USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 6/11/2013
GAIN Report Number: SP1307

Spain

Agricultural Biotechnology Annual

Spain's Annual Agricultural Biotechnology Report

Approved By:
Robert Hanson
Agricultural Counselor

Prepared By:
Marta Guerrero
Agricultural Specialist

Report Highlights:

This report offers an outlook of the situation of plant and animal biotechnology with regards to cultivation, research, policy and the marketing environment in Spain. Spain is the EU's member state with the largest area planted to GE crops. Spain has traditionally taken a science-based approach to biotechnology as it imports a large quantity of feed products to meet the needs of its robust livestock industry. Field trials as well as confined research on GE plants and animals are permitted, although subject to prior notice.

Table of Contents

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
GE Genetically Engineered
N/A Not available
GTA Global Trade Atlas
MAGRAMA Ministry of Agriculture, Food and Environment

Section I. Executive Summary:

Bulk commodities currently represent nearly one half of total U.S. agricultural exports to Spain. Although they experience wide variations depending on market conditions and the competitiveness of other suppliers, bulk commodities exports to Spain are significantly affected by delays in the approval of biotech events at the EU level.

Spain is a net importer of grains and oilseeds as domestic production is not sufficient to meet the demand of Spain's robust export oriented livestock sector. Spanish grain imports rank from 9 to 12 million MT and soybean and soybean imports combined amount to nearly 6 million MT.

Regarding GE crops production, Spain is the largest EU producer of Bt corn representing about 90 percent of the bloc's total area. 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.

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.

Research on GE animals in Spain is permitted, but subject to prior notice and authorization. GE animal imports for research purposes are also possible, although subject of notification to customs authorities. Spain does not produce commercial GE animals, clones or products; hence there are no known exports within these categories.

The GE crops policy agenda and rules are set in Brussels at the European Commission. At, the national level no regulatory changes have been carried out other than the final designation of the members of the National Biosafety Commission and the Inter-ministerial Council for GMOs, the two bodies involved in the biotech decision making process at the national level.

Field trials are allowed in Spain. In 2013, for the first time approval for deliberate release has been requested for a GE wheat trial to the National Biosafety Commission (CNB). In this GE wheat gliadins have been silenced, so the wheat would have a low reactivity in relation to celiac disease. The product obtained from this plot, if approval is granted, would be used to conduct clinical trials with celiac patients.

Section II:

Chapter 1: Plant Biotechnology

Part A: Production and Trade

Product Development

As set out in Spanish National Law 9/2003, for confined research and open field research prior notice and authorization are required. Confined use has to be authorized by the Ministry of Agriculture, Food and Environment and individual authorizations are subject to public information. On the contrary, 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.

Examples of biotech techniques which are not subject to authorization include include solanaceae genomics-assisted breeding. More information on Spain's Strategic Research Agenda can be found in Biovegen[i]'s website.

After the announcement in 2012 of the sequentiation of the melon and tomato genome by a international consortium participated by Spanish public research centers, in March 2013, an international consortium (International Peach Genome Initiative) in which 28 research centers and Universities of 5 countries (Chile, United States, France, Italy and Spain) where involved, announced the peach (Prunus Persica) genome sequentiation. Research is also being carried out in citrus sequentiation.

- Confined Research

Notifications to Spanish Competent Authorities in 2012 on confined research on GE plants included genetically Engineered Plants such as tobacco, chestnut, poplar, potato, arabidopsis and other not specified plant species. To date, no confined research in plants has been reported to competent authorities in 2013.

- Field testing

Field trials are permitted in Spain, although they are subject to prior notice. To date, notifications to Spain's competent authorities for deliberate release into the environment of GE products for other purposes than placing in the market in 2013 include sugar beet (herbicide tolerant) cotton (for reference material production) corn (Corn borer protection combined with herbicide resistance traits, vitamin enriched corn and GE corn agro-ecosystems impact assessment).

The deliberate release authorization request that has captured more attention from media is the GE wheat trial requested by the Sustainable Agriculture Institute, ascribed to the CSIC (National Scientific Research Superior Council). In this GE wheat gliadins have been silenced, so the wheat would have a low reactivity in relation to celiac disease. The product obtained from this plot, which is estimated to be about 500 Kg, would be used to conduct clinical trials with celiac patients, provided the approval is granted.

This field trial would be located in the municipality of Fuente Palmera (province of Cordoba) and would have an extension of 1,000 m^2. Good wheat trial practices would be observed and buffer zones include 2 meters band free from grass and a 200 m distance where no wheat or compatible species will be sown. A broad-spectrum herbicide would be applied on the trial area once the wheat is harvested. Waste plant material would be crushed and incorporated to the soil and next crop in the same area would be other than cereal to allow for identification of wheat plants.

