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## Spain

### Agricultural Biotechnology Annual

**2017**

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**Report Highlights:**

Spain is the largest grower of Bt corn in the EU-28 and has traditionally defended a science-based approach to agricultural biotechnology decisions. In Spain, GE corn plantings coexist with conventional corn since 1998. Spanish farmers can decide to grow biotech or conventional crops based on market conditions. Practically all feed marketed is default labeled as “contains GE products. On the food side, domestic manufacturers continue to reformulate to avoid the “Contains GMOs” claim; meanwhile an increasing number of imported consumer-oriented products are sold with the “Produced from GE crops” wording.

**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 Biotechnology Annual Report](#).

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## **Acronyms used in this report**

CGF Corn Gluten Feed  
DDGS Distiller's Dried Grains and Solubles  
EC European Commission  
EFSA European Food Safety Authority  
EU European Union  
FAS Foreign Agricultural Service  
GATS Global Agricultural Trade System  
GE Genetically Engineered  
GMO Genetically Modified Organism  
INIA Spanish Public Agricultural Research Institute  
IB Innovative Biotechnologies  
GTA Global Trade Atlas  
Ha Hectares  
MAPAMA Ministry of Agriculture, Fisheries, Food, and Environment  
MS Member State(s)  
MT Metric ton (1,000 kg)  
N/A Not available

## **Section I. Executive Summary**

Spain continues to defend a science-based and pragmatic approach to agricultural biotechnology decision making with regards to both cultivation and imports and consistently votes in line with EFSA's recommendation.

Spain is the largest grower, and along with Portugal, the only two cultivators of GE crops in the EU-28. Spanish area planted to GE corn represents 95 percent of total EU-28 area planted to GE crops. MON810 corn has been commercially grown in Spain uninterruptedly since 1998. Total area planted to corn varies every year based on water availability, irrigation costs, prices paid to farmers, pest presence and competition from alternative crops. GE corn and conventional corn plantings in Spain coexist. It is up to the farmer to decide what to plant based on previous season's corn borer incidence and market conditions for GE or conventional corn. Poor corn crop margins and the fact that the large majority of domestic food manufacturers, who normally purchase corn at a premium price and have eliminated GE products from food product composition to avoid labeling as "Contains GMOs," may have contributed to some farmers opting to plant conventional corn varieties.

GE Field trials are allowed in Spain, although subject to prior notice and authorization. Despite the unattractive investment environment for seed companies, in 2017 five different GE crops (wheat, canola, tobacco, potato and corn) are being tested.

Given Spain's structural shortfall of grains and protein crops, cultivation and imports of genetically engineered (GE) crops and products are essential for its robust export-oriented livestock sector. GE products imported to Spain consist mainly of corn and corn processing by-products and soybeans and products.

From the consumption perspective, practically all feed is default labeled as "contains GE products. While domestic food manufacturers continue to reformulate to avoid the "Contains GMOs" claim, an increased number of imported consumer-oriented products are sold with the "Produced out of GE crops" wording.

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

As for GE animals, subject to prior notice and authorization, research is permitted and abides by the same rules as those for GE plant research. Most of the notifications in this area consist of basic research for pharmaceutical purposes carried out by public institutions. However in 2017, INIA, the Spanish Public Agricultural Research Institute, communicated activities on GE rabbits, goats and sheep to study the molecular processes of reproduction.

## **Section II: Plant and Animal Biotechnology**

### ***Chapter 1: Plant Biotechnology***

#### **Part A: Production and Trade**

##### **a) PRODUCT DEVELOPMENT**

Both confined research and deliberate release (cultivation) to the environment of GE plants are permitted in Spain subject to prior notice, public information, and authorization ([Law 9/2003 – in Spanish](#)).

Confined research may be carried out on Innovative Biotechnologies (e.g. CRISPR/Cas, mutagenesis or marker assisted selection) since these technologies are not subject to official authorization and do not need to be reported. Despite the confined research and deliberate release can be carried out in the country, no new GE or Innovative Biotechnologies development are anticipated to be in the market within the next five years.

Spanish-based seed breeding companies see great potential for innovative biotechnologies for their breeding programs. Clustered Regularly Interspaced Short Palindromic Repeats and associated proteins

(CRISPR/Cas) is the technique considered the most promising. Whether or not this technology achieves full potential at the commercial level depends on a favorable regulatory framework.

For regulatory aspects of innovative biotechnologies, please see **Part B: Policy Section e) Innovative Biotechnologies**.

- Confined Research:

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

Up to date, in 2017, no confined research activities on GE plants have been communicated to competent authorities. Additional research may be 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 the Joint Research Center, in 2017, notifications for deliberate release into the environment of GE plants for any other purposes than placing on the market are:

- Multiplication of transgenic **wheat** lines derived from IND-ØØ412-7 event containing the bar gene, which provide tolerance to ammonium glufosinate-based herbicides, and the HaHB4 gene that gives hydric stress tolerance.
- Validation of flowering time and life cycle of transgenic Westar **canola** lines under field conditions.
- Biomass production assay in **tobacco** genetically modified with the adrenomedullin gene.
- Use of plastidial Glucose 6P dehydrogenase for production of **potato plants** with increased starch content.
- Evaluation of **corn** lines of A188 variety with high starch content by the increment of Sucrose synthase (SuSy) activity.

In **2016**, two notifications –the amplification and evaluation of a transgenic corn line with biofortified endosperm with three vitamins and evaluation of a transgenic corn Bt line (Cry1Ac, Cry1C and Vip3) and its hybrid Carolight (CaroBt)- were withdrawn by the requester. A notification on the validation of flowering time and life cycle of transgenic Westar canola lines under field conditions was submitted.

