

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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Required Report - public distribution

Date: 12/10/2018

GAIN Report Number: SP1830

Spain

Agricultural Biotechnology Annual

2018

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Report Highlights:

Spain is the largest grower of biotech corn in the European Union (EU) and a major consumer of genetically engineered (GE) soybean meal in animal feed. The country has traditionally defended a science-based approach to agricultural biotechnology. In June 2018, Spain split its cabinet level responsibilities for agricultural and environmental affairs into two different Ministries: the Ministry of Agriculture, Fisheries and Food, and the Ministry for Ecological Transition. This development has had no immediate impact on Spain's approach to biotechnology. The recent ruling by the European Court of Justice (ECJ) on new breeding techniques (NBTs) has sparked domestic discussions on the feasibility of its implementation at the Member State level. It has also raised concerns over its potential negative impact on Spain's research, and agricultural competitiveness.

Disclaimer: Spain, as a member of the 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

AECOSAN	Spanish Consumption, Food Safety and Nutrition Agency
CGF	Corn Gluten Feed
CIOMG	Inter-Ministerial Council for Genetically Modified Organisms
CNB	National Biosafety Commission
CPVR	Community Plant Variety Right
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
GOS	Government of Spain
GTA	Global Trade Atlas
Ha	Hectares
IB	Innovative Biotechnologies
INIA	Spanish Public Agricultural Research Institute
MAPA	Ministry of Agriculture, Fisheries and Food
MINECO	Ministry of Economy and Enterprises
MITECO	Ministry for Ecological Transition
MS	Member State(s)
MSCBS	Ministry of Health, Consumption and Social Welfare

MT	Metric ton (1,000 kg)
OEVV	Spanish Office for Plant Varieties

Glossary:

“Genetic Engineering” means transgenesis.

“Innovative biotechnologies (IB)” is used here as a synonym for the European term “New Breeding Techniques” (NBTs) and is generally referred to as genome editing. It excludes traditional genetic engineering (transgenesis), known in Europe as genetically modified organisms (GMOs).

EXECUTIVE SUMMARY

Spain allows GE (Genetically Engineered) and Innovative Biotechnologies (IB) confined research and field trials subject to prior notice and authorization. Spanish-based seed breeding companies see great potential for IBs for their breeding programs, however, no new GE or IBs developments are anticipated to be in the market within the next five years. The restrictive regulatory framework continues to discourage domestic research and development as well as prevent these technologies from achieving full potential at the commercial level.

Spain, along with Portugal, is one of the only two growers of GE crops in the EU. Spain is also the largest grower with Spanish GE corn planted area representing 95 percent of the total EU GE planted area. Spain’s total planted area for corn varies every year based on water availability, irrigation costs, prices paid to farmers, pest presence, and competition from alternative crops. In Spain, GE corn and conventional corn plantings coexist.

As the domestic production of feed ingredients is not sufficient to meet the demand of Spain’s robust export-oriented livestock sector, Spain relies heavily on imports of grains and oilseeds. GE products imported into Spain consist of soybeans and products but also corn and corn processing by-products. It is Spanish feed compounders’ general practice to label all feed by default as “contains GE products.”

In June 2018, Spain divided the former Ministry of Agriculture, Food and Environment (MAPAMA) into two different Ministries: the Ministry of Agriculture, Fisheries and Food and the Ministry for Ecological Transition. For the moment, this change has had no immediate impact on Government of Spain’s (GOS) approach to biotechnology. Spain continues to defend a science-based and pragmatic approach to regulating agricultural biotechnology concerning both cultivation and imports, and consistently votes in line with EFSA’s (European Food Safety Authority) recommendation.

The European Court of Justice (ECJ) ruling issued on July 25, 2018 to regulate genome editing as conventional GE products was reportedly a surprise to Spanish stakeholders. For the

scientific community, the ECJ decision is particularly worrisome as small research companies and public institutions that may not have the resources to navigate the burdensome approval process in place for conventional GE products. The ruling also sparked discussions on the feasibility of its implementation at the Member State level. Agricultural stakeholders have expressed their concerns about continuing to face third countries competition without having access to the same tools as their competitors. However, public awareness on this topic remains very limited.

Spain does not have a public register for 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 human consumption. 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.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

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

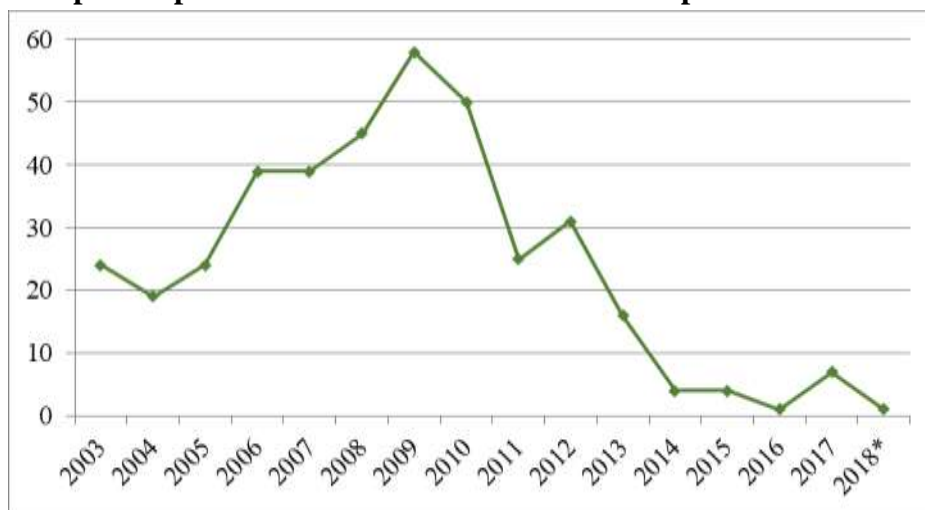
Confined research on Innovative Biotechnologies (IBs) may have been carried out in Spain since these technologies are not subject to official authorization and are not required to be reported. However, in the aftermath of the ECJ Ruling on July 2018, confined research on IBs is also subject to official authorization. Spanish-based seed breeding companies see great potential for IBs for their breeding programs. However, the restrictive regulatory framework discourages domestic research and development as well as prevent these technologies from achieving full potential at the commercial level. Despite the fact that confined research and deliberate release can be carried out in the country, no new GE or IBs development are anticipated to be in the market within the next five years.

