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Spain

Agricultural Biotechnology Annual

2015

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Report Highlights:

Spain is the EU-28 largest grower of Bt corn and it has traditionally defended a science-based approach to agricultural biotechnology. The Spanish poultry and livestock industries need to import grains and protein for feed so this need drives Spain's open approach to cultivation and imports of genetically engineered crops. At this time, regulatory constraints at the EU level are creating uncertainty among the food and feed chain links as well as an unattractive investment environment for new plant breeding developments and field trials.

Disclaimer: Spain, as a member of the European Union (EU), conforms to EU directives and regulations on agricultural biotechnology. It is therefore recommended that this report be read in conjunction with the EU-28 consolidated report.

Table of Contents:

Acronyms 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
DDG Distilled Dried Grains
N/A Not available
GTA Global Trade Atlas
MAGRAMA Ministry of Agriculture, Food and Environment
EFSA European Food Safety Authority

Section I. Executive Summary

Spain is the EU-28 largest grower of Bt corn. Area planted represents over 90 percent of total EU-28 area planted to GE crops Spain has always defended a science-based and pragmatic approach to agricultural biotechnology with regards to cultivation and imports. Given Spain's structural shortfall of grains and protein crops, cultivation and imports of genetically engineered (GE) crops products are essential for its robust export-oriented livestock sector.

MON810 corn has been commercially grown in Spain since 1998. Total area planted to corn varies every year based on water availability, irrigation costs, prices paid to farmers and competition from alternative crops. In 2015, area planted to corn is anticipated to decline for the second consecutive year. Consequently, GE corn plantings projections are also revised downwards.

Field trials are allowed in Spain, although subject to prior notice and authorization. Notifications to competent authorities for open field testing continue to decline steadily due to the unattractive investment environment for seed companies.

Spain voted in favor of renationalization in an attempt to move forward and open the door to cultivation of new events. As per the renationalization of import decisions, the technical experts within the administration consider the proposal inconsistent with WTO, common market and undermines EFSA's role. The large majority of agricultural stakeholders consider it very negative for Spain's food and feed chain.

As per GE animals, GE animal research abides by the same rules as GE plant research and it is also permitted, but subject to prior notice and authorization. To date, competent authorities have not publically released notifications on confined research in animals. Most of the notifications in this area consist of basic science research for pharmaceutical purposes carried out by public institutions. To our knowledge, there is no known research or development of GE animals for the food market in Spain.

There is no public register of research in cloning and notification on cloning research is not mandatory. According to media information, cloning is limited to research activities focusing on endangered species, mice, hogs, and fighting bulls, none of them intended for the food chain.

Section II: Plant and Animal Biotechnology

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a) Product Development

Both confined research and deliberate release to the environment is permitted in Spain although subject to prior notice, public information, and authorization (Law 9/2003). However, other breeding techniques such as mutagenesis or marker assisted selection are not subject of authorization and do not need to be recorded. Despite the confined research and deliberate release carried out in the country, no new GE development is anticipated to be in the market within the next five years.

- Confined Research:

Confined research in Spain is permitted although subject to prior notice and authorization.

To date, competent authorities have not reported any confined research in GE plants. However, it is our understanding that some research is being performed, with notifications consisting of basic research for pharmaceutical purposes carried out by public institutions.

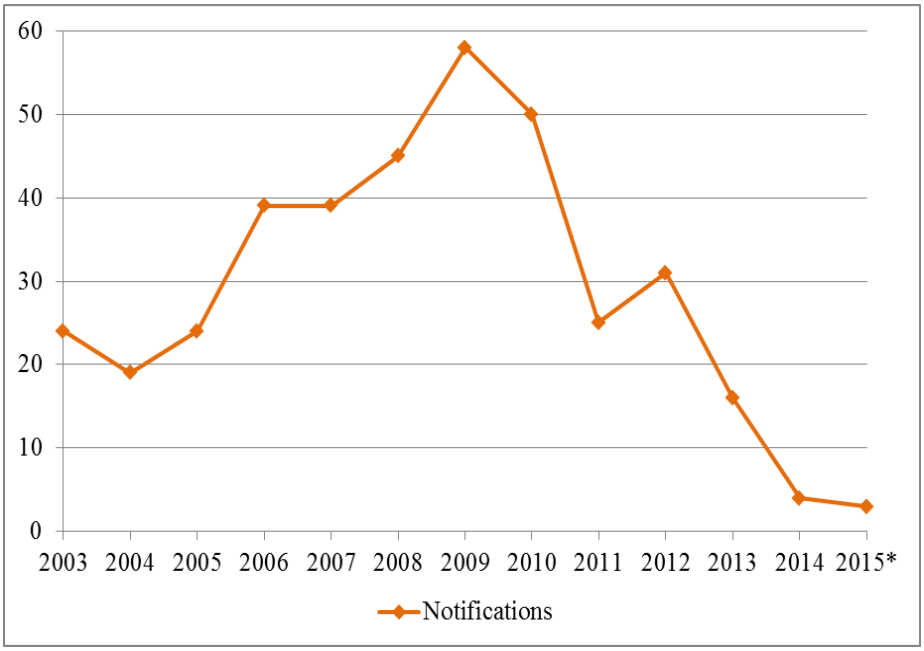
- Field testing:

Field trials are permitted in Spain although they are subject to prior notice and authorization.

To date, according to JRC (Joint Research Center), notifications for deliberate release into the environment of GE plants for any other purposes than placing on the market, include corn (Amplification and evaluation of a transgenic corn line with biofortified endosperm with three vitamins.) potato (Use of plastidial Glucose 6P dehydrogenase for production of potato plants with increased starch content), and plums (Using transgenic plants plum as rootstocks of commercial varieties of peach and apricot.) field trials.