Notifications to competent authorities for open field testing remain very low, reflecting public and private sector limited interest in developing GE crops adapted to Spain's conditions given the uncertain regulatory environment.

**Graph 1. Open Field Trials Notifications to Competent Authorities**



Source: Foreign Agricultural Service (FAS) Madrid based on Joint Research Center Information.  
\*2017 data are based on data available up to November 1<sup>st</sup> 2017.

## 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, crop margins, competition from alternative crops and public incentives in place (**Table 1**).

Twenty years after the first commercial planting in Spain, total corn area has declined by nearly 3 percent in Marketing Year (MY) 2017/18, registering an accumulated 20 percent reduction in area during the last five consecutive years. The corn area reduction in MY2017/18 is mainly explained by poor crop margins, competition by other crops and limited amounts of water for irrigation purposes in certain areas, along with the overall long term trend of increasing tree crops area at the expenses of arable crops and/or fallow land.

While crop diversification established by greening<sup>1</sup> may have played a role in reducing corn plantings, there are some corn growing areas, where area planted with corn is extremely inelastic as there are few other options available.

The large majority of Spain-based **feed grain** elevators, with the exception of those devoted to special market niches, do not keep separate production lines for GE and non-GE corn, as practically all

<sup>1</sup> 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.

marketed feed contains GE soybean as a source of protein, and consequently it is default labeled as “contains GE products.”

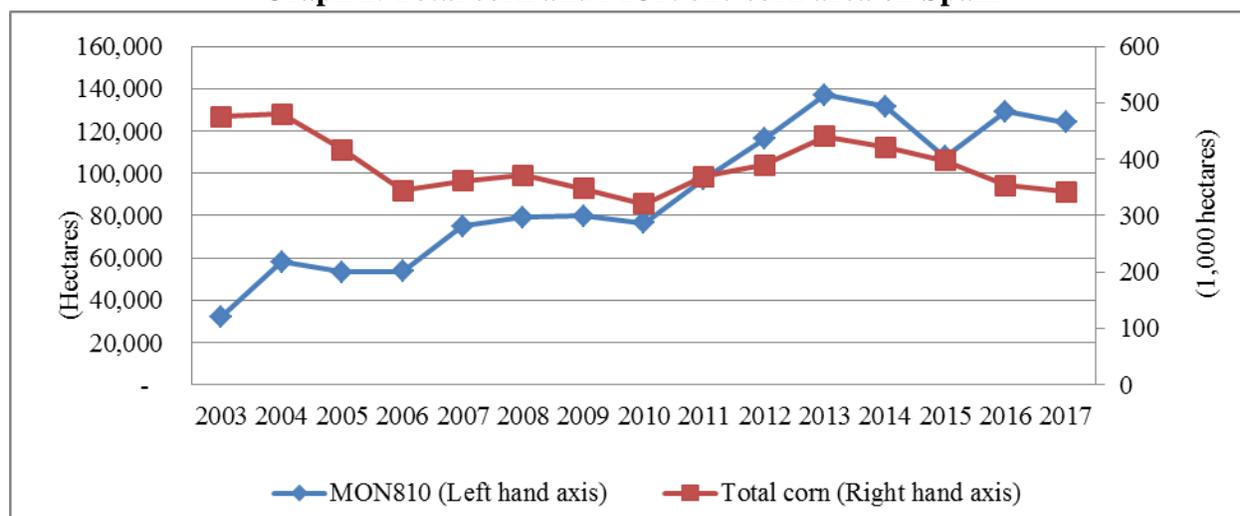
The corn processing industry whose production is intended to enter the **food chain** (wet millers and dry millers) source corn from GE free sources, in many cases under Identity Preserved (IP) programs.

**Table 1. Spain’s Corn Area and Production\***

Marketing Year	MY2013/14	MY2014/15	MY2015/16	MY2016/17	MY2017/18e
Area (1,000 Hectares [Ha])	431.7	421.6	398.2	353.2	342.0
Production (1,000 MT)	4,930	4,811.5	4,565.1	3,919.6	3,475

Source: MAPAMA and FAS Madrid estimates. \*Includes GE and non-GE corn.

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



Source: FAS Madrid based on MAPAMA data<sup>2</sup>.

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. In **2014** this tendency was stalled and Bt corn area declined. Further decline in Bt corn area was registered in **2015**, when the corn borer incidence was high. In **2016**, the previous seasons’ abnormally high pressure of the corn borer, led farmers to an extensive use of GE corn.

