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Report Highlights:

Spain remains the largest grower of genetically engineered (GE) corn in the European Union and a major consumer of GE corn and soybean products for animal feed. The country has traditionally defended a science-based approach to agricultural biotechnology. Agricultural stakeholders remain preoccupied by the potential consequences the European Union Court of Justice (EUCJ) ruling on new breeding techniques (NBTs) will have 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 Agricultural Biotechnology Annual European Union.

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Acronyms used in this report:

AESAN	Spanish 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
EU	European Union
FAS	Foreign Agricultural Service
GE	Genetically Engineered
GMO	Genetically Modified Organism
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 the Ecological Transition and Demographic Challenge
MS	Member State(s)
MOC	Ministry of Consumption
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 is the largest grower of genetic engineered (GE) crops (**98,152 hectares [**Ha] of Bt corn in 2020) in the European Union (EU). Spain and Portugal are the only two EU Member States (MS) growers of GE crops. MON810 corn has been commercially grown in Spain since 1998.

The combination of highly variable yields in winter-grains and a comparatively large export-driven livestock sector, positions Spain as the EU largest grain importer. Different than the majority of EU MS, Spanish imports of GE products are not limited to GE soybean and soybean products. These also include corn and corn by-products such as Distiller's Dried Grains with soluble (DDGS) and Corn Gluten Feed (CGF) as the country is not only deficient in protein meals but also in feed grains. Spanish total annual grain imports range from 12 to 17 million metric tons (MT) annually. On average, Spain's annual combined imports of soybean and soybean meal amount to nearly 6 million MT. The general practice for Spanish feed compounders is to label all feed as "contains GE products." Conversely, despite moderate acceptance of agricultural biotechnology among Spanish consumers, the presence of GE labels in food products is very limited. Food manufacturers still opt to reformulate their products to avoid using the label "Contains GMOs."

Given its strong dependency on imported feedstuffs and its trade-oriented agricultural sector, over the years, Spain has traditionally taken a science-based approach to regulating biotechnology. This has allowed Spain to avoid trade disruptions and defend farmers' access to agricultural innovation. However, being a vocal proponent of biotechnology, for both cultivation and imports, has become increasingly complicated in the European environment. In some cases, subjective approaches tend to have stronger influence over the decision-making process.

Spain's regulatory framework allows confined research and field trials for GE and Innovative Biotechnologies (IB) 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 IB developments are anticipated to be in the market within the next five years. The restrictive EU regulatory framework continues to discourage domestic research and development as well as prevent these technologies from achieving their full potential at the commercial level.

At the regulatory level, the efforts of the Spanish agricultural administration during the first half of 2020 were directed to address the Commission's questionnaire in preparation of the study regarding the European Union Court of Justice (EUCJ) ruling on new breeding techniques (NBTs).

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. 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 intended for human consumption.

Microbes are largely used in food production processes in Spain. However, the food industry opts for food ingredients obtained using microbial biotechnology as a tool, as opposed to containing microbial biotechnology, to avoid the lengthy deliberate-release regulatory framework, as well as the corresponding GE labeling requirements.

CHAPTER 1: PLANT BIOTECHNOLOGY
PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

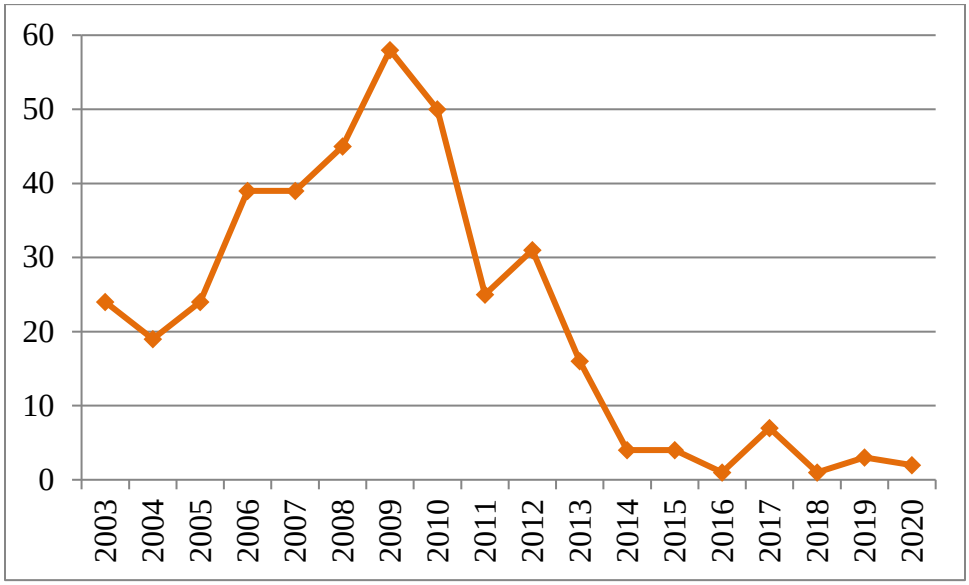
Both confined research and deliberate release to the environment of GE plants (field trials) are permitted in Spain subject to prior notice, public information, and authorization (Law 9/2003 – in Spanish). Confined research on IBs, is also subject to prior notice, public information, and authorization. The restrictive regulatory framework discourages domestic research and development. It also prevents these technologies from achieving their full potential at the commercial level. Even though confined research and deliberate release can be carried out in the country, no new GE or IBs development are anticipated to reach the market within the next five years.

- **Confined Research:** In 2019, confined research activities on GE plants communicated to competent authorities included research with arabidopsis and tomato plants, where the University Jaume I (Castellon) is studying resistance to abiotic factors. An interesting piece of EU-funded research by the Center for Research in Agricultural Genomics (CRAG), is the importance of drought-resistant plants by modifying the signaling process of a group of plant hormones called brassinosteroids.

  In 2020 up to the date of this report, notifications on GE plant research included tomatoes with high anthocyanin expression by Universidad Islas Baleares (in Spanish), GE petunias by Barberet & Blanc, and other non-specified plants by Semillas Fitó.

- **Field testing:** Notifications to competent authorities for open field testing remain very low. This reflects the public and private sectors' limited interest in developing crops adapted to Spain's conditions using GE or IBs given the restrictive regulatory environment to reach the market. In 2020, according to the Joint Research Center, one notification of deliberate release to the environment have been registered: The Spanish National Research Council (CSIC) presented a notification for a field test for of **tobacco** plants.

Graph 1. Open Field Trials Notifications to Competent Authorities



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

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. (**Table 1**).

Except for MY2019/20, when Spanish corn area grew marginally, total corn area in Spain has been declining since MY2013/14. Consistent with this long-term declining trend, in MY2020/21[1], total corn area lowered three percent. Accounting for the area decline are lower crop margins and persistent spring rains that reduce planting opportunities. Crop diversification established under EU's greening measures also contributed to a lesser extent.

[1] *Corn Marketing Year is October- September.*

Table 1. Spain's Corn Area and Production*

Marketing Year	MY2014/15	MY2015/16	MY2016/17	MY2017/18	MY2018/19	MY2019/20	MY2020/21
Area (1,000 Hectares)	421.6	398.2	359.3	333.6	322.4	357.6	345.7
Production (1,000 MT)	4,811.5	4,565.1	4,069.5	3,775.6	3,842.5	4,185.4	4,083.4

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

Bt corn is grown in thirteen of the seventeen Spanish autonomous regions. However, 80 percent of Spain's total GE corn area is concentrated in the Ebro River basin (autonomous regions of Aragon, Catalonia and Navarra), where the corn borer is endemic. Spanish planted area for Bt corn, grew steadily until 2013 (**Graph 2**) driven by an increased use of the technology in the so-called non-traditional areas (Andalusia, Castile-La Mancha and Extremadura).