Commercial Production

There are two biotech events approved for cultivation in the EU, from which only MON810 corn is cultivated in Spain. Spain is the largest EU producer of Bt corn representing about 90 percent of the bloc's total area. 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 (**Table 1**).

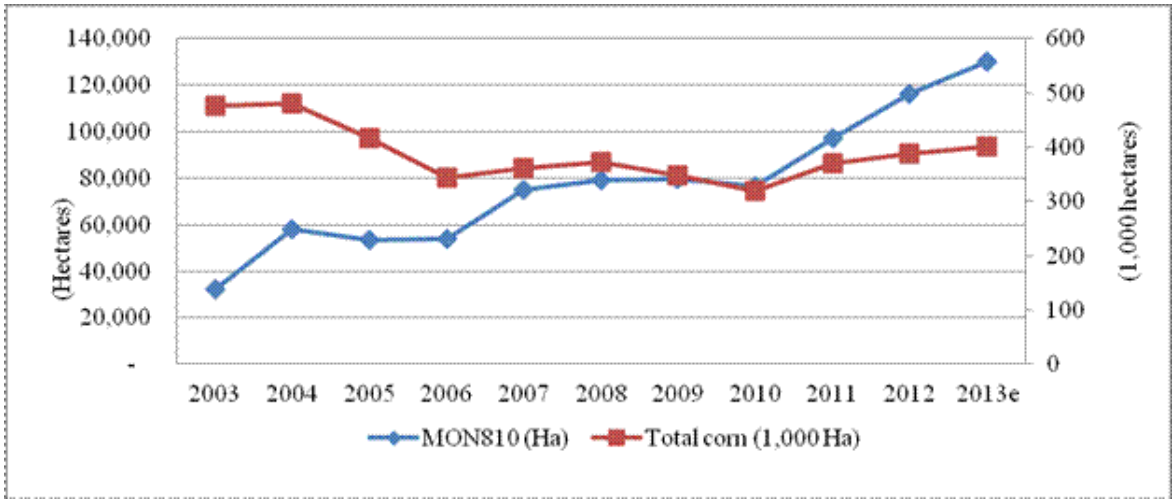
Table 1. Spain's Corn Area and Production*

Marketing Year	MY2010/11	MY2011/12	MY2012/13	MY2013/14e
Area (1,000 Ha)	315	370	387	392
Production (1,000 MT)	3,325	4,150	4,235	4,250

Source: MAGRAMA and FAS Madrid estimates. *Includes GE and not GE corn.

As corn does not represent a significant part of the Spanish diet, feed corn cultivated in Spain is devoted to the livestock sector. Feed grain elevators do not keep separate lines for biotech and non-biotech corn as practically all marketed feed contains GE soybean as a source of protein, and consequently it is default labeled as "contains GE products".

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



Source: FAS Madrid based on MAGRAMA data and FAS Madrid estimates.

Note: Since 2009, the Spanish Ministry of Agriculture, Food and Environment (MAGRAMA) publishes GE 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.

Area planted to Bt corn continues to increase every year (**Table 2**). In 2012, for the second consecutive year, a new record in terms of area planted to Bt corn was achieved. Statistics released by the Spanish Ministry of Agriculture, Food and Environment (MAGRAMA) showed how total area planted to corn grew by nearly 5 percent compared to 2011, reaching 388,470 ha (SP1234) in 2012.

Early estimates indicate that in 2013, GE corn area could amount to 130,000 hectares driven by an anticipated increase of corn plantings, which are found by farmers more competitive compared to other irrigated crops such as sugar beet, rice or cotton.

Table 2. Area of GE corn by Region (Hectares)

Region	2008	2009	2010	2011	2012	2013
Aragon	31,857	31,397	28,652	41,368	41,669	N/A
Catalonia	25,298	29,218	28,258	29,632	33,531	N/A
Extremadura	10,416	8,730	7,770	10,567	15,952	N/A
Navarra	5,150	4,691	4,477	4,096	5,801	N/A
Castile-La Mancha	4,739	3,417	3,187	5,816	7,883	N/A
Others	1,823	2,252	4,230	5,867	11,471	N/A
Total	**79,283**	**79,705**	**76,574**	**97,346**	**116,307**	**130,000**