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

Region	2012	2013	2014	2015	2016	2017
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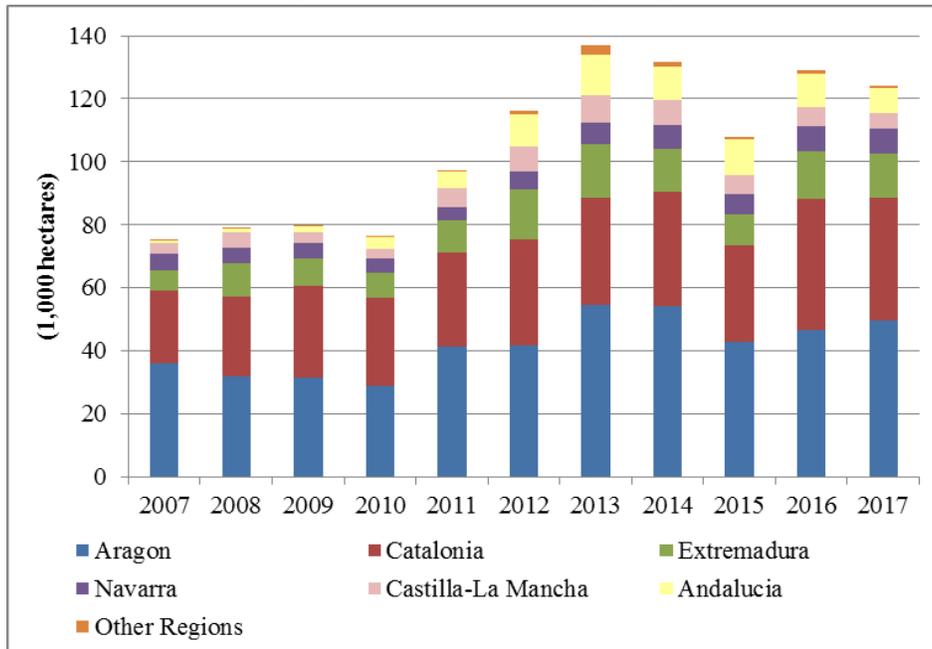
<sup>2</sup> Since 2009, the Spanish Ministry of Agriculture, Food and Environment (MAGRAMA) publishes GE crop area including not only corn varieties in the national register in the EU common catalogue, but also those varieties granted with a provisional authorization. Figures from 2009 up to present in the chart above have been updated accordingly.

<b>Aragon</b>	41,669	54,451	54,041	42,612	46,546	49,608
<b>Catalonia</b>	33,531	33,996	36,381	30,790	41,567	39,092
<b>Extremadura</b>	15,952	16,979	13,815	9,827	15,039	13,976
<b>Navarra</b>	5,801	7,013	7,264	6,621	8,066	7,778
<b>Castile-La Mancha</b>	7,883	8,766	7,973	5,734	5,932	5,039
<b>Andalusia</b>	10,362	12,862	10,692	11,471	10,919	8,013
<b>Others</b>	1,109	2,895	1,371	695	1,011	691
<b>Total</b>	<b>116,307</b>	<b>136,962</b>	<b>131,538</b>	<b>107,749</b>	<b>129,081</b>	<b>124,197</b>

Source: MAPAMA.

Data available for **2017** indicate that the Ebro River basin (autonomous regions of Aragon and Catalonia) has the largest share of GE corn, accounting for over 70 percent of Spain's total GE corn plantings, as the corn borer is endemic in this area. GE corn has declined in all regions where it is cultivated, with the exception of Aragon where it share increased 13 percent in **2017 (Graph 3)**.

**Graph 3. GE Corn Area by Region**



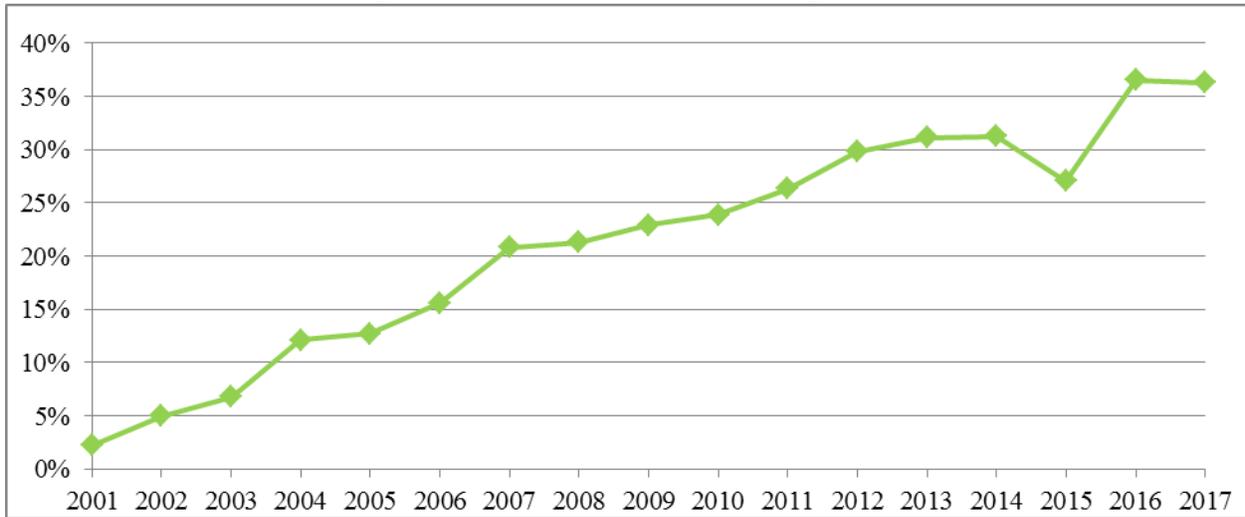
Source: FAS Madrid based on MAPAMA data.

As MON810 is the only GE event approved for cultivation in the EU, possibilities of growth are limited to those areas where the corn borer represents a problem. Approvals of new traits could raise the interest for GE crops in other regions of the country.

The fact that the large majority of domestic food manufacturers have eliminated GE products from food product composition to avoid labeling as “Contains GMOs” limits GE crops to those farmers supplying exclusively the animal feed industry. Better prices paid by the food corn processing industry along with irrigation water limitations resulting in a shift towards forage corn production, may have also contributed for some farmers to increase plantings of conventional corn varieties.

The decline in GE corn plantings (4 percent) has been slightly higher than the overall corn area decline (**Graph 2**). GE corn share in 2017 (36.3 percent) is marginally down from 36.6 percent historical record achieved in 2016 (**Graph 4**).