Since 2019[2], GE corn area in Spain is calculated considering an average planting density of 95,000 seeds per hectare. This change in methodology has altered the absolute value of area planted to Bt corn. Data available for **2020** indicates that Bt corn plantings declined by 7 percent, representing a reduction beyond the three percent registered in total corn area. Despite the overall drop which results in a reduction in Bt corn share (**Graph 3**), the use of Bt corn remains significant in the Ebro river basin, as its use reduces pest incidence in corn as a second crop[3], allowing farmers to obtain and profit from two grain crops on the same plot.

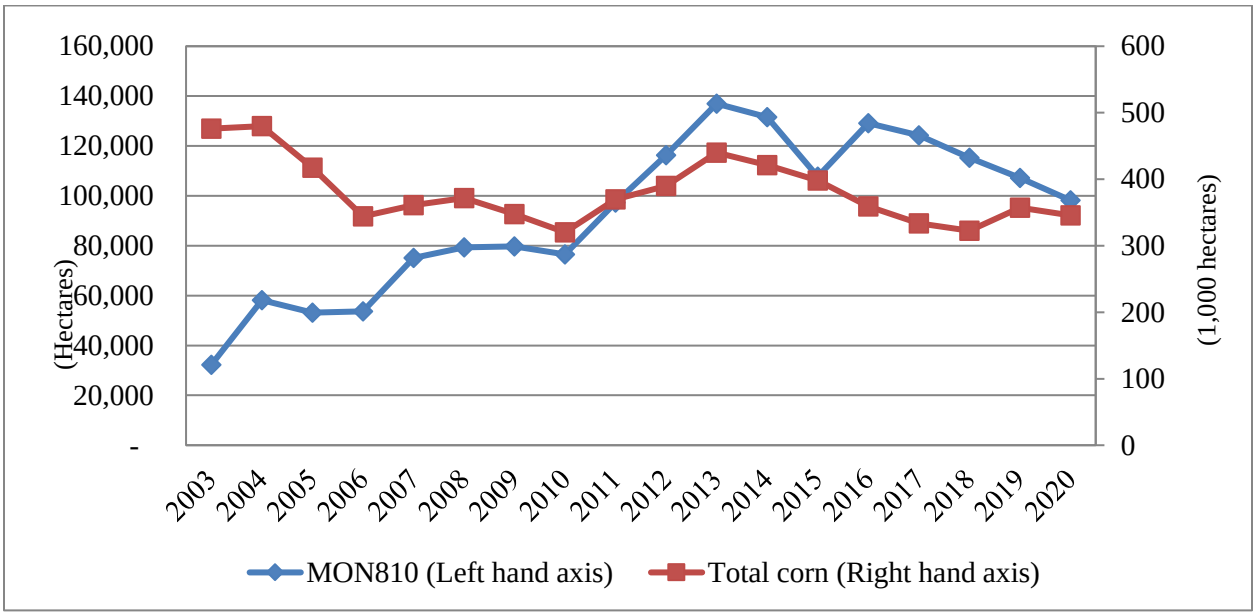
Table 2. Area of GE corn by Region (Hectares)

Region	2014	2015	2016	2017	2018	2019	2020
Aragon	**54,041**	**42,612**	**46,546**	**49,608**	**44,932**	**42,646**	**40,995**
Catalonia	**36,381**	**30,790**	**41,567**	**39,092**	**38,752**	**36,430**	**31,833**
Extremadura	**13,815**	**9,827**	**15,039**	**13,976**	**14,138**	**12,255**	**10,718**
Navarra	**7,264**	**6,621**	**8,066**	**7,778**	**8,101**	**8,253**	**8,310**
Castile-La Mancha	**7,973**	**5,734**	**5,932**	**5,039**	**3,805**	**3,101**	**2,601**
Andalusia	**10,692**	**11,471**	**10,919**	**8,013**	**4,972**	**3,795**	**2,724**
Others	**1,371**	**695**	**1,011**	**691**	**547**	**650**	**971**
Total	**131,538**	**107,749**	**129,081**	**124,197**	**115,246**	**107,130**	**98,152**

Source: MAPA.

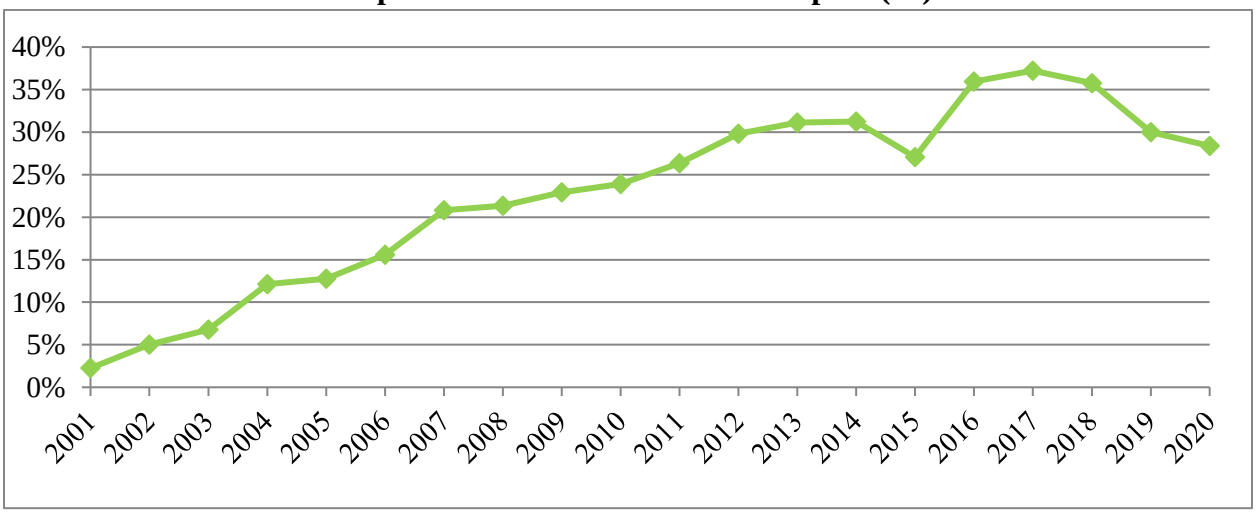
[2] *Until 2018, GE corn area estimates released by the Ministry of Agriculture are calculated considering the companies' seed sales declaration and assuming an average planting density of 85,000 seeds per hectare.*
[3] *Planting corn as a second crop is an agronomic practice fairly extended in the Ebro river basin. Farmers plant barley in winter to be harvested in Spring when a short-cycle corn is planted to be harvested in Fall.*

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



Source: FAS Madrid based on MAPA data[4].

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



Source: FAS Madrid based on MAPA data.