For regulatory aspects of innovative biotechnologies and ECJ ruling implications at the Member State level, please see **Part B: Policy Section e) Innovative Biotechnologies**.

- **Confined Research:** To date, in 2018, no confined research activities on GE plants have been communicated to competent authorities. Additional research may be taking place, with notifications consisting of basic research for pharmaceutical purposes.

- **Field testing:** Notifications to competent authorities for open field testing remain very low, reflecting public and private sector limited interest in developing crops adapted to Spain’s conditions using GE or IBs given the uncertain regulatory environment. To date, according to the [Joint Research Center](#), in 2018, notifications for deliberate environmental release of GE plants for any other purposes than market-placing come down to a biomass production assay in tobacco genetically modified with the *adrenomedullin* gene.

Graph 1. Open Field Trials Notifications to Competent Authorities



Source: Foreign Agricultural Service (FAS) Madrid based on Joint Research Center Information.

*2018 data are based on data available up to December 15th 2018.

b) COMMERCIAL PRODUCTION

Spain is the largest EU producer of Bt corn representing about 95 percent of the EU’s total GE crops area. MON810 corn has been commercially grown in Spain since 1998. Total area planted for corn changes every year based on water availability, crop margins, competition from alternative crops and public incentives in place (**Table 1**). It is worth noting, that total corn area registers a long-term decline since 2014.

Table 1. Spain’s Corn Area and Production*

Marketing Year	MY2014/15	MY2015/16	MY2016/17	MY2017/18	MY2018/19e
Area (1,000 Hectares [Ha])	421.6	398.2	359.3	332.7	326.6
Production (1,000 MT)	4,811.5	4,565.1	4,069.5	3,784.4	3,672.3

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

Planted area for Bt corn in Spain grew steadily until 2013 (**Graph 2** and **Table 2**) driven by an increased use of the technology that expanded to non-traditional areas. Since then, it declined driven by the total corn area decline. Nevertheless, with the exception of 2015 and most recently 2018, the share of GE corn increased over the years (**Graph 3**). The use of this technology

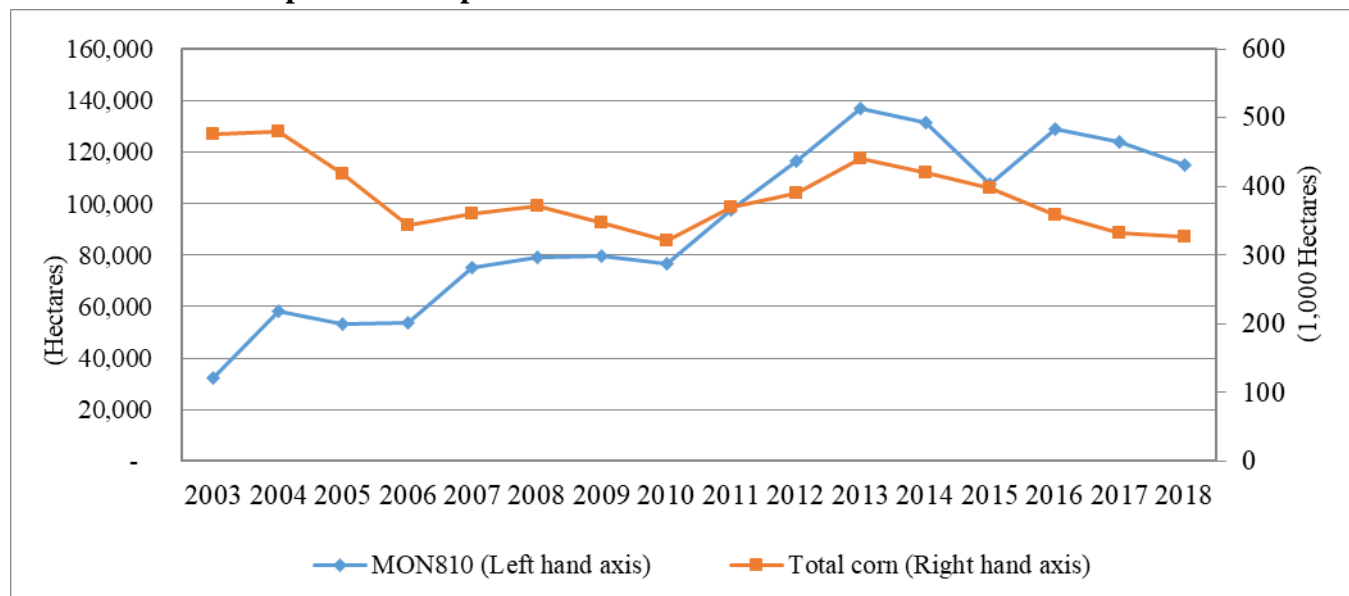
fluctuates yearly as farmers try to address the incidence of corn borer. A low corn borer incidence year is normally followed by a year with lower share of Bt corn. Conversely, during those years where the incidence of corn borer is high is followed by a larger share of Bt corn.

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

Region	2013	2014	2015	2016	2017	2018
Aragon	54,451	54,041	42,612	46,546	49,608	44,932
Catalonia	33,996	36,381	30,790	41,567	39,092	38,752
Extremadura	16,979	13,815	9,827	15,039	13,976	14,138
Navarra	7,013	7,264	6,621	8,066	7,778	8,101
Castile-La Mancha	8,766	7,973	5,734	5,932	5,039	3,805
Andalusia	12,862	10,692	11,471	10,919	8,013	4,972
Others	2,895	1,371	695	1,011	691	547
Total	136,962	131,538	107,749	129,081	124,197	115,246

Source: MAPA.