Notifications to competent authorities for open field testing continue to decline, reflecting private sector limited interest in developing GE crops adapted to Spain's conditions given the uncertain investment environment for seed companies.

Graph 1. Open Field Trials Notifications to Competent Authorities



Source: Foreign Agricultural Service (FAS) Madrid based on Joint Research Center Information.
**2014 data are based on data available up to May 31st 2015.*

b) Commercial Production

Spain is the largest EU producer of Bt corn representing about 90 percent of the EU'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, irrigation costs prices paid to farmers and competition from alternative crops (**Table 1**). Production of GE corn is used by the robust domestic feed industry.

Spain-based **feed grain** elevators do not keep separate production lines for GE and non-GE corn as practically all marketed feed contains GE soybean as a source of protein, and consequently it is default labeled as "contains GE products."

The corn processing industry whose production is intended to enter the **food chain** (wet millers and dry millers) source corn from GE free sources, in many cases under Identity Preserved (IP) programs.

For **dry milling**, Argentina and the Black Sea Region are the main source of GE free corn. Dry millers also source some GE free corn domestically.

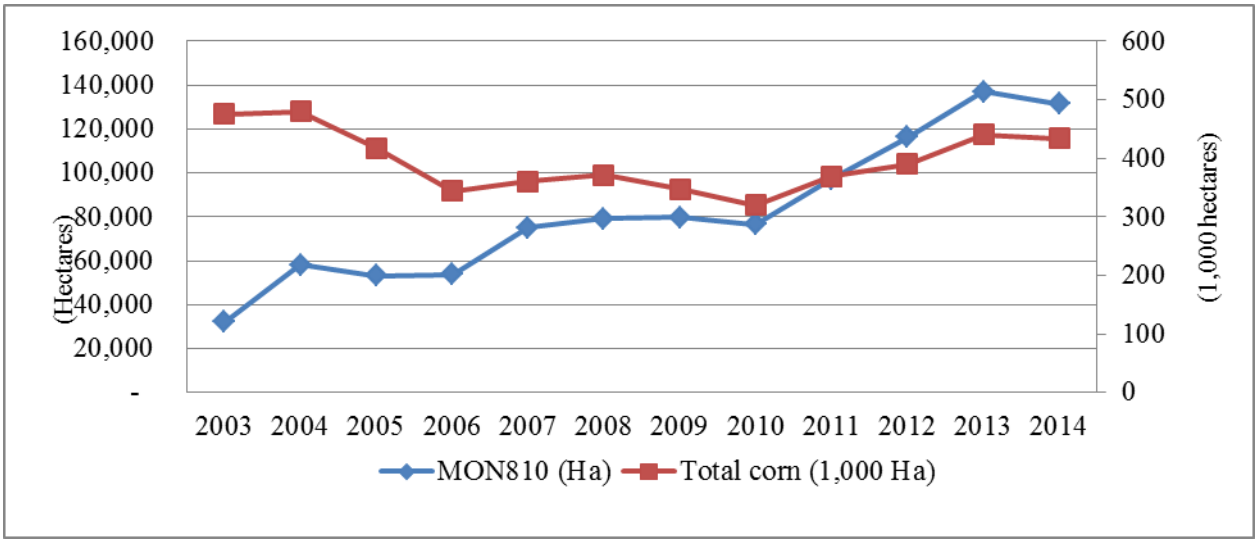
Wet millers source their corn from domestic producers of non-GE corn as well as from other EU origins (mainly France, but also from Bulgaria and Romania) and extra EU origins such as Ukraine, Argentina and Serbia.

Table 1. Spain's Corn Area and Production*

Marketing Year	MY2011/12	MY2012/13	MY2013/14	MY2014/15	MY2015/16e
Area (1,000 Hectares [Ha])	370	387	440	434	420
Production (1,000 MT)	4,150	4,235	4,930	4,750	4,650

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

Graph 2. Total corn and MON 810 corn area on Spain



Source: FAS Madrid based on MAGRAMA data and FAS Madrid estimates[1].

While area planted to Bt corn steadily increased up to 2013, (**Graph 2** and **Table 2**) driven by an increased use of the technology that expanded to non-traditional areas, and by an increase in overall corn plantings since 2014, this tendency has been negated. Overall corn area declined in 2014 and is anticipated to further constrain in 2015. Consequently, GE corn area has been reduced as well. Low market prices, high irrigation costs and, to a lesser extent, crop diversification established by greening measures[2], are forcing total corn area lower. Farmers are switching to alternative irrigated crops, namely high quality wheat, sugar beet, tomatoes for processing, cotton or rice depending on the region).

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

[1] *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.*

[2] *A large part of the support received by farmers (30%) is linked to greening measures. To comply with greening measures, crop diversification has to be observed. Farms between 10 and 30 ha must grow at least two different crops, and farms over 30 ha must grow at least three different crops in their arable land, which ultimately introduces slight variations in areas where monoculture is carried out.*

Region	2008	2009	2010	2011	2012	2013	2014	2015e
Aragon	31,857	31,397	28,652	41,368	41,669	54,451	54,041	N/A
Catalonia	25,298	29,218	28,258	29,632	33,531	33,996	36,381	N/A
Extremadura	10,416	8,730	7,770	10,567	15,952	16,979	13,815	N/A
Navarra	5,150	4,691	4,477	4,096	5,801	7,013	7,264	N/A
Castile-La Mancha	4,739	3,417	3,187	5,817	7,883	8,766	7,973	N/A
Andalusia	1,372	2,084	3,773	5,244	10,362	12,862	10,692	N/A
Others	451	168	457	603	1,109	2,895	1,371	N/A
Total	**79,283**	**79,705**	**76,574**	**97,326**	**116,307**	**136,962**	**131,538**	**120,000**

