genetic engineering remains among the highest within the EU (74 percent) and so remains Spain's support for GM food (35 percent of respondents agreed or totally agreed that GM food should be encouraged).

Labeling and traceability and control

There is not any non-biotech labeling regulation developed at the national level. As a member of the European Union (EU), Spain strictly follows the rules set out in Regulation (EC) 1829/2003 on Genetically Modified Food and Feed, and Regulation (EC) 1830/2003 on the Traceability and Labeling of Genetically Modified Organisms. EU food labeling regulations provide for a 0.9 percent threshold for the "adventitious", that is, accidental and technically unavoidable, presence of EU-authorized biotech event in a non-biotech food or feed. Products containing amounts above 0.9 percent must be labeled.

Since July 2011 the EU legislation sets at 0.1 percent the 'technical zero' level. This level corresponds to the lowest level of GE material taken into account by the EU reference laboratory for the validation of quantitative methods. It is only applicable to "adventitious" presence in feed material of non-approved GMOs for which an authorization procedure is pending in the EU or for which an authorization has expired.

Bt corn planted and harvested in Spain is utilized exclusively for the production of domestic compound feed and is labeled as containing "Genetically Modified Organisms". Meat from animals fed with GM feed does not have to be labeled.

Whereas most feed millers label feed as "containing GMOs", the large majority of food manufacturers, including multinational and national food manufacturers, with recognized labels have eliminated biotech products from food product composition. For instance, while the technical characteristics of conventional and GM corn are the same, according to sources, the Spain's starch industry does not use GM corn.

Spain follows EU-harmonized legislation on labeling. For detailed information on the EU-harmonized labeling legislation, please consult the EU-27 FAIRS Report well as the USEU website section on labeling.

Spain has a decentralized system for testing and controlling unauthorized presence of GMO in the feed and food chain. While the central government has total control over the controls carried out in customs, the 17 autonomous communities establish their own monitoring and sampling plans throughout the food and feed chain coordinated by national authorities. Sampling plans are based on risk assessment. Sampling is primarily done at the wholesale and the processing level.

Spain uses the Rapid Alert System for Food and Feed (RASFF) database to report food safety issues to consumers, the trade, and other member-states. Throughout 2011, no unauthorized biotech events have been notified in Spanish Points of Entry.

Since a threshold level for adventitious GMO presence in seeds has not yet been set, Spain sources of GE seeds come down to South Africa and Romania as well as domestically produced seeds.

Section V. Animal Biotechnology:

There is no known research of development of GE animals for the food market. The Ministry of Agriculture, Food and Environment keeps track of the GE animals used in confined facilities and publishes a complete list on their website.

GE animal research since 1992 consists on mice, hogs or fish for medical purposes, mainly

neuroscience. There is no known case of research of agricultural-relevant animals. Research in this field is carried out by both public and private research centers. GE animals are ruled by the same authorities as GE crops and notifications for confined use are regulated by the same provisions.

Notifications to Spanish Competent Authorities throughout 2011 include confined research on GE animals such as mice, zebra fish for research on human health applications. Up to 2012 March 2012, public and private research centers have notified to the competent authorities that they are researching in confined conditions on various GE animals including but not limited to zebra fishes and mice. The use of animals for medical research aimed at finding cures for diseases and generally speaking is found acceptable.

In the international arena, Spain is an active member of OIE and Codex, GE animals and participates in a wide rank of discussions, to date; GE has not been an issue in these fora. Since no GE animal is being developed for food purposes, the debate on that regard has not yet started.

Section VII. Additional Information

For further information on this report, please contact FAS Madrid:

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[i] *[ii] BIOVEGEN is the Spanish Technology Platform for Plant Biotechnology, a cooperation network among R&D stakeholders from industry, academia and the farming community, in the field of Plant Biotechnology. Its aim is to improve the competitiveness of the Agrifood Spanish sector.*