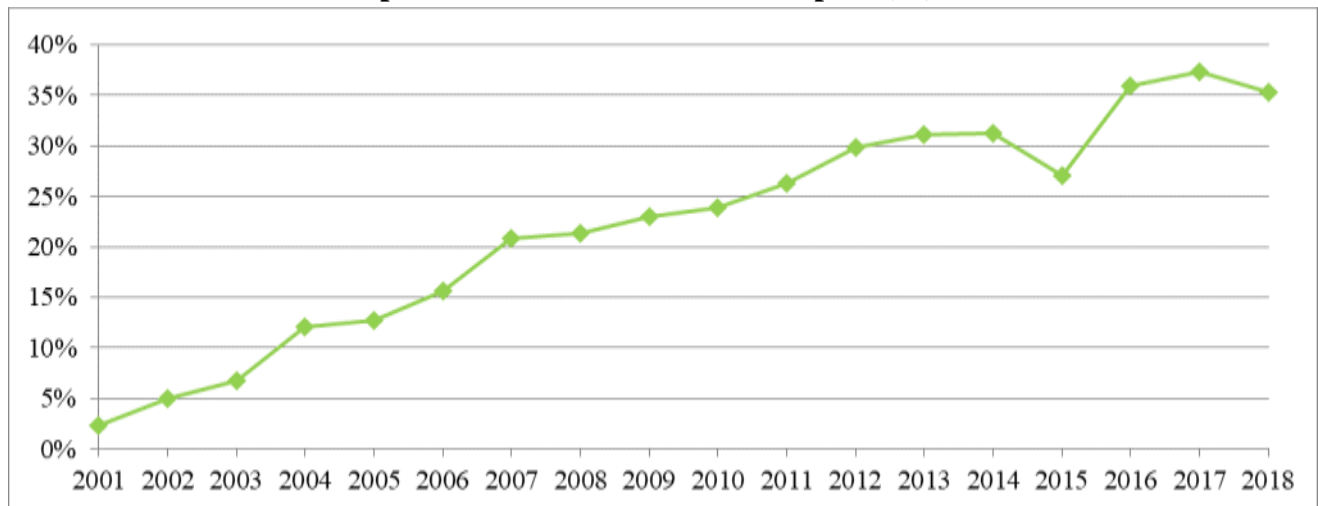
Graph 2. Total Spanish Area for Corn and MON 810 Corn



Source: FAS Madrid based on MAPA data¹.

¹ Since 2009, the Spanish Ministry of Agriculture, Fisheries and Food (MAPA) 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.

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



Source: FAS Madrid based on MAPA data.

Further Spanish expansion of GE corn area is limited by a number of factors:

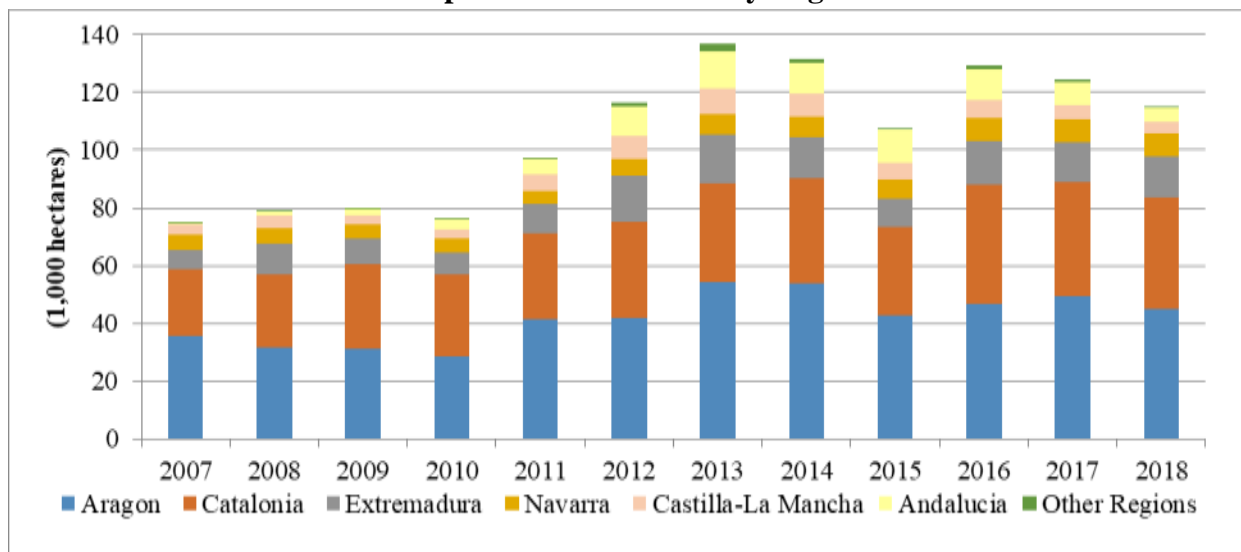
- **Total corn area registers a long-term decline:** Poor crop margins, competition by other crops, crop diversification established by greening², and limited amounts of water for irrigation purposes in certain areas continues to force total corn area down. In addition, the overall long-term trend of increasing the area for tree crops, at the expense of arable crops and/or fallow land, is also contributing to corn area decline. In MY2018/19, total corn area in Spain declined by nearly two percent in marketing, registering an accumulated 25 percent reduction in area during the last five consecutive years. However, some corn growing areas have few other planting options, so farmers continue to grow corn.
- **GE corn use is limited to areas where the corn borer represents a threat:** 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 in GE crops by other growers.
- **GE corn is only consumed by feed compounders:** The large majority of Spain-based feed grain elevators, except for those devoted to special market niches, do not keep separate production lines for GE and non-GE corn. Practically all marketed feed contains GE soybean as a source of protein, and consequently it is by 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 GE free corn, in many cases under Identity Preserved (IP) programs. The fact that the large majority of domestic food manufacturers have eliminated GE products from food product composition to avoid GE labeling

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.

requirements limits GE crops to those farmers supplying exclusively to the animal feed industry. Better prices paid by the food corn processing industry along with irrigation water limitations has resulted in a shift towards forage corn production. This may also have contributed to farmers switching to planting conventional corn varieties.

Data available for **2018** indicates that the Ebro River basin (autonomous regions of Aragon, Catalonia and Navarra) has the largest share of GE corn, accounting for over 75 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 Navarra where it share increased 4 percent in **2018** (**Graph 4**).

Graph 4. GE Corn Area by Region



Source: FAS Madrid based on MAPA data.