**Graph 4. MON 810 Area Share in Spain (%)**



Source: FAS Madrid based on MAPAMA data.

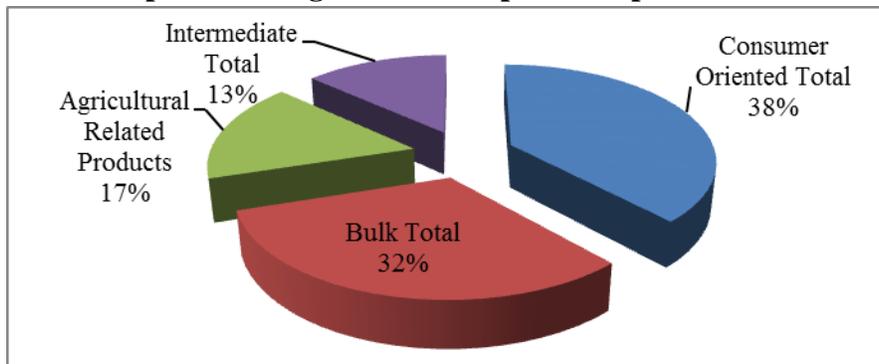
**c) EXPORTS**

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. 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) IMPORTS**

United States agricultural exports to Spain consist mainly of bulk commodities and consumer-oriented products, which accounted for 32 and 38 percent of the U.S. exports value in the period 2012-2015. Soybeans and tree nuts are the largest categories within these groups representing respectively nearly 22 and 35 percent of total agricultural trade (**Graph 5**).

**Graph 5. U.S. Agricultural Exports to Spain in value**



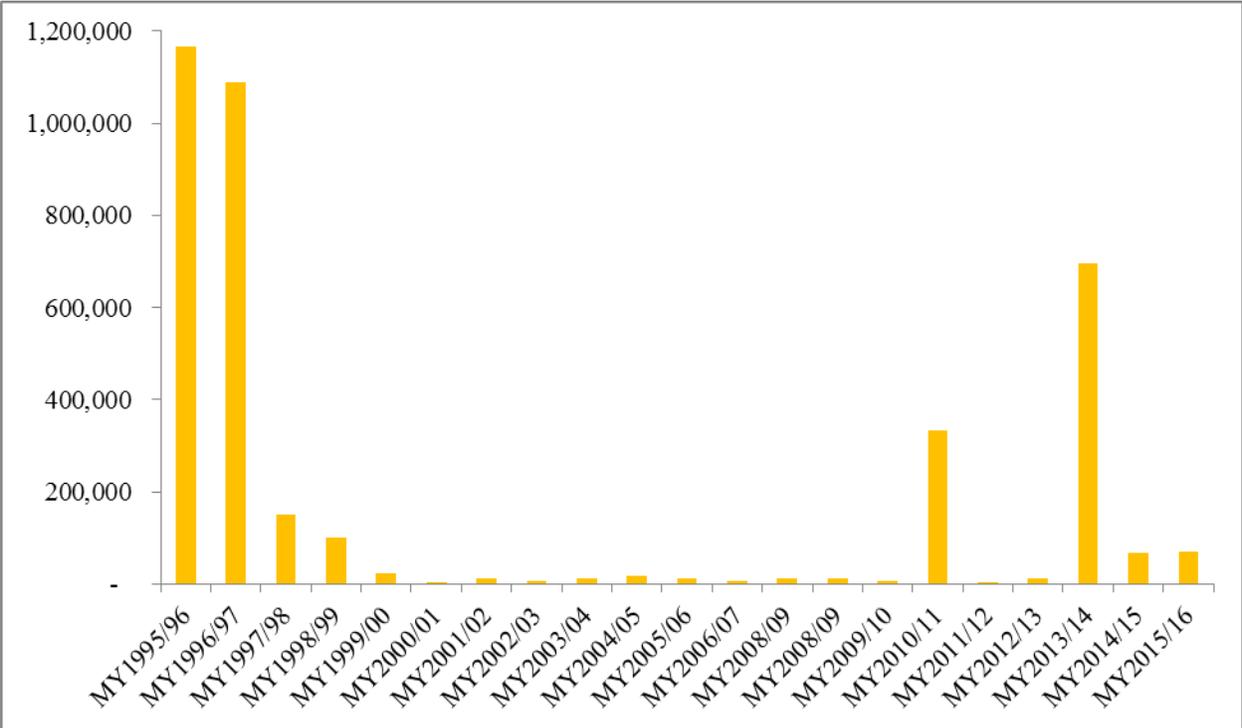
Source: FAS Madrid based on GATS data.

Spain imports a large amount of GE crops and products. The country’s dependency on imported feedstuffs and the science-based approach to GE crops have contributed to a high acceptance of the technology among farmers and ranchers, which has resulted in the expansion of GE crops cultivation and imports over the years. Products from agricultural biotechnology imported to Spain consist mainly of corn and corn processing by-products, soybeans and biotech products originating from countries such as in Brazil, Argentina, and the United States.

Spanish total grain imports range 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 price competitiveness compared to other feed grains. While corn imports have grown, the United States corn share of imports is negligible due to the fact that not all GE events produced in the United States are approved for import into the EU (asynchronous approval).

**Graph 6** contains U.S. corn exports to Spain throughout the last 20 years. It shows a drastic decline of U.S. corn exports to Spain starting in 1998, when GE corn was first planted in the United States. This is a direct consequence of the asynchronous GE events approvals between the United States and the EU.