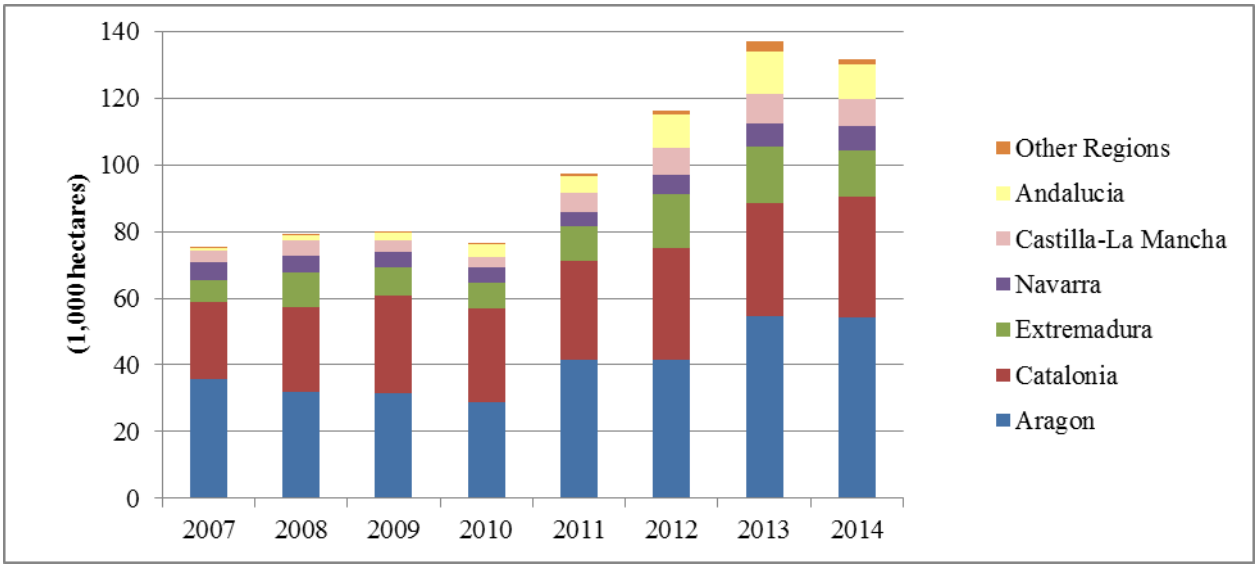
Source: MAGRAMA and FAS estimates. (N/A = not available)

Final data for 2014 indicate that the Ebro River basin (autonomous regions of Aragon and Catalonia) concentrated the largest share of GE corn, accounting for 70 percent of Spain's total GE corn plantings. The use of GE technology has gone down in non-traditional GE corn growing areas such as Andalusia and Extremadura

Since MON810 is the only GE event approved for cultivation, the possibilities of growth are limited to the size of the corn plantings in those areas were the corn borer represents a problem. Approvals of new traits for cultivation could raise the interest for GE crops in other areas.

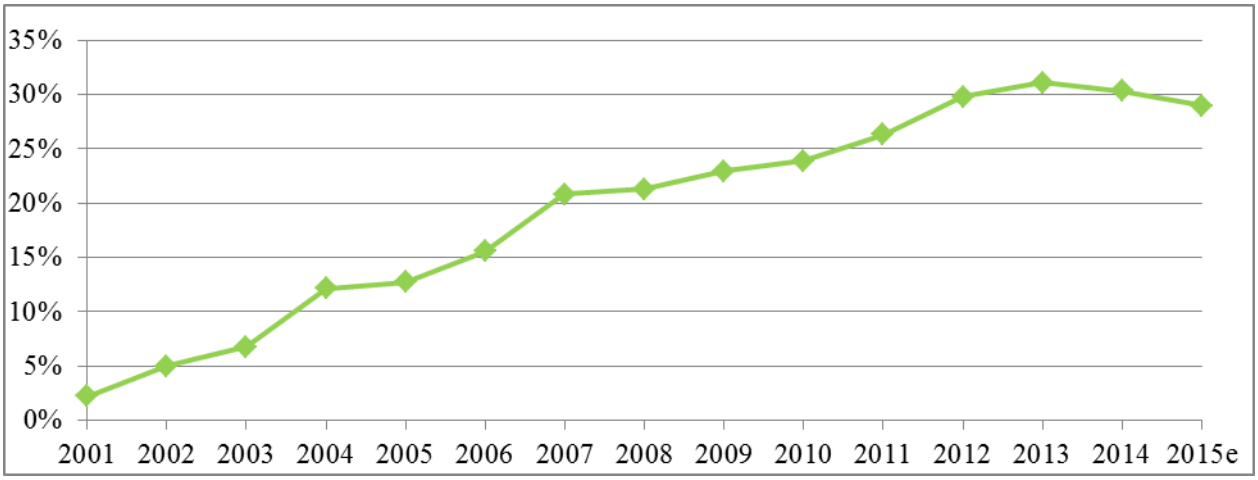
Additionally, the fact that the large majority of food manufacturers have eliminated GE products from food product composition to avoid labeling as "Contains GMOs" limits the option to grow GE crops to farmers supplying the food industry.