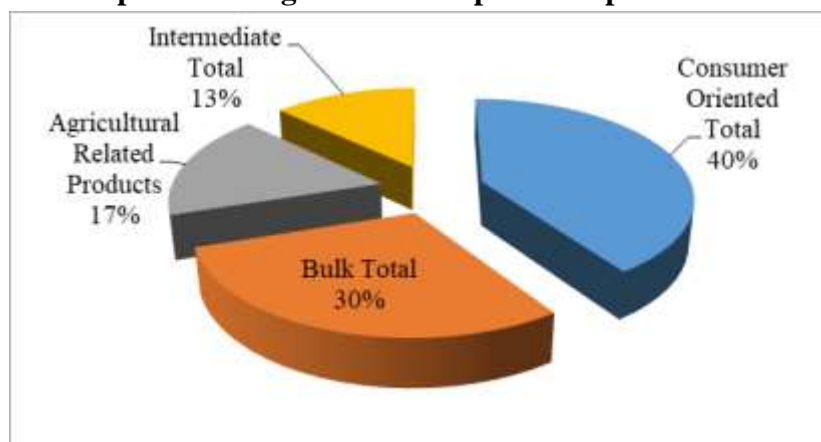
c) EXPORTS

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. Despite being the EU largest producer of GE crops, Spanish exports of GE product are negligible as production is fully utilized by the domestic feed industry.

d) IMPORTS

U.S. agricultural exports to Spain consist mainly of bulk commodities and consumer-oriented products, which accounted for 30 and 40 percent of the U.S. exports value during 2013-2017. Soybeans and tree nuts are the largest categories within these groups representing 21 and 37 percent of total agricultural trade, respectively (**Graph 5**).

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



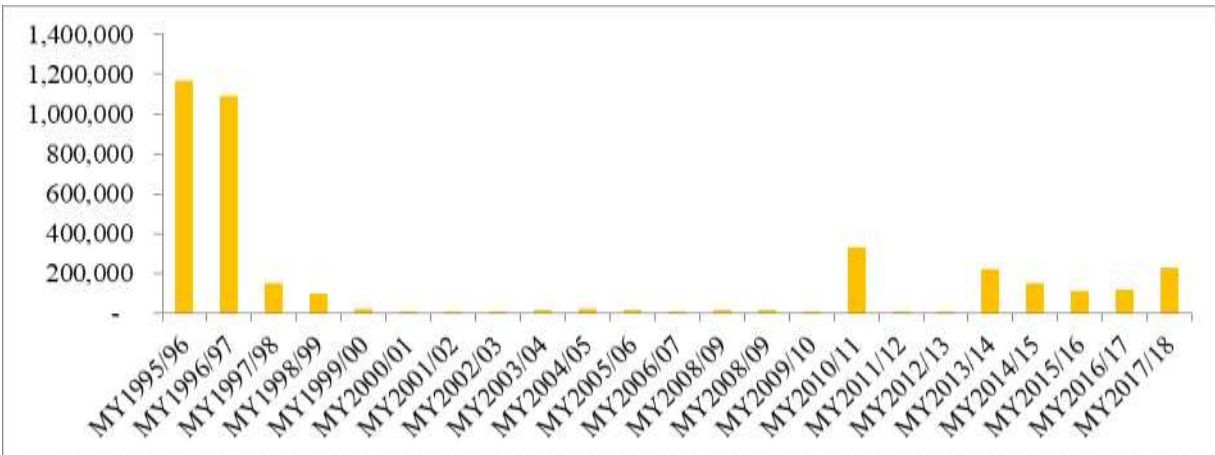
Source: FAS Madrid based on GATS data.

Spain imports a large amount of GE 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 feed-chain stakeholders. Over the years, these factors have led the expansion of GE crop cultivation and imports. Products derived from agricultural biotechnology imported to Spain consist mainly of corn and corn processing by-products, soybeans and products originating from countries such as in Brazil, Argentina, and the United States.

Spanish total grain imports range from 9 to 17 million MT. Over the past ten years, Spain's total corn imports have followed an upward trend due to increased price competitiveness compared to other feed grains, and the steady demand by the Spanish livestock sector. While total corn imports have grown, the United States corn share of imports is negligible as not all GE events produced in the United States are approved for import into the EU (known as asynchronous approval).

Graph 6 contains U.S. corn exports to Spain since MY1995/96 and shows the 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.

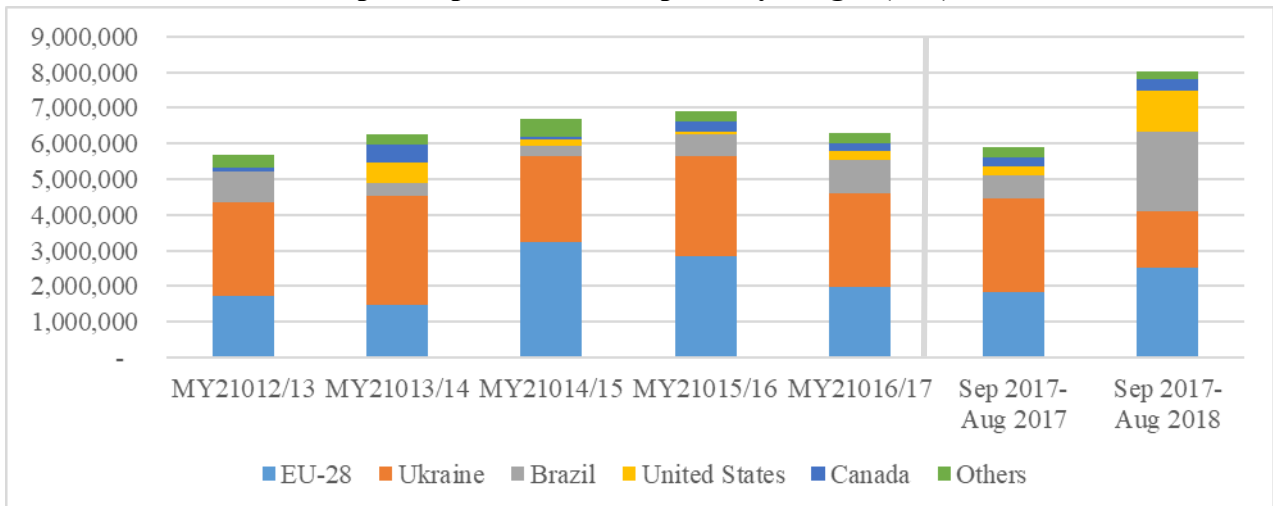
Graph 6. U.S. Corn Exports to Spain (MT)



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. As a result, Ukraine’s market share of the Spanish corn market has stabilized at over 40 percent. Currently, intra EU trade and imports of Ukrainian corn, supply the large majority (nearly 80 percent) of Spain’s grain imports (**Graph 7**).