**Graph 6. U.S. Corn Exports to Spain (MT)**

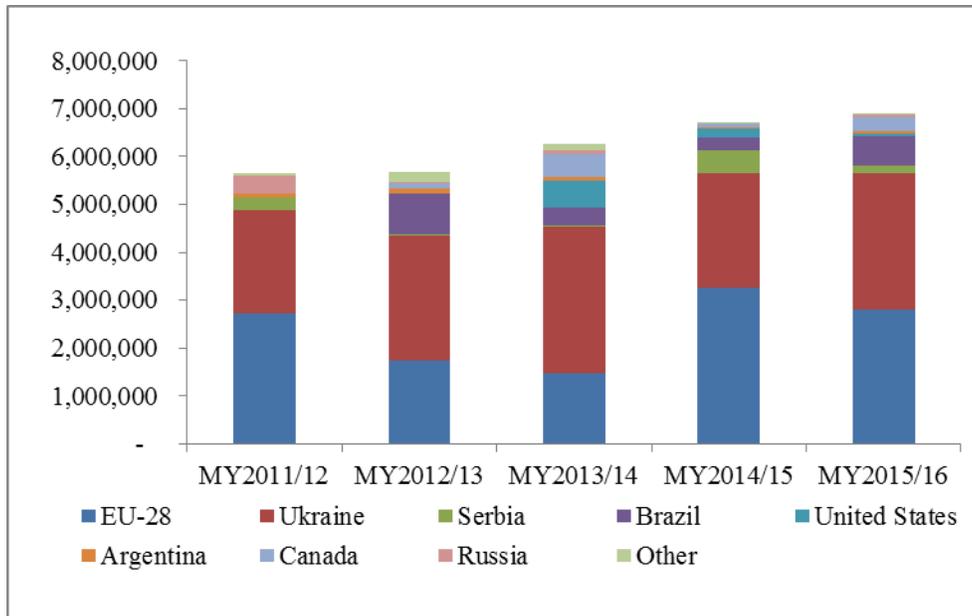


Source: Global Trade Atlas (GTA)

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 majority of the Spain’s grain imports (**Graph 7**).

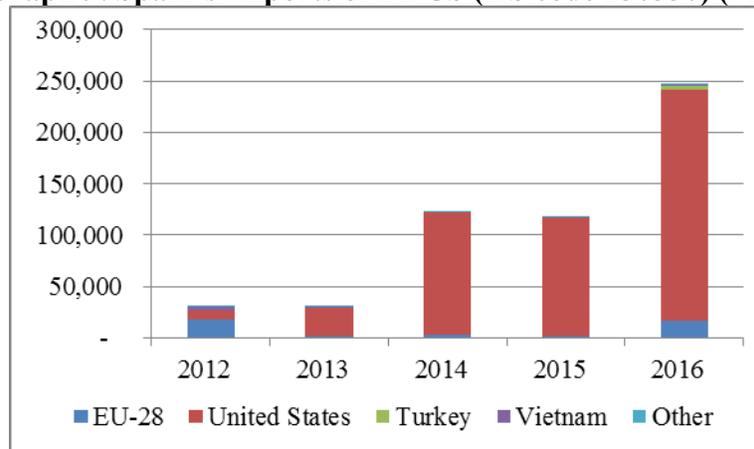
**Graph 7. Spain’s Corn Imports by Origin (MT)**



Source: Global Trade Atlas (GTA)

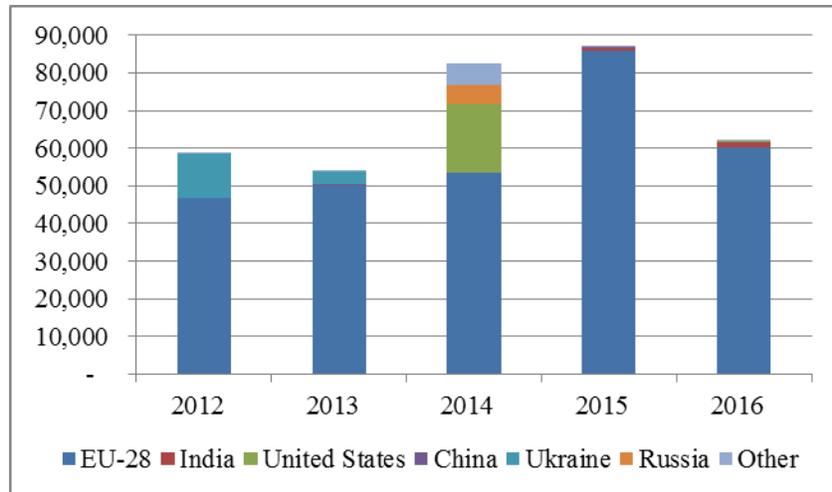
With regards to corn processing by-products, **Graph 9** demonstrates how since 2016, lower bioethanol production in the Spain has opened up new opportunities for Distiller’s Dried Grains and Soluble (DDGS) imports, in particular from the United States. In the case of Corn Gluten Feed (CGF) (**Graph 10**) intra-EU trade was particularly high in 2015.