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.

c) GE crops exports

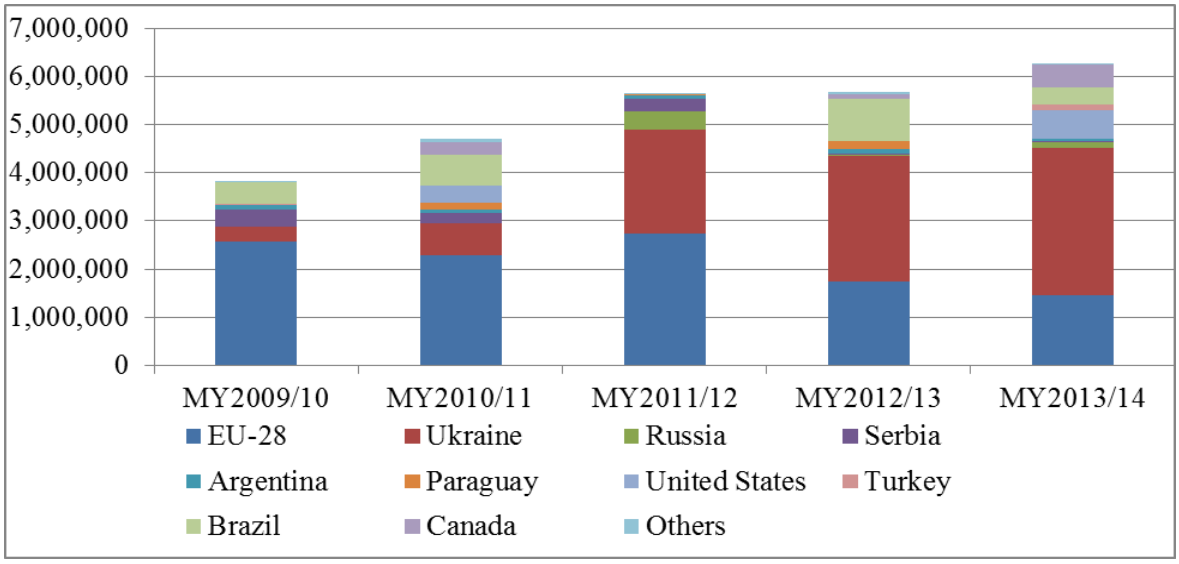
Spain is a net importer of grains and oilseeds as the domestic production is not sufficient to meet the demand of Spain's robust export-oriented livestock sector. Hence, despite being the EU largest producer of GE crops, GE product exports are negligible as production is used up by the domestic feed industry.

d) GE crops imports

Spain imports a large amount of GE crops and products. Products from agricultural biotechnology imported to Spain consist mainly of soybeans originating in Brazil and the United States and soybean meal originating in Argentina to be processed by the Spain-based crushing and feed industries respectively. Spanish grain imports rank from 9 to 12 million MT and soybean and soybean meal imports combined amount to nearly 6 million MT.

Spain's total corn imports have grown steadily over the last five marketing years due to increased competitiveness compared to other feed grains. While corn imports have grown, the United States corn share of imports is negligible due to the asynchronous approval of GE events in the EU. Agricultural biotechnology adoption in Argentina and Brazil, who were also traditional corn suppliers to Spain, has forced Spain-based feedstuff importers to find alternative corn providers such as Ukraine, Serbia and Russia. Currently, intra EU trade and imports of Ukrainian corn supply the large majority of the Spain's grain import market.

Graph 4 Spain's Corn Imports (MT)*



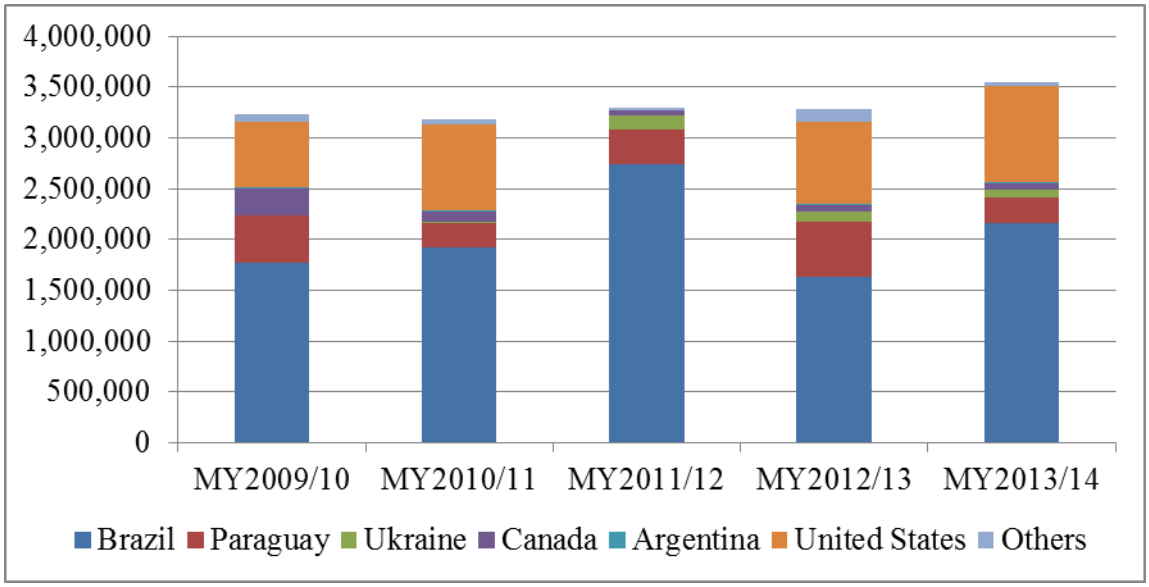
Source: Global Trade Atlas (GTA)

*Corn trade data are collected in Marketing Years basis. Corn MY runs October/September.

As it pertains to soybean and soybean products, the large majority of Spain's imports are GE products. Virtually all of the soybean products imported to Spain are GE, with the exception of those devoted to special markets niches.

Nevertheless, the impact of the slower pace of approval has been less significant in the protein feed ingredients than in the grain side. While Brazil and the United States supply the large majority of the Spanish soybean market (See **Graph 5**), Argentina and Brazil combined supply most of the soybean meal import market (See **Graph 6**).