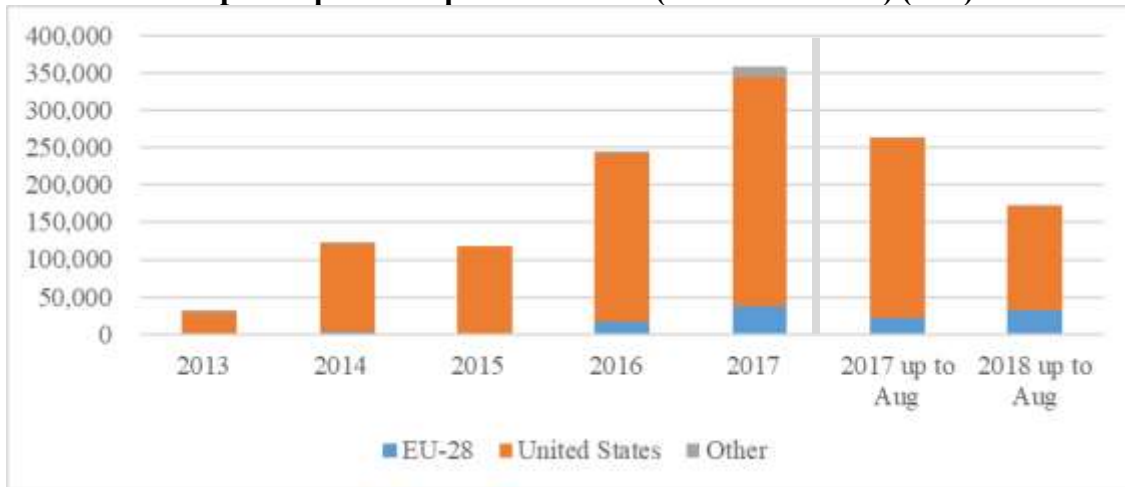
Graph 7. Spain’s Corn Imports by Origin (MT)



Source: Global Trade Atlas (GTA)

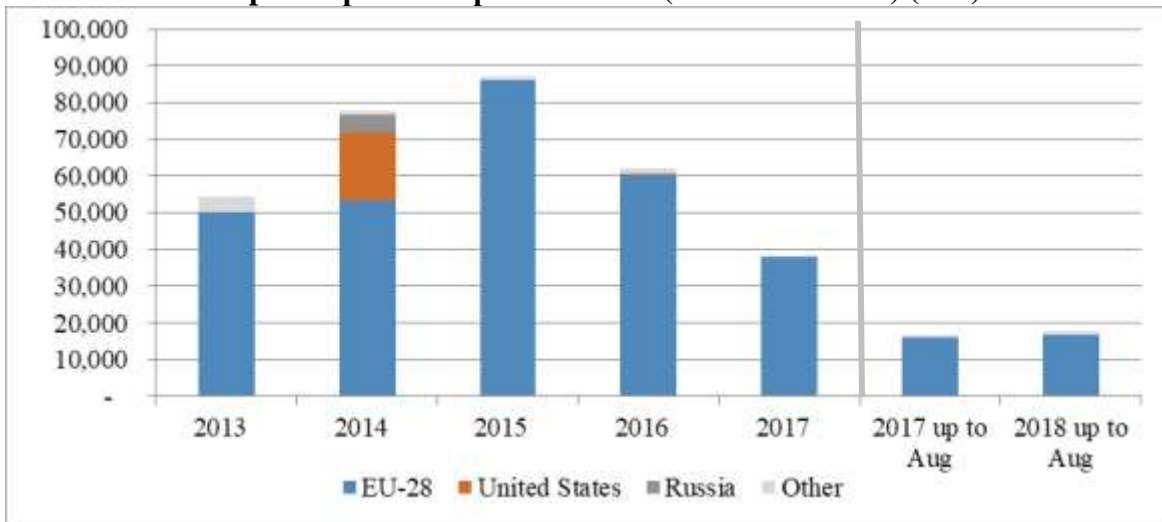
With regards to corn processing by-products, **Graph 8** below shows that in 2016 and 2017, lower domestic bioethanol production, along with competitive prices, opened new opportunities for DDGS imports. The large majority of these originated from the United States. In the case of Corn Gluten Feed (CGF) (**Graph 9**), intra-EU trade satisfies virtually all the Spanish demand.

Graph 8. Spain's Imports of DDGS (HS code 230330) (MT)



Source: Global Trade Atlas (GTA)

Graph 9. Spain's Imports of CGF (HS code 230310) (MT)

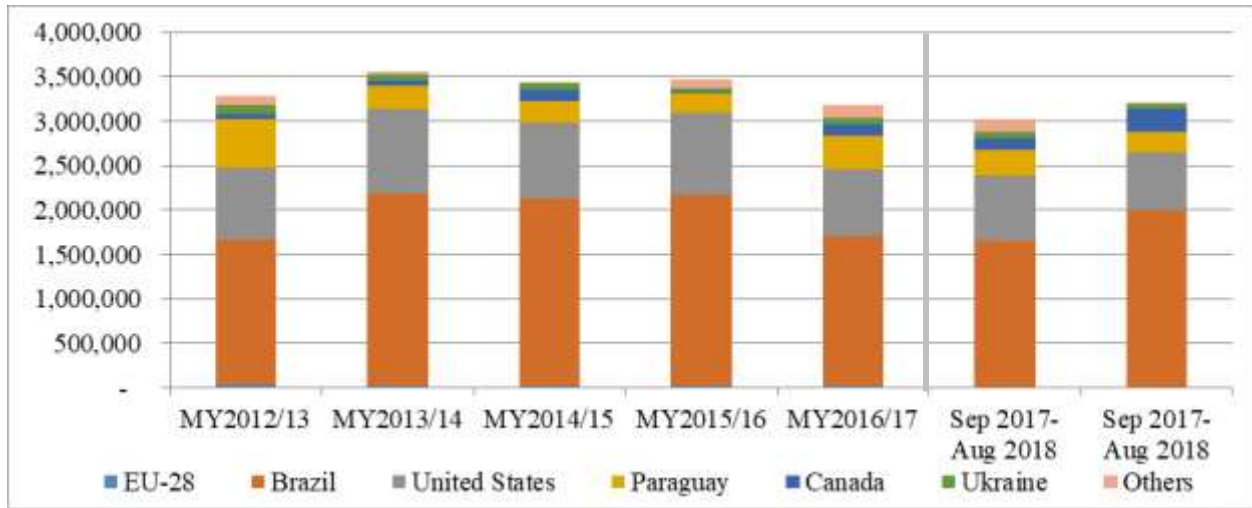


Source: Global Trade Atlas (GTA)

Spain's annual combined imports of soybean and soybean meal amount to nearly 6 million MT. Most of Spain's imports are GE. Brazil, followed by the United States, supplies most of the Spanish soybean imports (See **Graph 10**).