**Graph 9. Spain’s Imports of DDGS (HS code 230330) (MT)**



Source: Global Trade Atlas (GTA)

**Graph 10. Spain’s Imports of CGF (HS code 230310) (MT)**

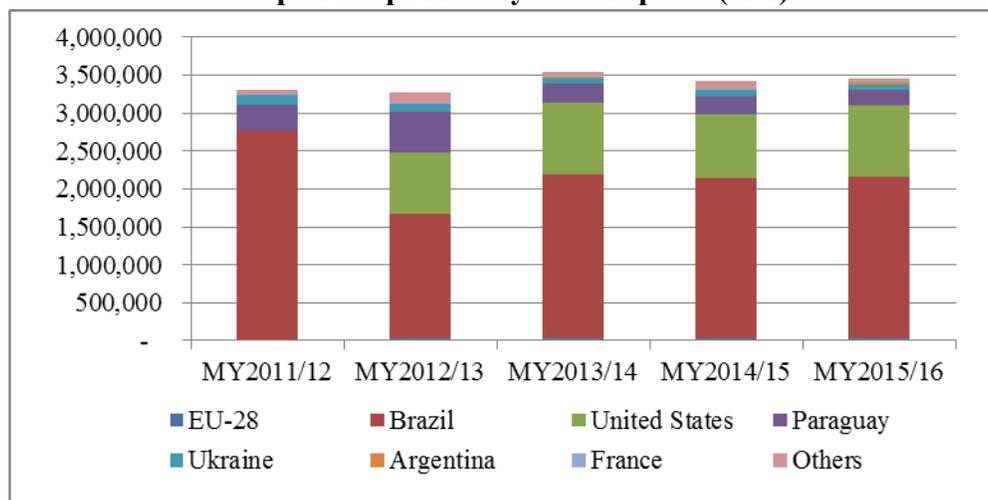


Source: Global Trade Atlas (GTA)

As it pertains to soybean and soybean products, the majority of Spain's imports are GE. 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 sector of imports.

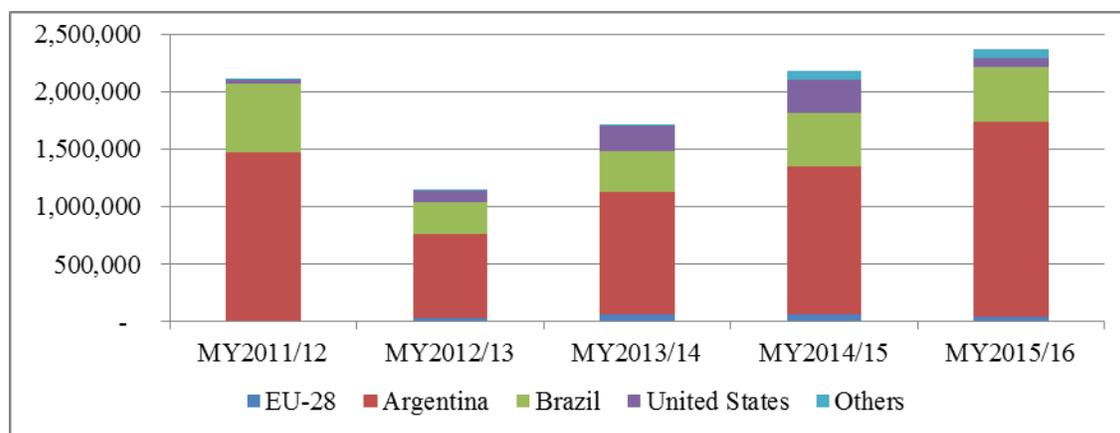
While Brazil and the United States supply the large majority of the Spanish soybean imports (See **Graph 10**), Argentina and Brazil combined supply most of the soybean meal import market (See **Graph 11**).

**Graph 10. Spain's Soybean Imports (MT)**



Source: Global Trade Atlas (GTA)

**Graph 11. Spain's Soybean Meal Imports (MT)**



Source: Global Trade Atlas (GTA)

### e) FOOD AID RECIPIENT COUNTRY

Spain is not a recipient of food aid and it does not provide GE commodities for food aid.

While in the case of emergencies, when the local markets have collapsed, in-kind food aid may be given, normally, in order to avoid pushing local prices down and discouraging domestic production in recipient countries, local purchases in recipient countries are preferred.

Spain is founding member of IFAD (International Fund for Agricultural Development), the UN Agency created to enable poor rural people to overcome poverty and hunger. It is also a member of FAO and a strong supporter of the World Food Program.

Within Spain's Ministry of Foreign Affairs and Cooperation, the Spanish Agency for International Development Cooperation (AECID) created in 1988, is responsible for elaboration, execution and management of the cooperation programs and projects, either directly, through its own resources or the collaboration with other national or international organizations and Non-Government Organizations (NGOs). This Agency, ascribed to the Under-Secretariat for International Cooperation (SECI) has an extensive structure overseas.

### f) TRADE BARRIERS

- **For bulk commodities and consumer-oriented products**

The asynchronous approval of GE events cultivated in the United States yet not authorized for import to the EU-28 remains the main trade barrier.

The expansion of GE crop production in traditional grain supplying countries had a significant impact on trade flows to Spain. For instance, in the corn market, 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 7**). Additionally, the little room for adventitious

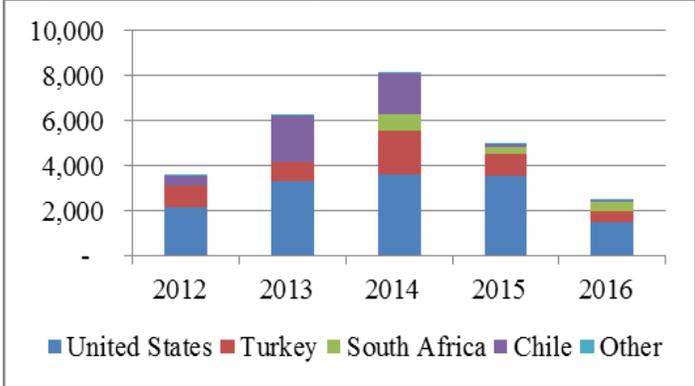
presence for non-approved events continues being a constraint for traders, who carry out a no-risk policy in their purchases.