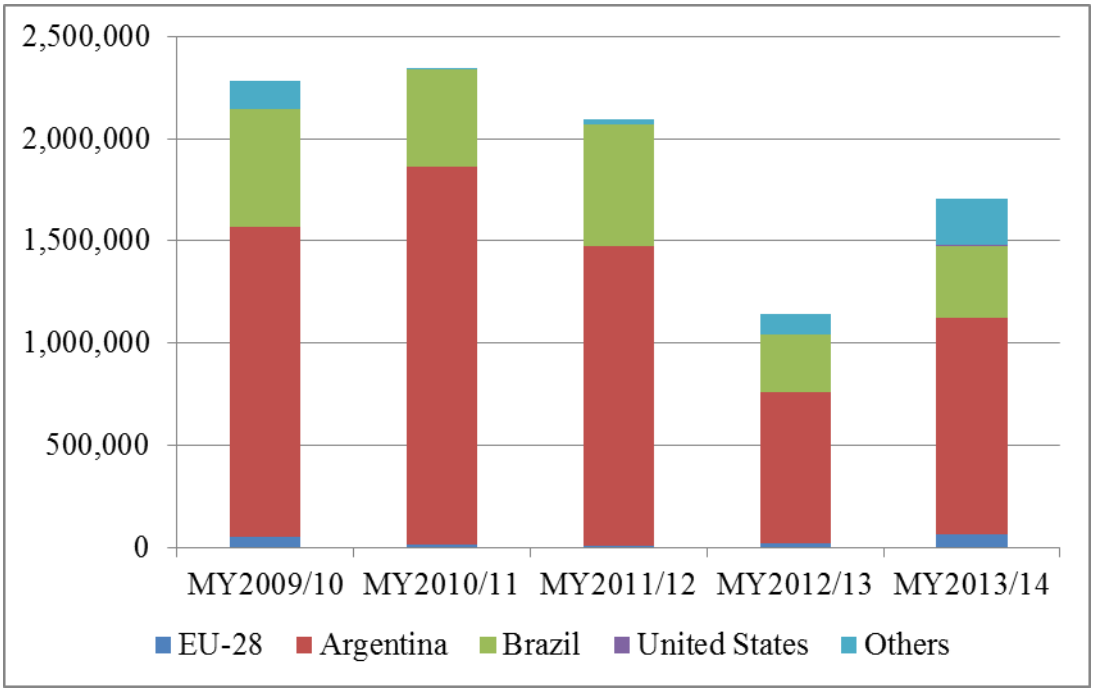
Graph 5 Spain's Soybean Imports (MT)*



Source: GTA.

*Soybean trade data are collected in Marketing Years basis. Soybean MY runs October/September.

Graph 6 Spain's Soybean Meal Imports (MT)*



Source: GTA.

*Soybean meal trade data are collected in Marketing Years basis. Soybean Seed MY runs October/September.

The country's dependency on imported feedstuffs, and the science-based approach to GE crops have contributed to a lower lower rejection to the technology, which has resulted in the expansion of GE crops cultivation and imports over the years.

e) Food Aid Recipient Country

Not applicable.

Part B: Policy

a) Regulatory Framework

The EU's agricultural biotechnology policy agenda and rules are set in Brussels. As an EU Member State (MS), Spain must abide by EU rules, which in the case of Regulations are directly applicable to all EU MS. EU Directives need to be transposed into national laws, so they provide the opportunity for Member States governments to exercise some discretion without altering the basic scope of the EU directive. For more information on EU-28 Agricultural Biotechnology Regulatory Framework please see EU-28 report.

In the field of agricultural biotechnology, the EU Directive 2001/18 on the deliberate release into the environment of "genetically modified organisms (GMOs)" was transposed to national regulation by Law 9/2003 on confined use and voluntary release of "GMOs".

This same piece of regulation created and defined the responsibilities of the two relevant authorities that weighed in on Spain's agricultural biotechnology decision making process, which are the National Biosafety Commission (CNB) and the Inter-ministerial Council for Genetically Modified Organisms (CIOMG). The CNB takes a scientific approach, whereas CIOMG's approach is technical.

At the national level, central and regional governments hold different responsibilities:

The central administration is responsible for:

- The marketing authorization for "GMOs" and products containing "GMOs."
- Authorizing confined use and deliberate release of "GMOs" for research and development (carried out under national programs).
- Authorizing pharmaceutical products for humans or animals containing "GMOs."
- Monitoring and control of field trials previous to the registration in the Commercial Varieties Catalogue.

The autonomous regions administrations are responsible for:

- Authorizing confined use and deliberate release of "GMOs" for research and development
- Monitoring and control of these activities, (with the exception of those belonging to the national government portfolio)

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 GE products submitted at either the national or regional level with a scientific approach. The CNB is comprised of representatives from different ministerial departments, representatives of the autonomous regions and experts in agricultural 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 products derived from biotechnology. 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 agricultural biotechnology. It includes representatives from the Ministry of Agriculture, Food and Environment (MAGRAMA), the Ministry of Health, Social Services and Gender Equality (MSSSI), Minister for Economic Affairs and Competitiveness (MINECO) and the Ministry of Internal Affairs (MIR). 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 of GE seed for planting. Information on the corn varieties registered for planting in Spain is available in the link. At present there are over 120 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 the Spanish Consumption, Food Safety and Nutrition Agency (AECOSAN), 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 agricultural biotechnology 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 body's main objective is to reassure public participation in agricultural biotechnology 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 non-governmental organizations, food industry, pharmaceutical industry, the entrepreneurial organization and the national network for rural development. The seed breeding industry is not represented in this consultative group.

b) Approvals

- For imports:

Approvals of events for imports are dealt with at the EU level. Please see the EU-28 Biotechnology Report for a list of approved GE events.

Member States have the chance to weigh in on the approval process through their participation in the EU committees, both at the technical and political level. For more information on the EU approval process, please see EU-28 Biotechnology Report.

With only a couple of exceptions, Spain has traditionally voted in favor of new events for imports in the Standing Committee on the Food Chain and Animal Health in Brussels.