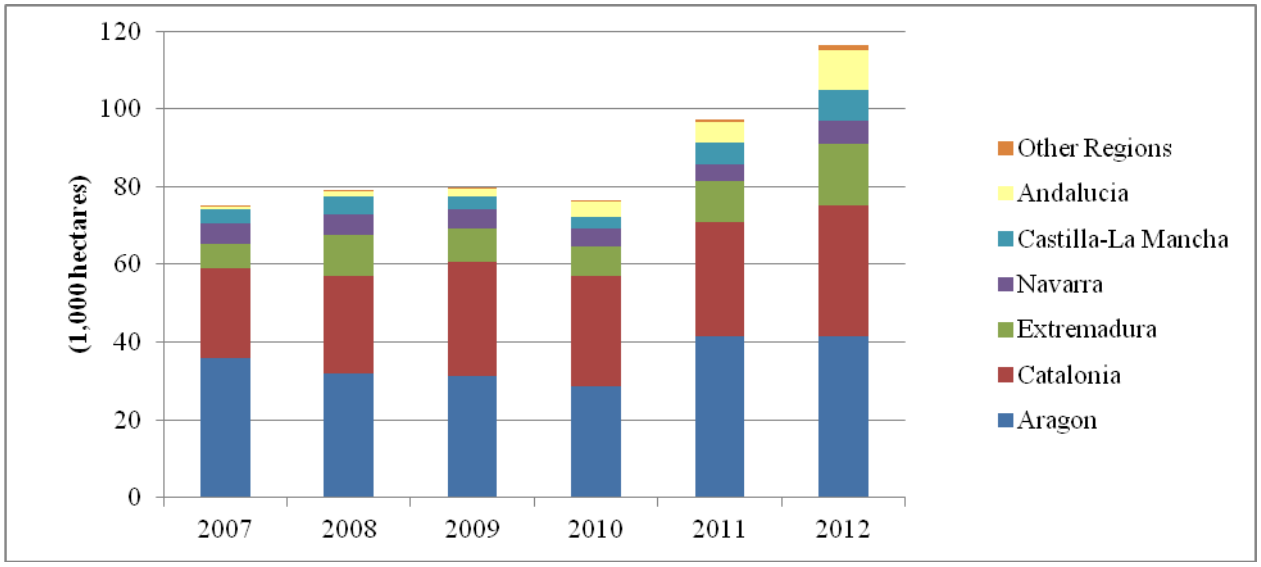
Source: MAGRAMA and FAS estimates.

Final data available for 2012 indicate that the regions of Aragon and Catalonia, both located in the Ebro

River basin, are the largest growing regions of MON810 representing 65 percent of Spain's total GE corn plantings.

MON810 continues to gain market share in other corn producing such as Andalucía, Castile-La Mancha and Extremadura. Nevertheless, the scope for further expansion for GE corn plantings in Spain is limited, since no traits other than insect resistance are available to farmers, hence GE corn use is limited to those areas where corn borer represents an issue.

Graph 2. GE Corn Area by Region



Source: MAGRAMA.

Graph 3. MON 810 Area Share in Spain (%)

Source: FAS Madrid based on MAGRAMA data and FAS Madrid estimates.

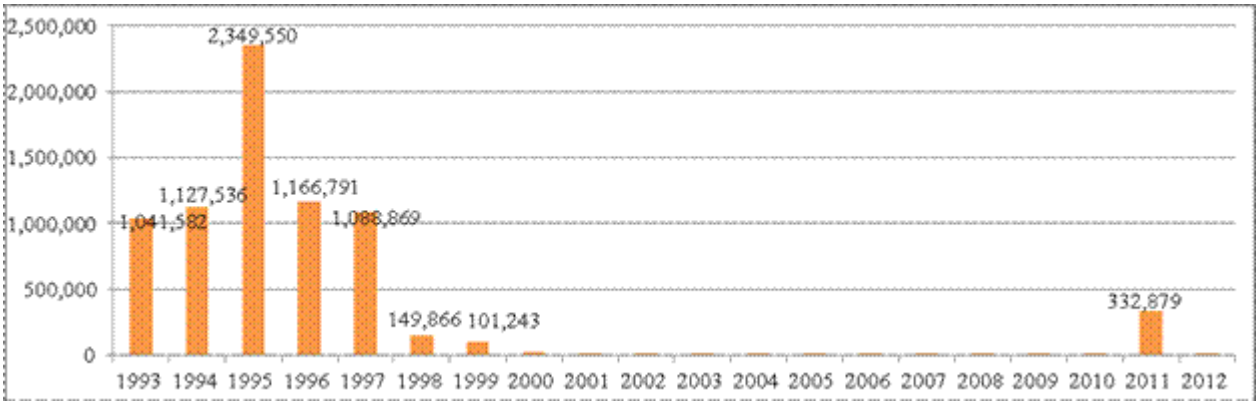
GE crops trade

Spain is a net importer of grains and oilseeds as the domestic production is not sufficient to meet the demand of Spain's robust export oriented livestock sector. Spanish grain imports rank from 9 to 12 million MT and soybean and soybean imports combined amount to nearly 6 million MT.