The presence of GE labels on **consumer-oriented** products is very limited in the Spanish market. The large majority of food manufacturers and processed food importers have either eliminated GE ingredients from food product composition or switched to GE free suppliers, respectively in order to avoid labeling and marketing food products with the claim “Contains GMOs”.

- **For Seed :**

Seed trade is affected by the zero tolerance of adventitious presence. The fact that the EU-28 only allows cultivation of MON 810, serves as a trade barrier for U.S. seed exports containing or with adventitious presence of other GE events. A threshold level for adventitious GE material presence has not yet been set. As a consequence, Spain is forced to source its corn seeds mainly in other EU-28 Member States (mainly France), which are the origin of 94 percent of Spain seed corn imports. Extra EU origins of corn seed, which only represent 6 percent of the seed import market, include origins such as the United States, Turkey, South Africa and Chile, where seed is produced under restrictive conditions that prevent from cross-contamination with seed from non-approved cultivation events.

**Graph 12. Spain’s Extra EU Imports of Corn Seeds (HS code 100510)**



Source: Global Trade Atlas (GTA)

## 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 the [EU-28 Biotechnology Annual Report](#).

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 \(in Spanish\)](#). [This applies to both the confined use and environmental release](#).

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 \(in Spanish\)](#).

### **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 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, Fisheries, Food, and Environment (MAPAMA), 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 \(in Spanish\)](#).

### **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 \(in Spanish\)](#). At present there are nearly 115 GE corn varieties approved for commercial cultivation.

Within the MAPAMA, 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 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 \(in Spanish\)](#). 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 upcoming decisions and it is entitled to prepare proposals for examination 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. 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 European Commission [website](#) 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.

- For cultivation:

Spain's position on renationalization of cultivation decisions evolved through the years. When this debate 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. Initially, the 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 was going to be carried out in 2016. However, [Law 50/1997](#) (in Spanish) on Government's role, sets that acting government's activity "shall be limited to the ordinary resolution of public affairs and shall not adopt any other measure except in the case of

emergencies or general interest, both duly confirmed,” having hence no capacity to transpose this piece of EU regulation to National Law.

[Royal Decree 364/2017](#) amending [Law 9/2003 \(in Spanish\)](#) transposes [Directive \(EU\) 2015/412](#) into National Law. The National Law establishes that in those cases where GE corn cultivation takes place near to borders with Member States that have banned GE cultivation, there will be measures put in place to avoid cross-border contamination.

The measures to be implemented will be decided by the Ministry of Agriculture, Fisheries, Food and Environment based on a Risk Evaluation carried out by the National Biosafety Commission (CNB). The Government will invite the involved Autonomous Regions to weigh in.

The measures defined will be proportional, no discriminatory, elaborated on a case-by-case basis and will observe the precautionary principle.

#### **c) STACKED EVENTS APPROVALS**

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

#### **d) FIELD TESTING**

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

#### **e) INNOVATIVE BIOTECHNOLOGIES**

There is little official information on innovative biotechnologies 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.

On request of the Cibus Company, the Spain’s National Biosafety Commission (CNB) studied Cibus rapeseed (an herbicide tolerant rapeseed obtained through oligonucleotide-mediated mutagenesis). On their October 9th 2014 meeting took, whose [summary](#) (in Spanish) publically available in the Ministry of Agriculture, Fisheries, Food, and Environment website, the CNB board members informed that they had concluded that the Cibus Rapeseed should be excluded from the scope of Directive 2001/18. However, if the company decided to carry out field trials additional information on the trial conditions, development and outcome would be required.

Spain’s competent authorities are waiting for additional guidance from the European Commission on Innovative Biotechnologies. Additional information can be found at [E16013](#).

For more information see Section a) Product Development within **Part A: Production and Trade**.

## **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. Latest version of the recommendations is available in the [link \(in Spanish\)](#).

Having said that, as a result of [Directive \(EU\) 2015/412](#) implementation by Royal Decree 364/2017, Spain has defined how it intends to avoid possible cross-border contamination into neighboring Member States not growing GE crops. Additional information can be found in Section C) on Approvals.

## **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 per ingredient 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 Food and Agricultural Import Regulations and Standards Report](#) well as the [USEU website section on labeling](#).

#### **h) 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 conducted 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 2017, only two shipments were rejected due to unauthorized presence of GE products (cotton seeds that originated in Argentina) in Spanish Border Inspection Points. This is the first rejection of shipments due to unauthorized genetically modified presence since 2014.

#### **i) 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<sup>3</sup> 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.

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<sup>3</sup> *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.*

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 (United States, Turkey, South Africa and Chile). 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.

#### **j) 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. 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, Fisheries, Food, and Environment [website \(in Spanish\)](#).

#### **k) 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 \(in Spanish\)](#) 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, Fisheries, 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 further costs implied in the protected varieties registration.

- The Register of Commercial Varieties enables breeders 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 to provide seed breeders' with a 25 years protection period for those varieties in the Protected Plant Varieties Catalog.

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 with 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.

## **l) 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, Fisheries, Food, and Environment and in particular, the Support Unit within Directorate General for Agricultural Production and Markets ([protocolo.cartagena@mapama.es](mailto:protocolo.cartagena@mapama.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](#).

## **m) INTERNATIONAL TREATIES AND FORUMS**

Spain is a member of various international treaties and conventions, including the International Plant Protection Convention ([IPPC](#)) and the Codex Alimentarius ([CODEX](#)). Spain's Points of Contact for each of the organizations are available in the links.