[4] *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.*

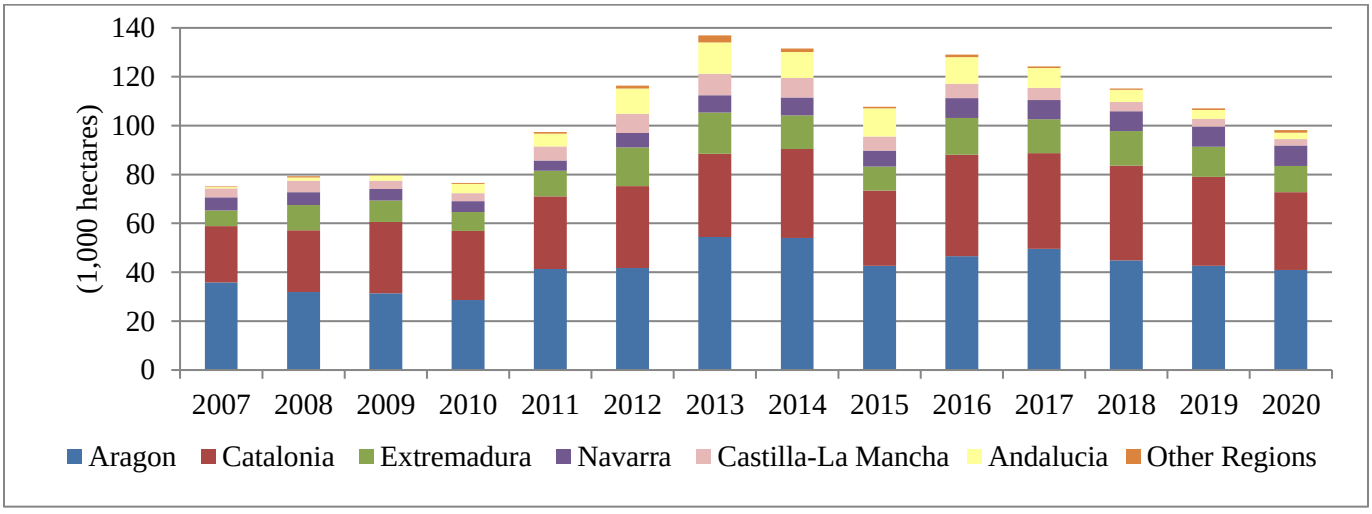
Factors Limiting Further Expansion of Spanish GE corn area:

- **Total corn area registers a long-term decline:** Poor crop margins, competition from other crops, and crop diversification established by EU greening measures[5], continue to force total corn area down. However, in some growing regions, corn plantings are extremely inelastic given the limited availability of alternative crops, so farmers continue to grow GE 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 were the corn borer represents a problem. Approvals of new traits could raise growers' interest in other GE crops.

- **Feed compounders are the only users of GE corn:** Most Spain-based feed grain elevators, except for those devoted to special niche markets, 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 labeled by default as "contains GE products." In many situations, the corn processing industry (wet and dry millers), whose production is intended for human consumption, sources non-GE corn from producers contracted into Identity Preservation (IP) programs. Since most domestic food manufacturers have eliminated GE products from their food product composition to avoid GE labeling requirements, they will restrict GE crop supplies to the animal feed industry.

Graph 4. GE Corn Area by Region



Source: FAS Madrid based on MAPA data.

[5] *A large part of the support farmers received (roughly 30 percent) is linked to greening measures. To comply with greening measures, farmers must observe crop diversification. 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 monoculture areas.*

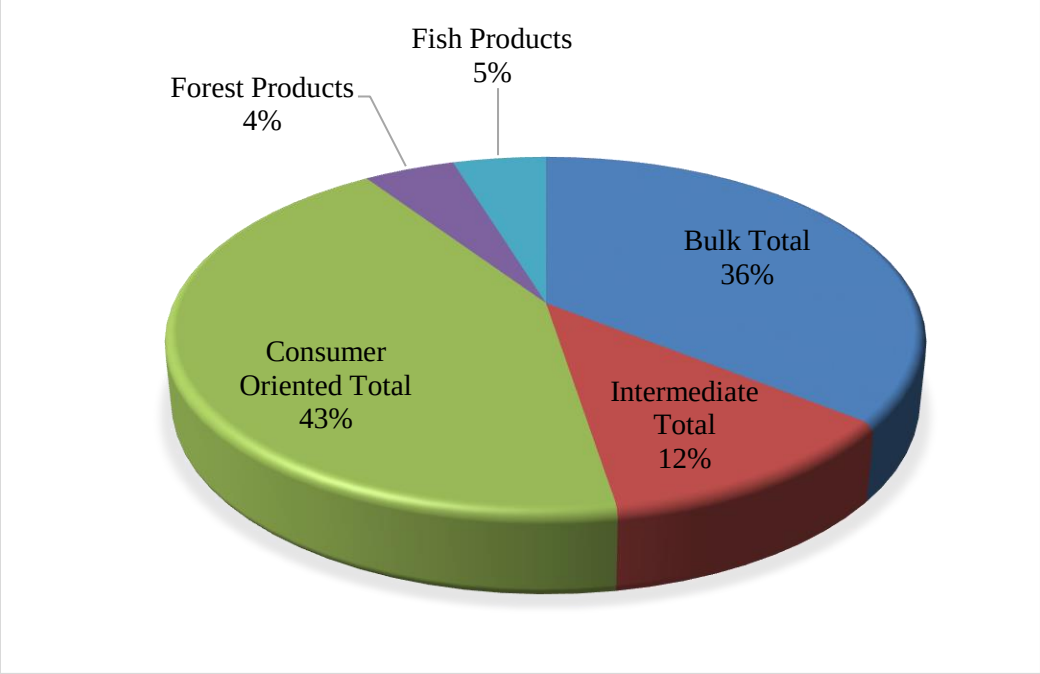
c) EXPORTS

Spain is a net importer of grains and oilseeds as domestic production is not enough to meet the demand of Spain's robust export-oriented livestock sector. In spite of being the EU Bt corn production power core, Spanish exports of GE products are negligible as production is fully utilized by the robust domestic feed industry.

d) IMPORTS

U.S. agricultural exports to Spain consist mainly of bulk commodities and consumer-oriented products, which accounted for 36 and 43 percent of the U.S. exports value during 2015-2019. Soybeans and tree nuts are the largest categories within these groups representing 23 and 40 percent of total agricultural trade, respectively (**Graph 5)**.