Spain has a two-tier system for the national decision making process to come up with the country's position:

  - The CNB carries out the risk assessment
  - The CIOMG decides the country's position taking into consideration CNB assessment.

The recent European Commission proposal on imports renationalization that would allow EU Member States to make final decisions on the imports of genetically engineered (GE) crops in their respective countries has been cautiously examined by both government and agricultural stakeholders.

From the technical experts point of view, this proposal could be inconsistent with WTO and common market principle and would further undermine the European Food Safety Authority's (EFSA) role.

The large majority of Spain-based agricultural stakeholders are against it as they consider it could very negatively affect the competitiveness of the Spanish agrifood sector. Given Spain's robust export-oriented livestock sector and its strong reliance on imported feedstuffs, losing access to vital imports of protein-rich ingredients would translate into significant competitiveness reduction.

- For cultivation: (more detailed information available in the **Trade Barriers** Section)

Spain's position on renationalization of cultivation decisions evolved through the years. When the debate on renationalization of cultivation decisions was first launched, Spain reacted cautiously putting forward concerns over common market implications and WTO rules compliance. However, Spain voted in favor of the renationalization of cultivation decisions in what we understand as an attempt to open the door to cultivation of new events. Transposal to Spanish law of Directive (EU) 2015/412 on the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms in their territory will be carried out in 2016.

c) Field testing

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

d) Stacked Events Approvals:

Based on EU regulations, approval procedures for single and for stacked events are the same.

e) Additional Requirements: GE Crops Field Register

While it was largely debated in the past, at the moment, there is no national registry of commercial GE fields in Spain. Until now, the Spanish agricultural administration is reluctant to publish the location of commercial GE crop plots, which could be misused.

Currently, the only information publically available about commercial GE crops plantings in Spain is the total area at the province, regional and national level that is calculated based on GE seed sales records, and it is publicly available at the Ministry of Agriculture, Food and Environment website.

f) Coexistence

Despite being the EU's largest GE crop grower, Spain has not yet implemented a 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 GE corn without any incident between farmers.

The Spanish agricultural administration would prefer clearer EU wide rules to develop coexistence plans to be provided by the European Commission, as opposed to national measures.

At present, coexistence in Spain is managed by following the good agriculture practices promoted by ANOVE, the National Association of Seed Breeders, which is published on a yearly basis and handed out along with seeds by the seeds distributors.

Having said that, as a result of Directive (EU) 2015/412 implementation, Spain will need to implement appropriate measures in border areas of their territory to avoid possible cross-border contamination into neighboring Member States in who may decide not to grow GE crops.

g) Labeling

Spain follows EU-harmonized legislation on labeling (Regulation European Commission (EC) 1829/2003 on Genetically Modified Food and Feed, and Regulation (EC) 1830/2003 on the Traceability and Labeling of Genetically Modified Organisms) and there is no "non-GMO" labeling regulation developed at the national level.

The EU food labeling regulations provide for a 0.9 percent threshold for the "adventitious," that is, accidental and technically unavoidable, presence of EU-authorized GE event in a non-GE food or feed. Food or Feed products containing amounts above 0.9 percent must be labeled as "Contains Genetically Modified Organisms".

Bt corn planted and harvested in Spain is mainly utilized for the production of domestic compound feed, which is by default labeled as containing "Genetically Modified Organisms" since the large majority of the soybean meal used in feed production is GE.

To avoid labeling as "Contains GMOs," on food packaging, the large majority of food manufacturers have eliminated GE products from food product composition.

More detailed information on the EU-harmonized labeling legislation is available in the EU-28 FAIRS Report well as the USEU website section on labeling.

h) Trade Barriers

- Asynchronous approvals:

The asynchronous approval of events cultivated in the United States and not authorized for imports in the EU-28 remain the main trade barrier. The beginning of GE corn plantings in the United States caused a drastic decline in United States corn imports to Spain. Depending on the size of the domestic crop, Spain needs to import between 9 and 12 million MT of grains. The expansion of GE crops in traditional grain suppliers to Spain has had a significant impact on trade flows. Ukraine, Serbia and Russia have progressively increased their market quota over the years at the expenses of lower imports from the United States, Argentina and Brazil (See **Graph 4**).

- GE-free Zones:

Aside from the commercial production and research areas for GE crops, some Spanish 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 in these zones.

- Renationalization of cultivation decisions:

The debate in regards to the renationalization of cultivation decision was first launched back in 2010, when Spain reacted cautiously. 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. For more information see Section c) Approvals for Imports within **Part B: Policy**.

i) 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 GE 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.

j) Cartagena Protocol Ratification

The EU is a signatory to the Cartagena's Biosafety Protocol (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 and in particular, the Support Unit within Directorate General for Agricultural Production and Markets

(protocolo.cartagena@magrama.es). 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.

k) 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-28 Biotechnology Report.

l) Related issues:

There is little official information on new breeding techniques being utilized in Spain, as for the time being, techniques such as mutagenesis or marker assisted selection are not subject of notification or authorization and do not need to be recorded. For more information see Section a) Product Development within **Part A: Production and Trade**.

m) Monitoring and testing

Spain monitoring and testing system is based on EU set rules. However, due to the country decentralized structure, testing and controlling are carried out at the regional level, while central government has the authority over 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. Only three shipments, originating from China (feed additives), were rejected in 2014 due to unauthorized presence of GE products in Spanish Border Inspection Points. To date, no shipments have been rejected in 2015.

n) Low Level Presence

As a member of the EU, Spain conforms to EU directives and follows EU regulations on agricultural biotechnology. Since July 2011 the EU legislation sets at 0.1 percent[3] 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.