Virtually all of the soybean products imported to Spain are GE, with the exception of those devoted to special markets niches. Post estimates non-GE soybean meal demand in Spain is less than 5 percent of total demand. The impact of the slower approval pace has been less significant in the imports of protein feed ingredients than in the grain sector.

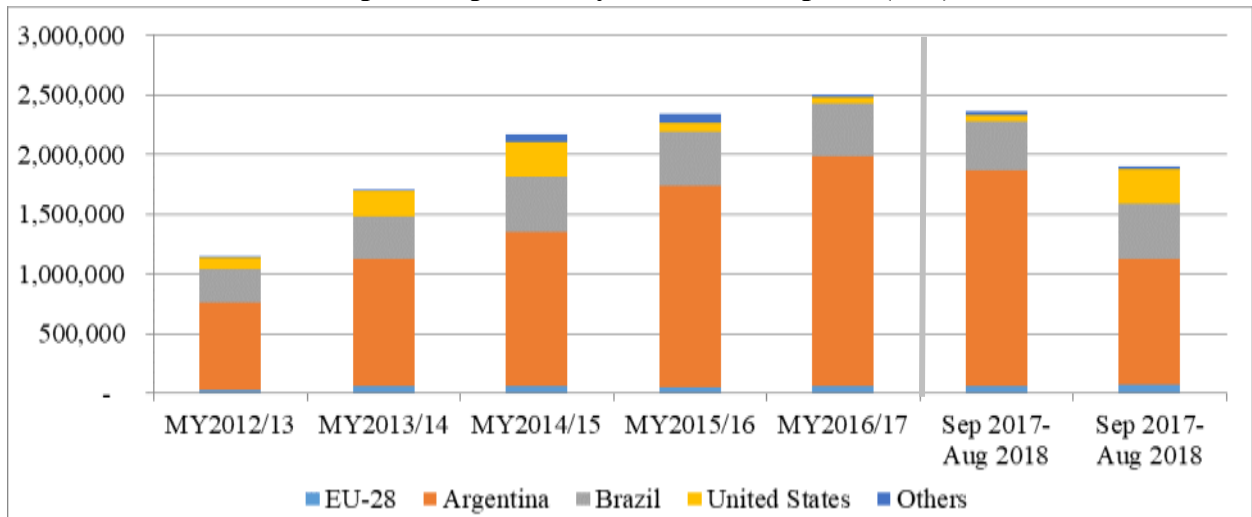
Graph 10. Spain's Soybean Imports (MT)



Source: Global Trade Atlas (GTA)

After hitting bottom in MY2012/13, Spain's soybean meal imports grew steadily up to until MY2017/18, when total meal imports registered a decline in favor of increased soybean imports (**Graph 10**). Over the years, Argentina with a nearly 70 percent share, and Brazil, covering over 20 percent, have supplied most of the Spanish soybean meal market (See **Graph 11**).

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



Source: Global Trade Atlas (GTA)

e) FOOD AID

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

In the case of emergencies when local markets have collapsed in-kind food aid may be provided. This avoids pushing local prices down and discouraging domestic production in recipient countries. Hence, local purchases in recipient countries are preferred. Spain is a 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 project. This is whether working directly, either through its own resources, or through 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.

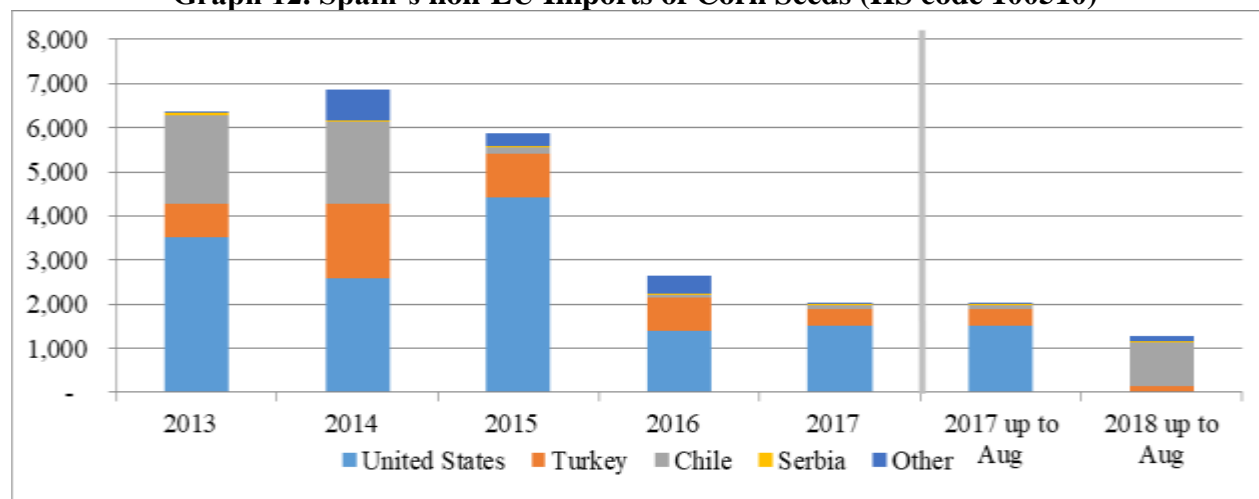
f) TRADE BARRIERS

- **For bulk commodities:** The asynchronous approval of GE events cultivated in the United States yet not authorized for import to the EU 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 limited allowance for adventitious presence³ for non-approved events continues to constraint traders, who carry out a no-risk policy in their purchases.
- **For consumer-oriented products:** The presence of GE labels on consumer-oriented products is very limited in the Spanish market. Most of the 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 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. Therefore, Spain is forced to source its corn seeds from other EU Member States (mainly France), which constitute 95 percent of Spain seed corn

³ Refers to the detection of unintentional presence of GE crops.

imports. Non-EU suppliers of corn seed, accounting for 5 percent of the seed import market, include the United States, Turkey, Chile and Serbia. These countries produce seeds under restrictive conditions that prevent from cross-contamination with seed from unapproved events.