Bulk commodities currently represent nearly one half of total U.S. agricultural exports to Spain, although they experience wide variations depending on market conditions and the competitiveness of other suppliers, bulk commodities exports to Spain are significantly affected by delays in biotech events approval at the EU level.

In regards to corn, **Graph 4** contains U.S. exports to Spain throughout the last 20 years and it shows how the beginning of GE corn plantings in the United States caused a drastic decline in US corn imports to Spain due to the asynchronous approval of biotech events in the EU.

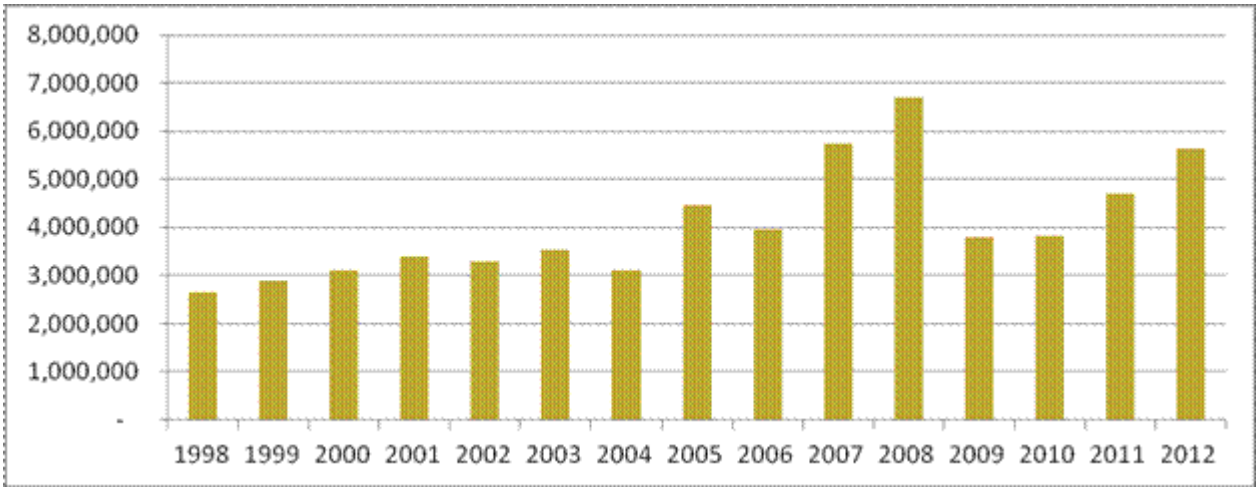
Graph 4. US Corn Exports to Spain (MT)*



Source: GTA *Corn trade data are collected in Marketing Years basis. Corn MY runs October/September, e.g.: 2012 label should read MY2011/12.

On the contrary, Spain's total corn imports have remained strong throughout the years amounting to about 4 million MT per year on average (**Graph 5**).