However, being an EU member, Spain votes along EU lines, unless it is a non-EU harmonized decision, wherein each MS has the right to vote.

For more information, see the [EU-28 Biotechnology Annual Report](#).

#### **n) RELATED ISSUES**

- 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.

### **Part C: Marketing**

#### **a) 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 sectors 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.

### **b) MARKET ACCEPTANCE AND MARKET STUDIES:**

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.

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.

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, when asked about environmental issues that worried citizens, Spaniards showed less concern over the use of GE crops than the EU average (13 percent versus 19% of the Europeans). Both Spaniards and Europeans expressed more concern about agricultural pollution originated by the use of fertilizers and pesticides than for the use of GE crops (26 percent and 25 percent respectively, compared to the previously mentioned 13 and 19 percent).

The 2016 Survey on Social Perception of Science and Technology in Spain conducted by FECYT (Spanish Foundation for Science and Technology) on a bi-annual basis, concludes that 33.4 percent of

the participants in the survey consider that concerns on plant biotechnology overcome the benefits of the technology, down from the 41.7 percent registered in 2014.

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 <sup>4</sup>by 95 Euros per hectare on average.

Another study published in November 2016, entitled “[Bt maize cultivation in Spain: Economic, social and environmental benefits \(1998-2015\)](#)” and founded by the Antama Foundation<sup>5</sup>, highlighted how the cultivation of Bt corn in Spain since 1998 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 conventional soybean products would mean a price increase of soybeans and soybean meal by 291% and 301%, respectively.

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<sup>4</sup> 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).

<sup>5</sup> 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.

The study “[\*Economic, Social and Environmental Benefits of Bt corn cultivation in Spain \(1998-2015\)\*](#)” (in Spanish) by Francisco J. Areal. University of Reading (United Kingdom) released in 2016 highlights the benefits of biotech cultivation in Spain in terms of increased yields and crop margins, reduced import needs, improved corn health (lower mycotoxins incidence) and additional net CO<sub>2</sub> fixation.

## ***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 D: Production and Trade**

#### **a) PRODUCT DEVELOPMENT**

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, Fisheries, Food, and Environment, notifications of confined research on GE animals throughout **1998-2016** was carried out with hogs, mice, flies and zebra fish. Most of the notifications in this area consist of basic science research for pharmaceutical purposes carried out by public institutions. However in **2017**, INIA, the Spanish Public Agricultural Research Institute communicated activities on farm animals such as GE rabbits, goats and sheep to study the molecular processes of reproduction.

**Table 3. Confined Research with GE Animals Notifications**

Year	Hogs	Mice/Rats	Zebra fish	Flies	Farm animals*
1998	x				
1999		x			
2000		x			
2001		x			
2002		x			
2003		x			
2004		x			
2005		x			
2006		x			
2007		x			
2008	x	x			
2009		x			
2010		x			
2011		x	x		
2012		x	x		
2013		x			
2014	x	x	x		
2015	x	x			
2016	x	x			
2017		x	x	x	x

Source: FAS Madrid based on MAPAMA data

\* GE rabbits, goats and sheep

Research on animal genome editing is being carried out in Spain by public Institutions such as the National Center for Biotechnology (CNB). Basic research with CRISPR-Cas9 in mice has been carried out since 2013. Additional information can be found in the [link](#).

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 the 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.

#### **e) TRADE BARRIERS**

GE or cloned trade barriers in Spain are the same as those established at the EU level.

For more information about the European framework, please see the latest [EU-28 Biotechnology Annual Report](#).

## Part E: Policy

### a) REGULATORY FRAMEWORK

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 \(in Spanish\)](#).

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

- Ministry of Agriculture, Fisheries, Food, and Environment: Within the Ministry of Agriculture, Fisheries, 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 to cloning agrees with the Commission's proposals<sup>6</sup>. Spain's administration agrees on the absence of food safety issues, however, concerns about ethical and animal welfare

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<sup>6</sup> 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](#).

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 establish 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.

In late 2016, the Commission released a [study](#) on the feasibility of labeling and tracing systems for products derived from cloned animals and their offspring.

#### **b) INNOVATIVE BIOTECHNOLOGIES**

Spain has not regulated the use of innovative biotechnologies in animals.

#### **c) LABELING AND TRACEABILITY**

Spain has implemented EU legislation on labeling and traceability. For more information on this topic, see the [EU-28 Biotechnology Annual Report](#).

#### **d) INTELLECTUAL PROPERTY RIGHTS**

Spain has implemented EU legislation. For more information on this topic, see the [EU-28 Biotechnology Annual 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 [EU-28 Biotechnology Annual Report](#).

#### **f) RELATED ISSUES**

Not available

## **Part F: Marketing**

### **a) 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 breeders have 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.

The 2016 Survey on Social Perception of Science and Technology in Spain conducted by FECYT (Spanish Foundation for Science and Technology) on a bi-annual basis, concludes that 31.3 percent of the participants in the survey consider that concerns on cloning overcome the benefits of the technology, down from the 42.6 percent registered in 2014.

### **b) MARKET ACCEPTANCE/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 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](#)"

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\*](#).

## Related Reports

<b>Report Title</b>	<b>Date Released</b>
<a href="#">Dutch Proposal to Legislate NBTs</a>	10/04/2017
<a href="#">Change in voting behavior may lead to GE crops not being approved</a>	09/11/2017
<a href="#">Agriculture Biotechnology Annual 2016– EU-28</a>	12/16/2016
<a href="#">Agriculture Biotechnology Annual 2016 – Spain</a>	11/17/2016