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



Source: Global Trade Atlas (GTA)

PART B: POLICY

g) 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 MS governments to exercise some discretion without altering the basic scope of the EU directive. For more information on EU 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 weigh in on Spain’s agricultural biotechnology decision-making process. These are the National Biosafety Commission (CNB) and the Inter-Ministerial Council for Genetically Modified Organisms (CIOMG). Under this two-tier system, the CNB carries out the risk assessment and the CIOMG decides the country’s position taking into consideration CNB’s assessment.

Since June 2018, following a new Spanish government and following Cabinet-Level reorganization, agricultural and environmental affairs were separated into two different Ministries: The Ministry of Agriculture, Fisheries and Food (MAPA) and the Ministry for

Ecological Transition (MITECO). The CNB is ascribed to the Ministry for Ecological Transition, and the CIOMG to the Ministry of Agriculture, Fisheries and Food.

- **National Biosafety Commission (CNB):** The National Biosafety Commission is an advisory body, ascribed to the MITECO, whose role is to scientifically assess the requests for cultivation, confined use and marketing of GE products submitted at either the national or regional level. The CNB is comprised of representatives from different ministerial departments, representatives of the autonomous regions and experts in 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 (EC) 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 and Food (MAPA), the Ministry of Health, Consumption and Social Welfare (MSCBS), Ministry of Economy and Enterprises (MINECO), and the Ministry of Internal Affairs. 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 on this [link \(in Spanish\)](#). At present there are 90 GE corn varieties approved for commercial cultivation. Within MAPA, 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 into the agricultural biotechnology decision-making process through their participation in the CIOGM or the 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.

Due to the country's decentralized structure, central⁴ and regional⁵ governments in Spain hold different responsibilities.

a) APPROVALS

- **For imports:** Approvals of events for imports are granted at the EU level. Please see the [EC 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 within the Standing Committee on the Food Chain and Animal Health in Brussels.
- **For cultivation:** Spain's position on renationalization of cultivation decisions has evolved through the years. When this debate was first launched, Spain reacted cautiously by putting forward concerns over common market implications and compliance with WTO rules. However, Spain voted in favor of the renationalization of cultivation decisions in what Post understood as an attempt to open the door to cultivation of new events. [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 the borders, a 20 meters isolation distance must be observed.

More information in Section e) Coexistence within **Part B: Policy**

⁴ *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" and monitoring and control of field trials previous to the registration in the Commercial Varieties Catalogue.*

⁵ *The autonomous regions administrations are responsible for authorizing confined use and deliberate release of "GMOs" for research and development and monitoring and control of these activities, (with the exception of those belonging to the national government portfolio)*

b) STACKED or PYRAMIDED EVENT APPROVALS

See section b) on approvals as the procedure in place is the same for single, stacked and pyramided events.

c) FIELD TESTING

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

d) INNOVATIVE BIOTECHNOLOGIES

As of the date of this report, the GOS has not yet issued an official position on IBs..

Spain's competent authorities approach towards IBs is rather positive. In 2015, in a prepared position paper (available in the [link](#), Spanish language only) Spanish authorities expressed their preference for a case-by-case approach for IBs and endorsed a product-focus basis. These approaches were preferred versus a process-focus, as the progress in science is outpacing updates in the regulatory framework.

Spain has traditionally taken a science-based approach in regard to agricultural innovation. The ECJ Ruling on July 25, 2018, determining that organisms produced with IBs must abide by EU [Directive 2001/18](#), has sparked domestic discussions on the feasibility of its implementation at the Member State level.

On September 5, 2018, two Spanish Scientist (Josep M. Casacuberta, Pere Puigdomènech) published an opinion at EMBO (European Molecular Biology Organization) site on [Proportionate and scientifically sound risk assessment of gene-edited plants](#). This article analyzes the consequences of the ECJ ruling on genome-edited products and discusses possible options for a scientifically sound and proportionate risk assessment of genetically engineered plants compatible with the Court's decision and the present GE legal framework.

Spanish agricultural stakeholders, who support agricultural innovation as a tool to improve competitiveness, have expressed their concerns of repeating the same mistakes as with conventional biotechnology. They are particularly worried about having to continue facing competition from third countries without having access to the same tools.

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

e) 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. Coexistence within Spain is managed by following the good agriculture practices promoted by the National Association of Seed Breeders, which is published on a yearly basis and handed out by seed distributors along with seeds. The latest version of the recommendations is available in the [link \(in Spanish\)](#). According to [the Ministerial Order APA/1083/2018](#), farmers who grow GE corn must establish an isolation distance of 20 meters from the French border.

Additional information can be found in Section a) on Approvals.

f) 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, most of the food manufacturers have eliminated GE products from food product manufacturing. In Spain, GE-free labeling is not regulated. However, some food manufacturers have opted for using GE-free wording in the labels on a voluntary basis as a marketing tool.

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](#).

g) MONITORING AND TESTING

Spain's monitoring and testing system is based on EU rules. However, due to Spain's decentralized governmental structure, testing and controlling are carried out at the regional level, while the central government maintains 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 assessments 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. As of the date of this report, no 2018 shipments have been rejected due to unauthorized presence of GE products in Spanish Border Inspection Points.

h) LOW LEVEL PRESENCE (LLP) POLICY

As a member of the EU, Spain conforms to EU directives and follows EU regulations on agricultural biotechnology. In July 2011 the EU legislation set a 0.1 percent⁶ 'technically zero' level for shipments devoted to the **feed** market. However, for products that will enter the **food** chain the tolerance is zero. Therefore, adventitious presence continues to be a concern for traders, who carry out a no-risk policy in their purchases, regardless of 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 directly affecting consumers, such as LLP for food, AECOSAN plays a bigger role in the CIOMG's 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 (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. For additional information, see f) Trade Barriers within **Part A: Production and Trade**.

i) ADDITIONAL REQUIREMENTS

While it was largely debated in the past, currently there is no national registry of commercial GE fields in Spain. The Spanish agricultural administration is reluctant to publish information about the location of commercial GE crop plots, as it could be misused. Currently, the only information publicly available about commercial GE crops plantings in Spain is the total area at the province, regional and national level. This is calculated based on GE seed sales records, and it is publicly available at the Ministry of Agriculture, Fisheries and Food [website](#) (in Spanish).