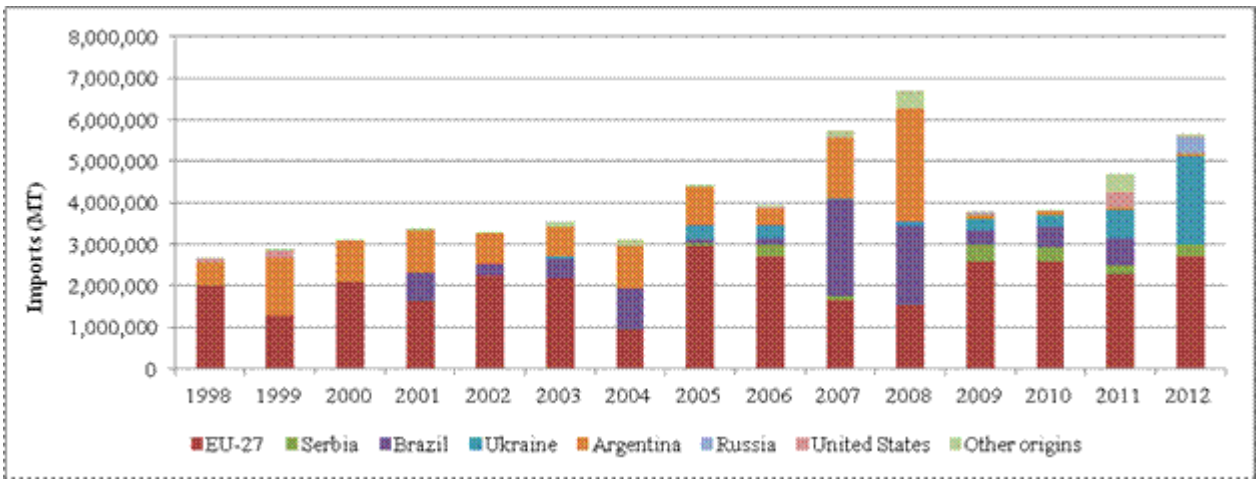
Graph 5. Spain's Corn Imports (MT)*



Source: GTA *Corn trade data are collected in Marketing Years basis. Corn MY runs October/September, e.g.: 2012 label should read MY2011/12.

Spain's total corn imports have remained strong during the last 15 years amounting to about 4 million MT per year on average, however, origins have varied in this time, partially driven by more competitive prices and partially driven by regulatory constraints on biotech. U.S. corn suffered a dramatic decline since the beginning of commercial GE corn plantings. While Argentina and Brazil quickly filled in the gap at that time, after a few years, the pace of biotech adoption in these countries has forced to Spain based importers to find alternative providers such as Ukraine, Serbia and Russia (**Graph 6**).

Graph 6. Corn imports by Origin* (MT)

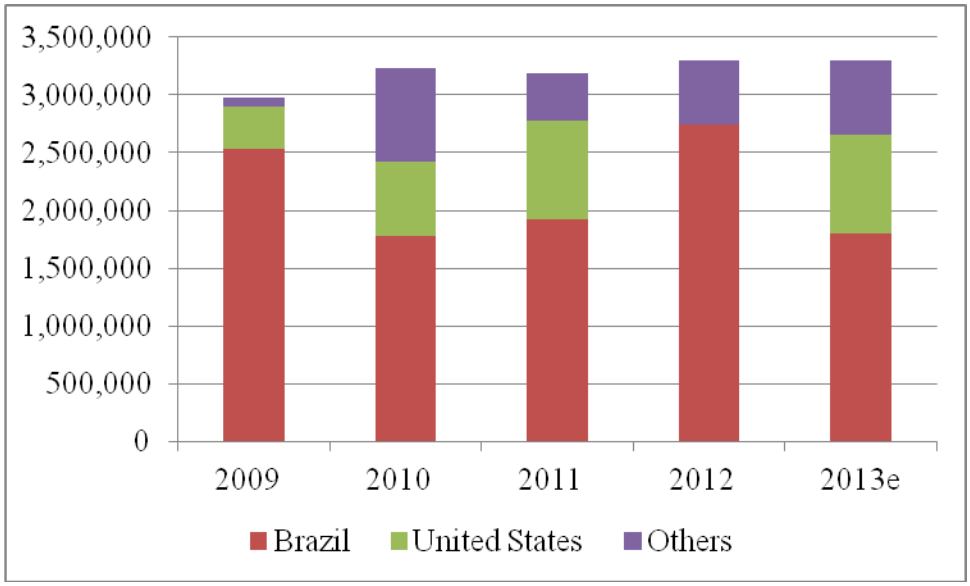


Source: GTA *Corn trade data are collected in Marketing Years basis. Corn MY runs October/September, 2012 label should read MY2011/12.

When it comes to protein feed ingredients, most of Spain's imports are biotech products such as

soybean meal and soybeans. Virtually all of the soybean products imported to Spain are GE, with the exception of those devoted to special markets niches. In the case of soybeans, the impact of biotechnology on U.S. origin imports has been less significant as U.S. exporters managed to maintain about a 20 percent share of Spanish soybean imports (**Graph 7**). Argentine and Brazil combine to supply the large majority of Spain's soybean meal imports.

Graph 7. Spain's Soybeans Imports* (MT)



Source: GTA and FAS Madrid estimates

*Soybeans trade data are collected in Marketing Years basis. Soybeans MY runs October/September, 2012 label should read MY2011/12.

Food Aid Recipient Country

Not applicable.

Part B: Policy

Regulatory Framework

The EU Regulations directly apply in all EU member States, however, EU 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. For EU-27 Biotech Regulatory Framework please see EU-27 report.

Spain transposed the European Directive 2001/18 regarding GMOs to national regulation by Law

9/2003 on confined use and voluntary release of genetically modified organisms. This regulation 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).