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



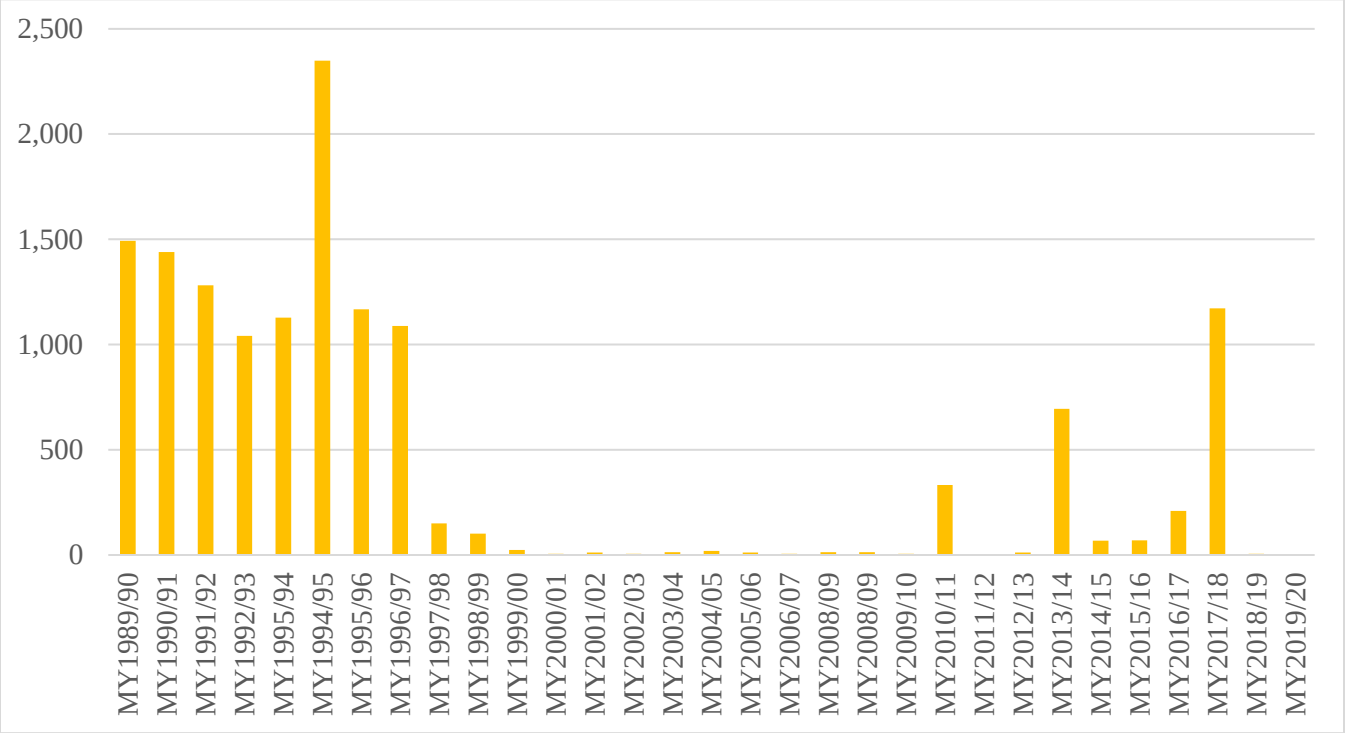
Source: FAS Madrid based on Trade Data Monitor, LLC data.

Spain imports a large amount of GE products. The country's dependency on imported feedstuffs affect to both grains and oilseeds. The strong reliance on imports 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 shipped to Spain consist mainly of corn and corn processing by-products, and soybeans and products, originating from countries such as Brazil, Argentina, and the United States.

Spanish total annual grain imports range from 12 to 17 million MT. The imported amount depends on the size of the highly variable domestic grain crop, the pasture availability and the evolution of demand from the livestock sector. 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 from Spain's export-driven livestock sector.

Graph 6 illustrates U.S. corn exports to Spain since MY1989/90 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.

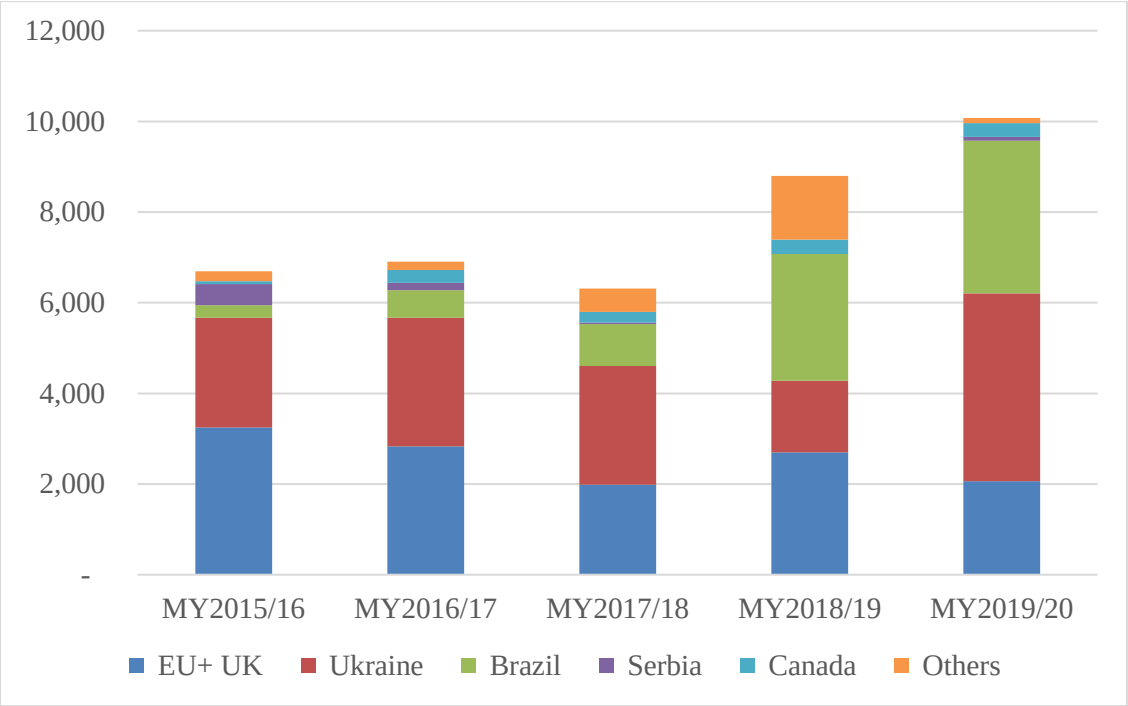
Graph 6. U.S. Corn Exports to Spain (1,000 MT)



Source: Trade Data Monitor, LLC data.

The progressive adoption of agricultural biotechnology in countries such as the United States, Argentina and Brazil forced Spain-based feedstuff importers to find alternative corn providers, such as Ukraine. In MY2017/18, Spanish imports of U.S. corn recovered to significant levels since MY1996/97. Since MY2018/19, Spain's imports of U.S. corn are virtually zero as a result of the EU 25 percent retaliatory duty imposed on U.S.- sourced corn since June 2018.

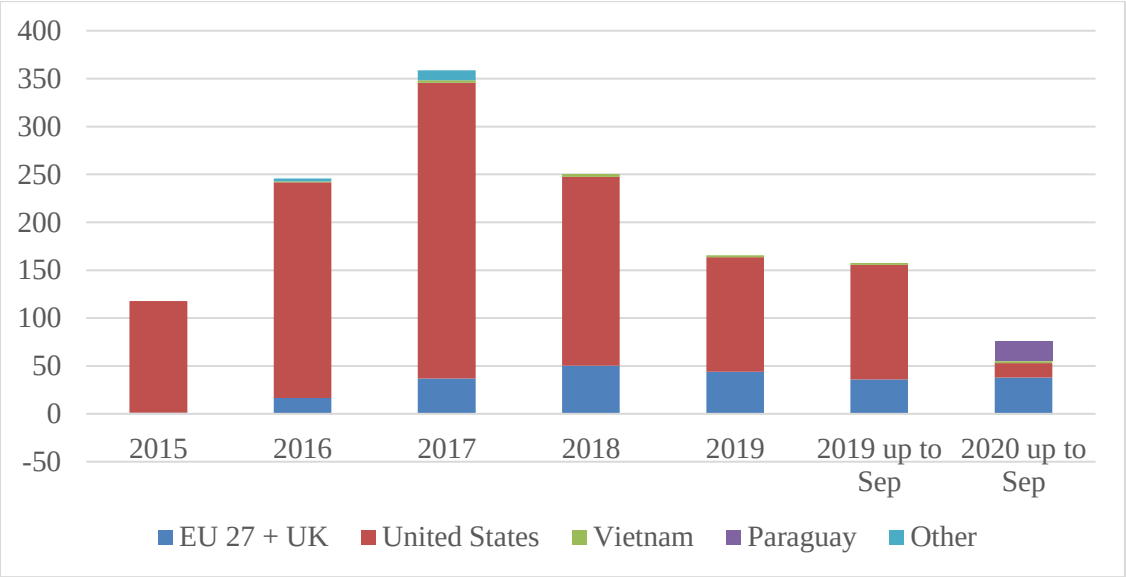
Graph 7. Spain's Corn Imports by Origin (1,000 MT)



Source: Trade Data Monitor, LLC data.