The Spanish food industry would support a low-level presence (LLP) solution for food. At the government level, Spain's position is decided through the (CIOMG), which puts together representatives of each Ministry involved in the regulation of agricultural biotechnology (See **Regulatory Framework** Section). However, in those matters affecting directly consumers, such as LLP for food, AECOSAN plays a bigger role in the Council decisions.

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.

As the cultivation of GE crops and seed trade outside the EU continues to grow, the Spanish seed industry would benefit by clear rules regarding adventitious presence of GE seeds in conventional seed lots and a defined EU-wide threshold levels for labeling prior to any other regulatory development.

Part C: Marketing

a) Market Acceptance

The presence of GE labeled consumer-oriented products is very limited in the Spanish market. The large majority of food manufacturers have eliminated GE products from food product composition to avoid labeling as "Contains GMOs."

On the contrary, 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.

[3] *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 products of agricultural biotechnology for which an authorization procedure is pending in the EU or for which an authorization has expired.*

Meat obtained from animals fed with GE feed does not have to be labeled so end consumers cannot show a preference in their meat purchases.

b) Public/Private Opinions

Spain's government has traditionally taken a pragmatic and science-based approach to the agricultural biotechnology regulatory process. Spain works hard to ensure that science is an important ingredient in the decision making process. Spain defends the role of the European Scientific institutions.

Within the agricultural sector, biotechnology is perceived as a tool to improve the competitiveness of farms through higher yields and lower input use. The use of agricultural biotechnology is also considered beneficial for the agro-food sector as a whole given the country's dependency on imported raw materials. The large majority of Spain's farmers associations are in favor of planting GE 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. However, since Bt corn is the only GE crop currently approved for cultivation in the EU, not all farmers benefit directly from the use of agricultural biotechnology. Approval of new traits that would address issues affecting different crops, or crops oriented to consumers benefits would raise the interest among other growers, regions and/or consumers.

The Spanish feed and livestock industries have been traditional supporters of agricultural biotechnology. Spain boasts of one of the EU largest livestock sector and, in the case of the pork sector, exports nearly one third of the production to EU and third markets. Consequently, given that livestock producers face global competition and Spain's dependency on imported feedstuffs, the Spanish feed and livestock industry have claimed on numerous occasions an increased access to GE products will help them compete equally in the world markets.

There is not a strong reaction from Spanish retailers or meat consumers to meat fed with GE feed.

c) Marketing Studies:

There are not many recent country-specific studies on marketing or acceptance of agricultural biotechnology in Spain.

In regards to public perceptions on agricultural biotechnology, Eurobarometer 2010 concluded that Spain's index of optimism for agricultural biotechnology/genetic engineering was among the highest within the EU (74 percent) and so is 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).

In a more recent study (August 2013) carried out by the Food and Resource Economics Department from the University of Florida comparing perceptions of biotechnology in fresh versus processed food Spain was categorized as a country with low-rejection of GE food. The study also stated that respondents in Spain showed optimistic attitudes of towards the benefits of agricultural biotechnology and a high proportion of them were assigned to a GE tolerant cluster. The University of Florida study concluded that the benefit valued the most from respondents in Spain was the reduction of pesticide use that genetic engineering allowed.

Regarding GE crops production benefits, a study on "*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 in 2012 by the Spanish Journal to Agricultural Science, a publication managed by INIA (Spanish Public Agricultural Research Institute), concluded that the use of Bt corn in Spain increases farmers' partial gross margins [4]by 95 Euros per hectare on average.

Another study published in November 2013, entitled *"15 years of Bt maize cultivation in Spain: Economic, social and environmental benefits"* and founded by the Antama Fundation[5], highlighted how the cultivation of Bt corn in Spain since has reduced total corn imports by more than 853,000 MT.

A study entitled *Genetically Modified Soy: an irreplaceable raw material in the EU. Assessment of Alternatives and Economic impact on the Spanish Feed and livestock farming sector*, by Francisco J. Areal. University of Reading (United Kingdom) concludes that soybean products are key for feed production given its high protein content and its high protein price competitiveness. Genetically engineered soybean and products imports to Spain during the period 2000-2014 has meant 55,000 million euros in savings when compared to the alternative of importing conventional soybean and products during the same period. According to this study, the replacement of GE soybean products by

[4] *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).*

[5] *Fundacion Antama is a non-profit organization that promotes awareness of new technologies applied to agriculture. The Foundation is supported by the seed companies based in Spain and institutions in favor of agricultural biotechnology.*

conventional soybean products would mean a price increase of soybeans and soybean meal by 291% and 301%, respectively.

Part D: Capacity Building and Outreach

a) Activities

FAS Madrid has not carried out any capacity building or outreach activity using USDA funds.

FAS Madrid continues maintaining and sharing information available on agricultural biotechnology related issues with key stakeholders, serving as a source of reliable information.

FAS Madrid monitors regulatory developments at the country and regional levels. FAS Madrid engages with host country officials during the EU decision-making process or when EU directives are transposed into national law. This is in an effort to inform them on key technical issues, U.S. position and potential trade implications as FAS Madrid tries to contribute to the elaboration of rational policies that do not undermine Spain and United States common interests.

b) Strategies and Needs:

N/A

Chapter 2: Animal Biotechnology

Under Animal Biotechnology, Animal Genetic Engineering and Animal Cloning are included. 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

a) Product Development

There is no known research or development of GE animals intended for the food market in Spain.

Research conducted using **animal biotechnology** is permitted although it is subject to prior notice through the same procedure and institutions as plant biotechnology. According to the public log managed by the Spanish Ministry of Agriculture, Food and Environment, notifications of confined research on GE animals throughout 2014 was carried out with mice and zebra fish for medical purposes. To date, no confined research in animals has been reported by competent authorities in 2015. However, it is our understanding that most of the notifications consist on basic science research for pharmaceutical purposes carried out by public institutions.

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.