The EU's biotechnology policy agenda and rules are set in Brussels. At the national level, central and regional governments hold different responsibilities. Spain has one of the most decentralized governments in the EU. The central government is responsible for the marketing authorization for GMOs and products containing GMOs. 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 Community 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.

National Biosafety Commission (CNB)

The National Biosafety Commission 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 of representatives from 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 composition of the CNB is available in the link.

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. The CIOMG coordinates its work with the CNB and liaises with the European Commission and the Autonomous Communities. 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 composition of the CIOMG is available in the link.

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 GE seed for planting. Information on the corn varieties registered for planting in Spain is available in the link. At present there are over 100 GE corn varieties approved for commercial cultivation.

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 non above listed Ministerial Departments weigh in to the GE decision process through their participation in the Inter-ministerial Council for GMOs (CIOGM) or the National Biosafety Commission (CNB).

Civil Society Participation - Consultative Committee for GMO

While the cultivation of GE 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.

Approvals of Single and Stacked Events

Spain is one of the most open MS to biotechnology and has traditionally voted in favor of new events for imports in the Standing Committee on the Food Chain and Animal Health in Brussels. Spain's position is decided in the CIOMG, which is chaired by the Secretary General for Agriculture and it is comprised by representatives of the Ministries that are somehow related to biotechnology. The CIOMG takes into consideration the assessment conducted by the CNB.

Field testing

Field trials are permitted, although subject to prior notice. (More information in Part A: Production and Trade: Product Development)

Additional Requirements: GE Crops Field Register

While is has been discussed in the past, there is no commercial GE fields register regulation enforced yet in Spain. The only information publically available about commercial GE crops plantings in Spain is the total area at the regional and national level, which is calculated based on GE seed sales records and it is publicly available at the Ministry of Agriculture, Food and Environment website.

Coexistence

Spain has not enforced any coexistence regulation. A first draft of a coexistence decree was made public in 2004 but abandoned due to the lack of consensus among the interested parties. Despite the lack of coexistence measures, Spanish farmers continue to grow biotech corn without any incident between farmers. Coexistence in Spain is managed by following the good agriculture practices promoted by ANOVE, the National Association of Seed Breeders that are published on a yearly basis and handed out along with seeds by the seeds distributors.

Labeling

Spain follows EU-harmonized legislation on labeling. 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.

As corn does not represent a significant part of Spanish diet, Bt corn planted and harvested in Spain is mainly utilized for the production of domestic compound feed, which is labeled as containing "Genetically Modified Organisms". On the contrary, the large majority of food manufacturers have eliminated biotech products from food product composition.

More detailed information on the EU-harmonized labeling legislation is available in the EU-27 FAIRS Report well as the USEU website section on labeling.

Trade Barriers

- GE-free Zones: Aside from the commercial production and research areas for GE crops, some municipalities/ provinces have declared themselves GE free zones. These zones are created by political declaration at the municipality, province or regional level. Most of these areas are located in regions where the type of agricultural production cannot benefit from the current GE events available 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.

Intellectual Property Rights (IPR)

The Community Plant Variety Right (CPVR), issued by the Community Plant Variety Office (CPVO) in Angers, (France), provides intellectual property rights for protection of plant varieties. However, the European Patent Convention (EPC) of October 1973 excludes patents for plant varieties. The CPVR enables breeders to be granted a single intellectual property right operative across the EU. The CPVR coexists with individual Member States' national plant protection legislation as an alternative form of protection.

Spain has its own Plant Varieties Protection System although harmonized with the EU regulations so that Common Market rules are observed. Plant Varieties Protection Rights are regulated by Law 3/2000 that harmonizes Spanish legislation with EU Regulation and the Union for the Protection of New Varieties of Seeds (UPOV) rules.

Within the Ministry of Agriculture, Food and Environment, the Spanish Office for Plant Varieties (OEVV) manages import requirements, seed registration and certification, and commercial seed catalogs for planting seeds and nursery products.

Spain has a two-step registration process. The OEVV manages a National Catalogue of Commercial Varieties that can be freely marketed in the country and a National Catalogue of Protected Varieties. This system allows breeders to assess varieties potential and to get farmer’s feedback before incurring in the further costs implied in the protected varieties registration.

- The Register of Commercial Varieties enables to start reproducing and commercializing plant varieties in Spain.

- Register of Protected Varieties enables the owner to collect property rights and the carry out the exclusive exploitation of a plant variety Spain.

An application form has to be presented for new plant varieties to be registered in the Commercial Varieties Catalog. Prior to their registration in the Commercial Varieties Catalog the new varieties are tested to verify that they meet the condition of being different, homogeneous and stable.