Regarding corn processing by-products, **Graph 8** shows that in 2016 and 2017, lower domestic bioethanol production, along with competitive prices, opened new opportunities for imports of Distiller's Dried Grains with Solubles (DDGS). However, ample domestic DDGS supplies and competitively priced soybean meal have resulted in a reduction of Spain's imports of DDGS in 2018 and 2019. Data available for 2020 show a surge in imports originated in Paraguay, even though total DDGS imports are below previous year's levels.

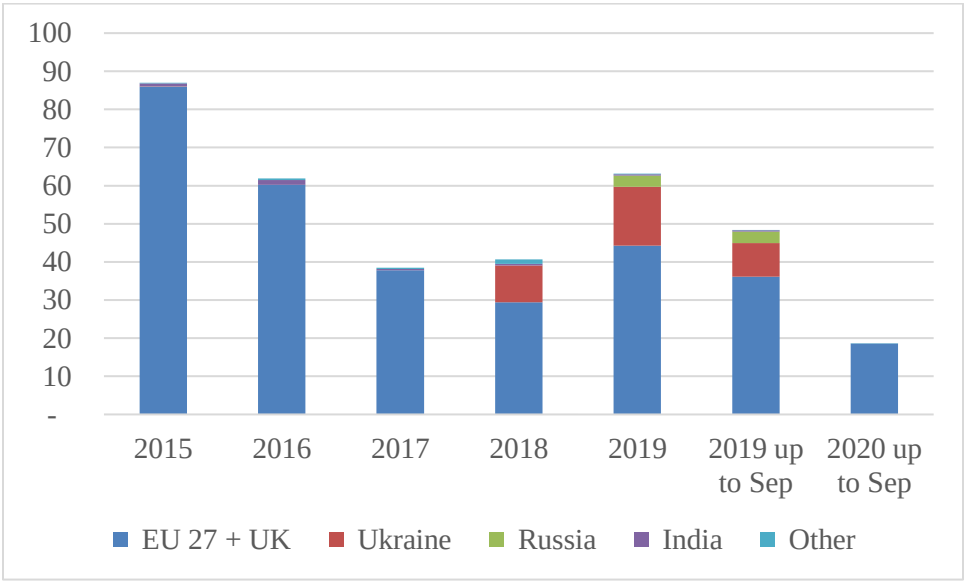
Graph 8. Spain's Imports of DDGS (HS code 230330) (1,000 MT)



Source: Trade Data Monitor, LLC data.

In the case of Corn Gluten Feed (CGF) (**Graph 9**), trade within the EU (mostly non-GE) satisfies virtually all the Spanish demand.

Graph 9. Spain's Imports of CGF (HS code 230310) (1,000 MT)



Source: Trade Data Monitor, LLC data.

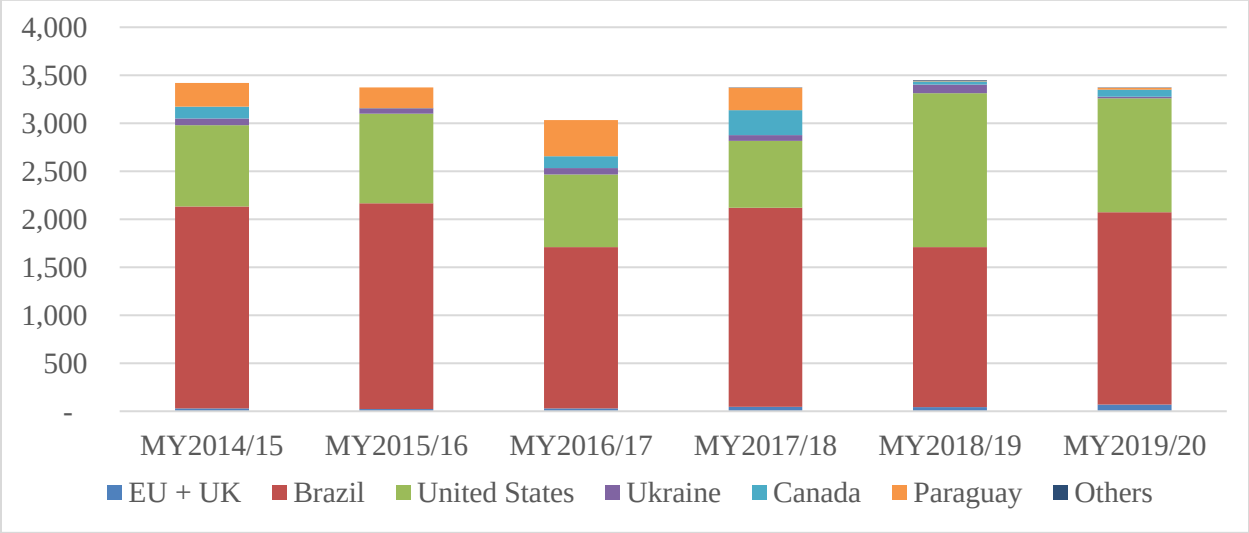
Spanish oilseed production is comprised of olives and sunflower, both primarily intended for the food market. Rapeseed production is small and normally exported to neighboring Portugal or France. Hence, Spain needs to import most of the protein feed ingredients.

On average, Spain's annual combined imports of soybean and soybean meal amount to nearly six million MT. Data available for MY2019/20 show that a slightly lower demand for both meal and oil resulted in a reduction in soybean seed imports.

Most of Spain's soybean imports are GE. Brazil, followed by the United States, supplies most of the Spanish soybean imports (See **Graph 10**). In MY2018/19[6], competitively priced U.S. soybeans allowed the United States to increase its market share. In MY2019/20, trade data indicate that U.S. soybeans are losing market share to Canada.

Virtually all Spanish imports of soybean products are GE, except for those devoted to niche special markets. Post estimates Spanish non-GE soybean meal demand is around 5 percent of total sales and partially satisfied by Spanish beans (4,300 MT in 2020). The impact of the slow EU approval rate of GE products has had less impact on the imports of protein feed ingredients (primarily soy) than in grain imports.

Graph 10. Spain's Soybean Imports (1,000 MT)