There is no public register of research in cloning and notification on cloning research is not mandatory. According to information provided by media, cloning is limited to research activities and attempts include so far:

- Wild goat 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) in 2003.

- Cloned mice by a public institution (Department of Cell Biology, Physiology and Immunology at the Autonomous University of Barcelona (UAB) in 2009.

- Cloned swine by the Department of Animal reproduction at the Murcia University in 2009

- Cloned bullfighting bull by researchers at Valencia's foundation for Veterinarian Investigation along with the Center for Investigation Prince Felipe in Valencia in 2010. Reportedly, this bull did not present the original bull's desired behavior and was dismissed from breeding purposes.

- Reportedly, in 2014 Scientists from the Centre of Research and Agro-food Technology of Aragon (CITA) failed to collect enough funds for a second attempt to clone a Pyrenean Wild goat.

b) Commercial Production

There are neither GE animals nor cloned animals commercially used in Spain. There is no production of GE animals or clones intended for the food market in Spain. GE animals in Spain are authorized for research purposes.

c) Exports:

Spain does not produce commercial **GE animals**, **clones** or products; hence there are no known exports within these categories.

d) Imports:

GE animals have been imported to Spain for research purposes. Genetically engineered animal imports are subject of notification to customs authorities.

Since import documents do not indicate whether embryos or semen is sourced from a **cloned animal**, the Spanish livestock industry may have imported semen and embryos from cloned animals.

Part F: Policy

a) Regulation

Genetically engineered 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**). Additionally, specific regulations for animal research were introduced by Royal Decree 53/2013.

Regarding **cloning**, there are two ministerial departments involved in the position definition: the Ministry of Agriculture, Food and Environment and the Ministry of Health.

- Ministry of Agriculture, Food and Environment: Within the Ministry of Agriculture, Food and Environment, there are different units that play a role in the decision making process in cloning related issues. The Sub directorate General for Livestock Resources coordinates cloning and it has a technical approach to cloning as a breeding technology. The Sub directorate General for Animal Health watches animal welfare implications. Also, the Sub Directorate General for Sanitary Agreements and Border Control has a role in enforcement if restrictions to trade were to be implemented.

- Ministry of Health: AECOSAN (Spanish Consumption, Food Safety and Nutrition Agency) an independent agency ascribed to the Ministry of Health, whose constituents are consumers, is invited to weigh in food risk related aspects and pays particular attention to the placing on the market of food from animal clones.

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.

After an internal debate assessing the Commission's proposals, national authorities decided to continue to defend a science-based approach in the decision making process pertaining to cloning.

Spain's position in regards cloning agrees with the Commission's proposals[6]. Spain's administration agrees on the absence of food safety issues, however, concerns about ethical and animal welfare implications still exist. The Government of Spain would rather limit cloning within the EU to endangered species, animal breed preservation and pharmaceutical applications.

Government officials support a pragmatic approach about placing food from animal clones on the market. While it would ban the import of clones, it will stablish no restriction in regards to placing in the market food or animal products (semen and embryos) derived from clones and would also defend the lack of labeling and traceability requirements for offspring, as they are impossible to detect by analytical means. .

b) Labeling and Traceability:

Spain has implemented EU legislation on labeling and traceability. For more information on this topic, see the Consolidated EU-28 Biotechnology Report.

c) Trade Barriers

[6] *A proposal on the placing on the market of food from animal clones and a proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes.*

At the moment, there are no known trade barriers related to GE or cloned animals.

d) Intellectual Property Rights

Spain has implemented EU legislation. For more information on this topic, see the Consolidated EU-28 Biotechnology Report.

e) International Treaties/Fora

Spain's participation in international treaties and fora is no different from that of the EU. For more information on this topic, see the Consolidated EU-28 Biotechnology Report.

Part G: Marketing

a) Market acceptance

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 or the recovery of endangered species is generally regarded favorably.

EU wide and Member States specific perceptions about animal cloning can be found in the 2008 Eurobarometer Report "Europeans' attitudes towards animal cloning"

b) Public/Private Opinions

Spain is a country with a robust livestock sector and is pragmatic regarding the use of new technologies in the field of agriculture and livestock production.

Similarly to the situation in other countries, while the technical experts understand the technology and defend a science-based approach, fears about public opinion still weigh heavy in the decision making process. Experts agree on the fact that cloning is not a food safety issue, however, animal welfare and ethical aspects raise concerns.

Spanish livestock breeding interest has showed a limited interest in cloning so far due to the high-implied costs. Additionally, while the preservation of positive productive traits through cloning is considered beneficial by livestock breeders, the erosion of biodiversity is considered as a blockage for this technology.

f) Market studies:

There are not many country-specific studies on marketing or acceptance of cloning in Spain. However, the use of cloning for endangered species with particular focus in the Pyrenean Wild Goat has recently been published in the Conservation Biology Magazine: *The Arguments against Cloning the Pyrenean Wild Goat*.

Part H: Capacity Building and Outreach

a) Activities:

FAS Madrid has not carried out any capacity building or outreach activity using USDA funds.

FAS Madrid serves as a source of reliable information and continues maintain and share information available on animal biotechnology and cloning related topics with key stakeholders.

b) Strategies and needs:

N/A

Related Reports

Report Title	Date Released
Agriculture Biotechnology Annual 2014– EU-28	01/09/2015
Agriculture Biotechnology Annual 2014 – Spain	06/20/2014
Spain Continues Expansion of GE Corn Plantings	09/25/2013
Agriculture Biotechnology Annual 2013– EU-27	09/10/2013
Agriculture Biotechnology Annual 2013 – Spain	07/10/2013
MON810 Corn Area Hits New Record in the Iberian Peninsula	10/08/2012
MON810 Corn Area Reaches Record Level on the Iberian Peninsula	10/06/2011