The registration in the Protected Plant Varieties Catalog is voluntary. The Spanish law on Plant Varieties Protection Rights intends enhance of breeders' rights providing varieties in the Protected Plant Varieties Catalog with a 25 years protection period.

It is not possible to hold protection for the same plant variety under both the Community and a national system at the same time. When a variety is granted with the CPVR the breeder has to choose whether to keep the national or the European right. GE seed breeders opt for the Community protection over the national protection.

MON810 is the only biotech event commercially grown in Spain and, as most of the corn cultivated in Spain, including GE varieties, it is a hybrid. IPR is not an issue for Spain's GE crops as hybrid seeds are not replanted.

Cartagena Protocol Ratification

The EU is a signatory to the Cartagena's Biosafety Protocol, and so is Spain as a Member State of the European Union. Spain adhered to the Protocol on January 2002.

At the national level, the Protocol is followed by the Ministry of Agriculture, Food and Environment being and particularly the Support Unit within Directorate General for Agricultural Production and Markets is focal point. Spain regularly attends to the Cartagena Protocol Meeting of Parties.

Additional information on the Cartagena's Biosafety Protocol can be found in its official website.

International Treaties and Fora

Spain's participation in international treaties and fora is not different from that of the EU. For more information on this regard it is recommended to read the Consolidated EU-27 Biotechnology Report.

Monitoring and testing

Spain is comprised by 17 Autonomous Regions and it has a decentralized system for testing and controlling unauthorized presence of GMO in the feed and food chain, however, the central government has control over the controls carried out in customs.

The Autonomous Regions establish their own monitoring and sampling plans throughout the food and feed chain coordinated by national authorities. Sampling plans are based on risk assessment and it 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. In, 2012, only 2 shipments were rejected due to presence of unauthorized genetically modified products.

Low Level Presence

Since July 2011 the EU legislation sets at 0.1 percent[ii] the 'technical zero' level for shipments devoted to the **feed** market. However, for products that will enter the **food** chain the tolerance is zero. As a consequence, adventitious presence continues to be a concern for traders, who carry out a no risk policy in their purchases, regardless the final use.

In the case of **seeds**, a threshold level for adventitious GE material presence has not yet been set. As a consequence, Spain is forced to source its GE seeds from a limited number of origins (South Africa and domestically produced seeds). The domestic seed breeding industry continues to request the definition of a threshold limit of adventitious presence in seeds to open the trade to other seeds producers.

Part C: Marketing

Market Acceptance

Biotech products available in Spain, as in other European countries, are mainly utilized for compound feed production. The large majority of livestock breeders use compound feed labeled as containing "Genetically Modified Organisms" and the GE free feed market niche is rather small. The large majority of food manufacturers have eliminated biotech products from food product composition. Meat obtained from animals fed with GE feed does not have to be labeled so final consumers do not show a preference in their meat purchases.

Public/Private Opinions

Spain's Government has traditionally taken a science-based approach biotech regulatory process and works hard to ensure that science is an important ingredient in the process. Biotech is perceived as a tool to improve the competition of farms, and agro-food sector as a whole.

In the production side, the large majority of Spain's farmers associations are 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.

Also, since Spain is one of the major livestock producers within the EU, the feed and livestock

industries are traditional supporters of biotech. There is not a strong reaction from retailers or meat consumers.

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 GE food (35 percent of respondents agreed or totally agreed that GE food should be encouraged).

In a Eurobarometer survey carried out in 2011 regarding environmental issues that worried citizens, Spanish citizens showed less concern over the use of GE crops than the EU average (13 percent versus 19% of the Europeans). Moreover, Spaniards were far more concern about agricultural pollution originated by the use of fertilizers and pesticides (26 percent compared to 25 percent of the Europeans).

As the number of biotech crops approved for cultivation is limited, farmers growing other crops have not been able to benefit from the technology. New approvals would contribute to raise more interest from other growers, regions or consumers.

Marketing Studies:

According to a study entitled "*How can specific market demand for non-GM maize affect the profitability of Bt and conventional maize? A case study for the middle Ebro Valley, Spain"* published by the Spanish Journal to Agricultural Science, a publication managed by INIA (Spanish Public Agricultural Research Institute), the use of Bt corn in Spain increases farmers' partial gross margins[iii] by 95 Euros per hectare on average.

Part D: Capacity Building and Outreach

FAS Madrid continues maintaining and sharing information available on biotech related issues with key stakeholders. FAS Madrid engages with host country officials during the EU decision making process or EU directive transposal into national law to inform on key technical issues, U.S. position and potential trade implications.