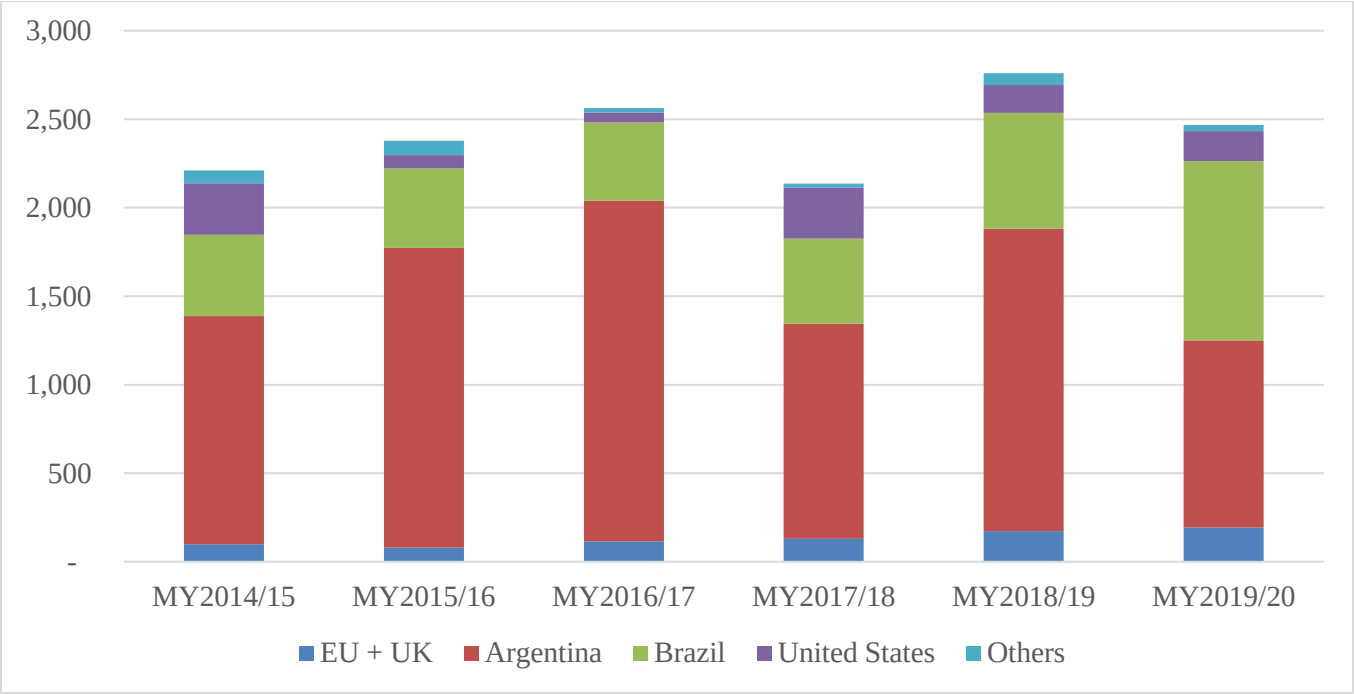


Source: Trade Data Monitor, LLC data.

In MY2018/19, Spain's total soybean imports grew, and favorable U.S. soybean prices led to an increase in the U.S. market share. While in 2019 animal feed production, Spain's primary soybean meal consumer, continued to expand, this trend is not expected to extend to in 2020. This will likely drive down soymeal imports. In average years, Argentina (holding roughly a 70 percent share) and Brazil (holding a 20 percent share) traditionally supply most of the Spanish soybean meal market (see **Graph 11**). Data available for MY2019/20, show a surge in the Brazilian share of the Spanish soybean market.

[6] *Soybeans Marketing Year is October September.*

Graph 11. Spain's Soybean Meal Imports (1,000 MT)



Source: Trade Data Monitor, LLC data.

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 Spain may provide in-kind food aid. This avoids pushing local prices down and discouraging domestic production in recipient countries. Hence, Spain prefers local purchases in recipient countries. Spain is a founding member of IFAD (International Fund for Agricultural Development), the United Nations Agency created to enable poor rural people to overcome poverty and hunger. It is also a member of the Food and Agricultural Organization and a strong supporter of the World Food Program. Created in 1988, the Spanish Agency for International Development Cooperation (AECID), within the Ministry of Foreign Affairs and Cooperation, is responsible for the elaboration, execution, and management of the cooperation programs and projects. This is whether working directly (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

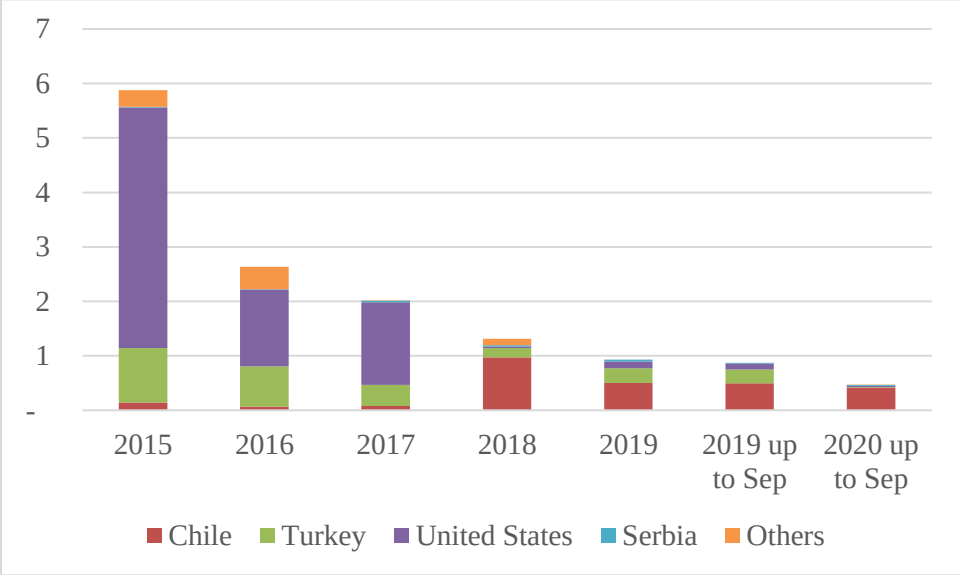
– **For bulk commodities:** The asynchronous approval of GE events cultivated in the United States but not authorized for export to the EU remains the main trade barrier. The expansion of GE crop production in

traditional grain supplying countries has significant impact on trade flows to Spain. For instance, in the corn market, Ukraine, Serbia, and Russia have progressively increased their market share over the years at the expense of lower imports from the United States, Argentina and Brazil (See **Graph 7**). Additionally, the limited allowance for adventitious presence[7] 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 manufacturing or switched to GE- free suppliers, 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. The EU has not yet set a threshold level for the adventitious presence of GE material in seed. Therefore, Spain is forced to source its corn seeds from other EU Member States, mainly France which contributes over 90 percent of Spanish imports of corn seed. Non-EU suppliers of corn seed, accounting for five percent of the seed import market, include the Chile, United States, Turkey, Serbia and South Africa. These countries produce seeds under restrictive conditions that prevent adventitious levels of seed from unapproved GE events.

Graph 12. Spain's Non-EU Imports of Corn Seeds (HS code 100510) (1,000 MT)



Source: Trade Data Monitor, LLC data.

[7] *Refers to the detection of unintentional presence of GE crops.*

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 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 Agricultural Biotechnology Annual European Union.

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 and Demographic Challenge (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 Consumption (MOC),

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 Food Safety and Nutrition Agency (AESAN), ascribed to the Ministry of Consumption oversees 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 from 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, central[8] and regional[9] governments in Spain hold different responsibilities.

[8] *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 before the registration in the Commercial Varieties Catalogue.*

[9] *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, (except for those belonging to the national government portfolio)*

b) 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 the Agricultural Biotechnology Annual European Union. 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 decisions on renationalization of cultivation as an attempt, (in Post's understanding) 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**

c) STACKED or PYRAMIDED EVENT APPROVALS

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

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

Competent Authorities: Spain's competent authorities' approach towards IBs is rather positive. In 2015, in a position paper (available on this 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 to a process-focus, as the progress in science is outpacing updates in the regulatory framework. Spain has traditionally taken a science-based approach regarding 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 January 2019, the Spanish **National Biosafety Commission** published a report in response to the ECJ Ruling addressing a request put forward by Spain's Inter-ministerial Council for GMO. The report concludes that given its specificity, directed mutagenesis should be considered a low- risk technology. Since some products obtained through genome editing are non-distinguishable from spontaneous mutations, this prevents detection and limits ruling enforcement possibilities, such as imports control. Hence, it is their recommendation to carry out a major overhaul of the Directive 2001/18/EC.