Additionally, according to the Spanish Fund for Agricultural Guarantee's (FEGA) [yearly coordination circular](#), when submitting the CAP payment application form, farmers must declare

⁶ *This level corresponds to the lowest level of GE material considered 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.*

all the agricultural plots on their holding, and for statistical purposes, whether they are growing GE corn varieties.

j) 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 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 rules. Within the Ministry of Agriculture, Fisheries and Food, 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 registration of protected varieties.

- 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 concurrently hold protection for the same plant variety under both the Community and a national system. 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.

k) 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 EU. Spain adhered to the Protocol on January 2002. At the national level, the Protocol is followed by the Ministry of Agriculture, Fisheries and Food and in particular, the Support Unit within Directorate General for Agricultural Production and Markets (protocolo.cartagena@mapa.es). Spain regularly attends the Cartagena Protocol Meeting of Parties.

Additional information on the Cartagena's Biosafety Protocol can be found in its [official website](#).

l) 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. Spain is an associate state to [IICA](#) (Inter-American Institute for Cooperation on Agriculture) and the country hosts the permanent representative of IICA for Europe in Madrid. For more information, see the [EU-28 Biotechnology Annual Report](#).

m) 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 Post's 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 component 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 use of inputs. The use of agricultural biotechnology is also considered beneficial for the agricultural and food industry sector given the country's dependency on imported raw materials. Most 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. 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 repeatedly claimed that an increased access to GE products will help them compete equally in the global market.

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. In particular, the recent developments on access to varieties developed using IBs have sparked the interest of new stakeholders to the biotechnology discussion; as new varieties obtained worldwide using these techniques involve a larger number of species than GE crops.

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

b) MARKET ACCEPTANCE / STUDIES

The presence of GE labeled consumer-oriented products is very limited in the Spanish market. Much of the food manufacturers have eliminated GE products from food product manufacturing to avoid labeling as “Contains GMOs.” In contrast, most 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 regard 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). Similarly, it concluded Spain supports GE food with 35 percent of respondents agreeing or totally agreeing 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 average EU citizen (13 percent versus 19 percent of surveyed Europeans). Both Spaniards and Europeans expressed more concern about agricultural pollution -originated from using fertilizers and pesticides- than for the use of GE crops.

The 2016 Survey on Social Perception of Science and Technology in Spain conducted by the Spanish Foundation for Science and Technology (FECYT) 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.

Another study published in November 2016, entitled “[Bt maize cultivation in Spain: Economic, social and environmental benefits \(1998-2015\)](#)” and founded by the Antama Foundation⁷, 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

⁷ *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.*

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.

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 improved additional net CO₂ fixation.

One June 2018, PG Economics presented a Study on [Farm income and production impacts of using GM crop technology 1996–2016](#). This paper estimates the value of using Genetically Engineered crops technology in agriculture at the farm level.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Animal Genetic Engineering and Animal Cloning are included under Animal Biotechnology. 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. 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

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 MAPA, 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.

In **2017**, the Spanish Public Agricultural Research Institute (INIA), 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	Mice/Rats	Zebra fish	Flies	Hogs	Other 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
2018	X	X		X	

Source: FAS Madrid based on MAPA data

* GE rabbits, goats, and sheep

Public institutions, such as the CNB are leading Spanish research on animal genome editing. 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 taken place since 2003. Currently, public research centers and universities are trying to learn and improve the technology. Thus far, no private companies are involved 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:

- Wild goat by Scientifics from the Centre of Research and Agro-food Technology of Aragon (CITA) along with colleagues from the INIA in 2003.
- Cloned mice by a public institution (Department of Cell Biology, Physiology and Immunology at the Autonomous University of Barcelona 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.
- In 2014, scientists from the 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. In Spain, GE animals 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 to notification requirements by customs authorities. Since import documents do not indicate whether embryos or semen is sourced from a **cloned animal**, the Spanish livestock industry may already have imported semen and embryos from cloned animals.

e) TRADE BARRIERS

Trade barriers for GE or cloned animals 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 and Food and the Ministry of Health.

- Ministry of Agriculture, Fisheries and Food (MAPA): Within MAPA, there are different units that play a role in the decision-making process in issues related to cloning. 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. Additionally, 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 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.

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

b) APPROVALS

No GE animals are approved for feed and food uses in Spain. Food from clones falls under the scope of the [Novel Food Regulation](#) and is subject to pre-market authorization. No applications have been submitted or approved for food from clones.

c) INNOVATIVE BIOTECHNOLOGIES

Spain has not regulated the use of IBs in animals.

d) 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](#).

e) INTELLECTUAL PROPERTY RIGHTS

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

f) INTERNATIONAL TREATIES and FORUMS

Spain's participation in international treaties and forums is no different from that of the EU. For more information on this topic, see the [EU-28 Biotechnology Annual Report](#).

g) 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, there are concerns regarding implications to animal welfare and ethical aspects.

Thus far, Spanish livestock breeders have shown a limited interest in cloning due to the high-implicated 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 every two years by FECYT, concludes that 31.3 percent of the participants in the survey consider that concerns on cloning overcome the benefits of the technology. This is 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 MS 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 preservation 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

Report Title	Date Released
The Netherlands Calls for an Amendment of the GMO Directive	12/13/2018
EU Court Extends GMO Directive to New Plant Breeding Techniques	07/27/2018
European Court Examines Whether Some NBTs Are Exempted from GMO Law	01/30/2018
Advisory Legal Opinion Expected for New Plant Breeding Techniques	01/16/2018
Agriculture Biotechnology Annual 2017– EU-28	11/22/2017
Agriculture Biotechnology Annual 2017 – Spain	11/22/2017
Dutch Proposal to Legislate NBTs	10/04/2017
EC Proposes Changes in Comitology Rules	03/01/2017
Change in voting behavior may lead to GE crops not being approved	09/11/2017