Chapter 2: Animal Biotechnology

Under Animal Biotechnology we include Animal Genetic Engineering and Animal Cloning. While Animal Genetic Engineering implies modification of the animal's DNA, Animal Cloning is a type of

assisted reproduction which does not modify the animal's DNA but, on the contrary it can contribute to preserve valuable genetic characteristics of livestock animals or endangered species.

Part E: Production and Trade

Biotechnology product development

There is no known research or development of GE animals for the food market in Spain. The main focus of GE animal research is for medical purposes. 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.

Research in this field is carried out by both public and private research centers. GE animal research since 1992 is oriented to medical purposes, mainly for neuroscience, and carried out in confined conditions.

Notifications to Spanish Competent Authorities throughout 2012 included confined research on GE animals such as rats, mice, zebra fish, common fruit fly and frogs mainly for research on human health applications. To date, only confined research on GE mice has been reported in 2013.

As for cloned animals, in Spain, Somatic Cell Nuclear Transfer (SCNT) has occurred since 2003. Currently, public research centers and universities are trying to learn and improve the technology. No private companies are involved so far in this kind of research.

Since notification on cloning research is not mandatory the following information is compiled based on press releases. Examples of cloned animals in Spain reported by media are limited to the research arena and the first attempt was a wild goat back in 2003 by Scientifics from the Centre of Research and Agro-food Technology of Aragon (CITA) along with colleagues from the National Research Institute of Agriculture in Madrid (INIA). Some mice were also cloned in 2009 again by a public institution (Department of Cell Biology, Physiology and Immunology at the Autonomous University of Barcelona (UAB) and some swine by the Department of Animal reproduction at the Murcia University. In 2010, the first cloned bullfighting bull was born. This achievement was reached by researchers at Valencia's foundation for Veterinarian Investigation along with the Center for Investigation Prince Felipe in Valencia. No other cloning research has been reported by the media.

Commercial Production

There are neither GE animals nor cloned animals commercially used in Spain.

Biotechnology imports and exports

GE animals have been imported to Spain for research purposes. GE animal imports are subject of notification to customs authorities. Spain does not produce commercial GE animals, clones or products; hence there are no known exports within these categories.

Part F: Policy

Regulation

GE animals are ruled by the same authorities as GE crops and notifications for confined use or release to the environment are regulated by the same provisions (See Chapter 1. Part B: Policy. Regulatory Framework). In addition to that, specific regulations for animal research have been introduced by Royal Decree 53/2013.

Country position on animal biotechnology

Research conducted using **animal biotechnology** is permitted although it is subject to prior notice through the same procedure and institutions as plant biotechnology.

In regards to **cloning**, there are two ministerial departments that will likely be involved in the position definition: the Ministry of Agriculture, Food and Environment and the Ministry of Health. Within the Ministry of Agriculture, Food and Environment, the Sub directorate General for Livestock Resources coordinates this issue and it has a technical approach to cloning as a breeding technology, while the Sub directorate General for Animal Health watches animal welfare implications. Also the Sub Directorate General for Sanitary Agreements and Border Control would also participate in the debate as if restrictions to trade were implemented, they would be responsible for their enforcement.

Additionally, AESAN (Spanish Food Safety and Nutrition Agency) an independent agency ascribed to the Ministry of Health, whose constituents are consumers, weighs in on consumption aspects of food derived from cloned animals or its progeny.

Implementation of EU directives/ Country specific perspectives/country specific legislation

Domestic regulation applicable to GE plants also applies to GE animals. Spain has not specifically

regulated GE animals or clones. As per cloning, national authorities will launch an internal debate once the European Commission presents a regulation proposal.

Part G: Marketing

Market acceptance and Public/Private Opinions/ Market studies

At the consumer level, cloning or GE animals are not widely discussed. The use of animals for medical research aimed at finding cures for diseases is generally regarded favorably.

Within the livestock industry, cloning is understood as an alternative breeding tool; however, while positive productive characteristics of livestock animals are considered interesting to be kept, industry sources defend the introduction of variability. Also, livestock breeders have not shown much interest on the issue because of the high costs implied.

Part H: Capacity Building and Outreach

N/A

[i] *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.*

[ii] *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.*

[iii] *In the study "Partial gross margin" is defined as the difference between farmer's income and those variable costs which may be different in Bt and conventional maize production (i.e. seed and pesticide costs). Other variable costs not affected by the choice of Bt or conventional maize production were not included in the partial gross margin analysis (i.e. costs which may not be different between both crops, such as herbicide treatments, fertilizers and energy and water use).*