On February 2019, the Spanish **Inter-ministerial Council for GMO (**CIOMG) reacted to the ECJ ruling with a report analyzing its consequences of the current EU regulations. The report called on the Commission to carry out a wider review and modernization of the biotechnology policy in the European Union.

During the EU Farm Council held on May 14, 2019, Spain was among the fourteen EU Member States that called upon Ministers to update EU laws in relation to Innovative Biotechnologies and called for clarity over the EU approval process for products developed using these technologies.

On November 2019, through Decision (EU) 2019/1904 the Council requested the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study. Spain participated in this study by responding to the EU Commission questionnaire during the Spring 2020. The study is expected to be delivered by April 2021. The CIOMG, the competent authority on the subject, based its responses to the Commission's questionnaire with information provided by the different entities involved in the management of biotechnology (MAPA, AESAN, Ministry for Universities, MITECO, Ministry of Industry, Trade and Tourism, Ministry of Interior, Official Control Laboratories), private sector stakeholders, and reviews of scientific publications and competent authorities in third countries.

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. 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(Spanish language only), 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.

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 to manufacture domestic compound feed, which is by default labeled as containing "Genetically Modified Organisms," since most 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 ingredients/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.

h) 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. Since 2017, no shipments have been rejected due to unauthorized presence of GE products in Spanish Border Inspection Points.

i) 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 percent[10] 'technically zero' level for shipments

[10] *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-*

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 brings 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, AESAN 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. Consequently, 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.**

j) ADDITIONAL REQUIREMENTS

Until 2019, the only information publicly available about commercial GE crops plantings in Spain was the total area at the province, regional, and national level. This was 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 (see the 2019 release, in Spanish), when submitting the CAP payment application form, farmers must declare all the agricultural plots on their holding, and for statistical purposes, whether they are growing GE corn varieties. The Spanish agricultural administration has been reluctant to publish information about the location of commercial GE crop plots, as the information could be misused.

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 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

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approved products of agricultural biotechnology for which an authorization procedure is pending in the EU or for which an authorization has expired.

(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 Registration of Commercial Varieties enables breeders to start reproducing and commercializing plant varieties in Spain.
- The Registration 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 must 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-year 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 must 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 it is a hybrid, as with most of the corn cultivated in Spain including GE varieties. 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 EU. Spain ratified the Protocol in 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 on 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. 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 Agricultural Biotechnology Annual European Union.

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 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

Competent Authorities: Spain's government has traditionally taken a pragmatic and science-based approach to regulating agricultural innovation. Regarding traditional agricultural biotechnology (transgenic), Spain has continuously relied on science as a basis for regulatory decisions. Its main regulatory bodies responsible for biotechnology affairs have reacted to the ECJ ruling with their own reports, analyzing the scope of the ruling's consequences. Spanish Competent Authorities maintain science is an important component in the decision-making process and defend the role of the European Scientific institutions.

Agricultural Stakeholders: Broadly speaking, 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 to the agricultural and food industry sectors 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 in the farming sector. This is particularly true for the **Spanish feed ingredients supply chain, feed, and livestock industries**, who have been traditional supporters of agricultural biotechnology.

Spain boasts of one of the EU largest livestock sectors. In the case of the pork sector, Spain exports nearly one third of its production to EU and third markets. Consequently, given that livestock producers face global competition, and that Spain depends on imported feedstuffs, the Spanish feed and livestock industry have repeatedly claimed that increased access to GE products will help them compete equally

in the global market. In addition, in areas where the corn borer represents a problem, corn growers widely accept and adopt the technology.

Some **farmers or food processors** that initially did not benefit from the GE technology are becoming more interested as they could see their competitiveness affected. New traits developed by using IB bring new stakeholders to the discussion as these technologies can bring positive traits to crops other than line crops, include consumer or environmental benefits. However, if regulated like conventional biotechnology crops, the introduction of these new crops in other agricultural producing countries will translate to Spanish farmers facing increased competition without having access to the technology.

Retail and Consumers: 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 manufacturing to avoid labeling products 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 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.

Regarding public perception 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 that Spaniards 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 from using fertilizers and pesticides than for the use of GE crops.

The 2018 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 31.2 percent of the participants in the survey consider that concerns on plant biotechnology overcome the benefits of the technology. This is down from the 33.4 percent registered in 2016. According to the Eurobarometer 2019 survey on food safety in the EU, only 17 percent of Spaniards expressed concerns over GE ingredients in their foods, compared to the 27 percent of the citizens that expressed concern at the EU level.

A study entitled "*Challenges facing European agriculture and possible biotechnological solutions*" and published in July 2015 identifies and analyzes agricultural challenges for nine major crops (including corn) in 13 EU countries (including Spain). The study examines how these challenges are addressed by public and private research sectors, using either conventional breeding, marker-assisted selection, transgenesis, cisgenesis, RNAi technology or mutagenesis. This study found that for the nine major crops in Europe, 40 percent of the challenges identified were addressed neither in the scientific literature nor in recent European public research programs. The private sector was addressing only a few of these "neglected" challenges confirming the considerable gap between farmer's needs and current breeding and biotechnology research. This study concluded that the current political situation in certain EU countries is an impediment to GE research to address these agricultural challenges in the future.

Another study published in November 2016, entitled "Bt maize cultivation in Spain: Economic, social and environmental benefits (1998-2015)" and founded by the Antama Fundation[11], 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 from the 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.

The study "*Economic, Social and Environmental Benefits of Bt corn cultivation in Spain (1998-2015)*" (in Spanish) by Francisco J. Areal from the 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 CO_2 fixation.

In June 2019, a study entitled *"Twenty-one years of using insect resistant (GM) maize in Spain and Portugal: farm-level economic and environmental contributions"* was presented by Graham Brookes, Agricultural Economist at PG Economics. This study analyzes the economic and environmental benefits of Bt corn cultivation in Spain and Portugal. The study concludes that farming Bt corn has

[11] *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.*

enabled farmers in the Iberian Peninsula to obtain an additional production of 1.89 MMT and an income increase of 283.4 Million Euros due to improved yields.

In September 2020, the Spanish Ministry of Agriculture, Fisheries and Food released a number of studies containing the regulatory framework applicable for innovative biotechnologies in third countries such as Argentina, Australia, Brazil, Canada, China, United States, Japan and New Zealand) (all links in Spanish language only).

Also, the Ministry has elaborated a bibliographic review of innovative biotechnologies and how these can fit in the EU's Strategies and Policies such as Common Agricultural Policy, Climate Change, and Green Deal and Farm to Fork Strategy as well as the possibilities that Innovative Biotechnologies present to address new demands by society (all links in Spanish language only). These bibliographic reviews highlight the potential that innovative biotechnologies hold in order to increase productivity and sustainability of the agricultural sector, improve crops resistance and reduce the dependency on agricultural imports, to reduce the environmental impact of agriculture, to enhance the nutritive composition or extend shelf life of food.

CHAPTER 2: ANIMAL BIOTECHNOLOGY[12]

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

In Spain, research conducted using **animal biotechnology** is permitted although prior notice must be provided through the same procedure and institutions as plant biotechnology. According to the public log managed by the Spanish MITECO, notifications of confined research on GE animals between 1998-2020 was carried out with hogs, rodents, 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.

[12] *Note: 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.*

Table 3. Confined Research with GE Animals Notifications

Year	Rodents*	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	
2019	X		X		
2020	X			X	

Source: FAS Madrid based on MAPA data

*Rats, mice and hamsters

** 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

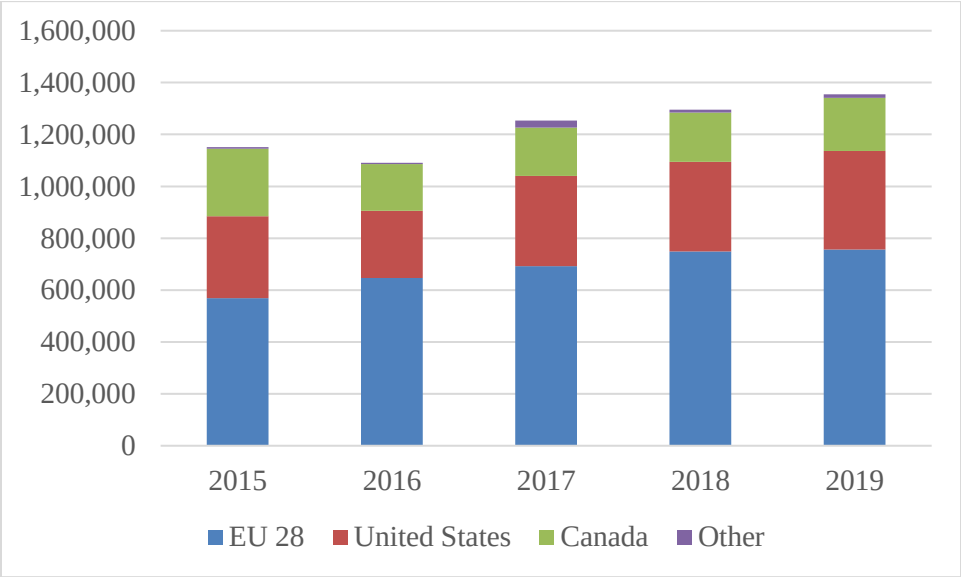
Spain does not produce commercial **GE animals**, **clones,** or products; hence there are no known exports within these categories.

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.

Total Spain's imports of bovine semen are in the pace of recovery since 2017, after a long-term decline (**Graph 12**). The United States is the second largest supplier of bovine semen after other EU Member States (lead by the France, **Graph 12** below). In the 2015- 2019 period, the average U.S. market share represented over 27 percent of imports in quantity and nearly 52 percent of the import market in value. In 2019, Spain's imports of bovine genetics from the United States accounted for $ 4.6 million.

Graph 12. Spain's Imports of Bovine Semen (HS Code 051110) (Units)



Source: Trade Data Monitor, LLC data.

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, see the latest Agricultural Biotechnology Annual European Union.

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 Consumption.

The 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 takes a technical approach to cloning as a breeding technology. The Sub Directorate General for Animal Health monitors 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 Consumption: AESAN an independent agency ascribed to the Ministry of Consumption, whose constituents are consumers, is invited to weigh in food risk related aspects and pays 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 and follows EU legislation.

d) LABELING AND TRACEABILITY

Spain has implemented EU legislation on labeling and traceability. For more information on this topic, see the Agricultural Biotechnology Annual European Union.

e) INTELLECTUAL PROPERTY RIGHTS

Spain has implemented EU legislation. For more information on this topic, see the Agricultural Biotechnology Annual European Union.

f) INTERNATIONAL TREATIES and FORUMS

Spain's participation in international treaties and forums is no different from that of the EU. As a member of the EU, Spain is member of Codex and of the World Organization for Animal Health (OIE). For more information on this topic, see the Agricultural Biotechnology Annual European Union.

g) RELATED ISSUES

N/A

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 on animal welfare and ethical aspects.

Thus far, Spanish livestock breeders have shown a limited interest in cloning due to the implied high costs. Additionally, while livestock breeders consider the preservation of positive productive traits through cloning as beneficial, the erosion of biodiversity is considered a negative consequence of the technology.

The 2016 Survey on Social Perception of Science and Technology in Spain conducted every two years by FECYT, concluded 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. It is worth noting that the 2018 release of this Survey, the enquiry on public perception on cloning was dropped from the Survey.

b) MARKET ACCEPTANCE/STUDIES

At the consumer level, cloning or GE animals are not widely discussed. In general, the use of animals for medical research aimed at finding cures for diseases or the recovery of endangered species is favorably regarded. 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 the preservation of 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.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY[13]

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

In Spain, microbes are largely used in food production processes such as fermentation (in bread, beer, dairy, wine among others). Genetic engineering (GE) has expanded the use of microbes in food and feed applications to produce additives, probiotics, food safety substance detection tools, bioproducts, bioprocesses and other technologies for feed, veterinary drugs and biofuels production.

The Spanish Association of Bioindustries (ASEBIO- in Spanish) maintains a weblog of **product** developments by its members in the biotechnology agri-food sector. Based in the information complied by the Bioindustries organization, most of the research activities concentrate on veterinary products. The second largest category of microbial biotechnology research activities includes ingredients, additives, probiotics and bioproducts, and bioprocesses. According to the 2019 Annual Report *by Spanish Bioindustry* Association (ASEBIO) *food biotechnology companies represented 38 percent of the biotechnology companies in Spain, holding the second largest group after human health biotechnology companies.*

b) EXPORTS

There are no official statistics available regarding exports of microbial biotechnology products. However, Spain exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

c) IMPORTS

There are no official statistics available regarding exports of microbial biotechnology products. However, Spain imports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS

Trade barriers for GE microbes and foods containing derived ingredients in Spain are the same as those established at the EU level. For more information about the European framework, see the latest Agricultural Biotechnology Annual European Union.

PART H: POLICY

[13] *Agricultural microbial biotechnology in this report is defined as using biotechnology, predominately genetic engineering (GE), to alter one or more characteristics of a microorganism (single-celled organisms, such as bacteria and fungi) mass-cultured through fermentation to produce of food ingredients.*

a) **REGULATORY FRAMEWORK**

Separate pieces of EU legislation cover GE microorganisms depending on whether deliberate release or contained use is concerned.

- **Contained** use is regulated by Directive (Directive 2009/41/EC)[14]. To qualify for confined use, both the GE microbe – or production organism – and the recombinant DNA (rDNA), used to genetically alter the organism must be absent from the final product.

- If criteria for contained use are not met, the product would fall under the scope of **deliberate release to the environment**, regulated by EU Directive 2001/18/EC[15].

These Directives were transposed to national regulation by Law 9/2003 (in Spanish) and implementation Royal Decree 178/2004 (in Spanish), as amended by Royal Decree 452/2019 (in Spanish).

In practice, the Spanish food industry opts for ingredients obtained using microbial biotechnology where the GE microorganism is not present in the final product, as opposed to where the GE microbe or recombinant DNA remain in the final product, to avoid the burdensome regulatory framework and labeling requirements.

- **Competent Authorities:**

Law 9/2003 (in Spanish) created and defined the responsibilities of the two competent authorities that weigh in on Spain's microbial 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. For more information about these entities' role, see More information in Section a) Regulatory Framework within **Plant Biotechnology Chapter. Part B: Policy.**

[14] *This Directive defines "contained use" as "any activity in which microorganisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment."*

[15] *In case of falling under deliberate release category, the GMM must also comply with EU Regulation (EC) 1829/2003 regarding market access requirements and authorization procedure for genetically modified food and feed as well as with Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.*

b) APPROVALS

Contained use is permitted in Spain subject to prior notice, public information, and authorization (Law 9/2003 – in Spanish).

c) LABELING and TRACEABILITY

In the case of contained use, as the GE microbe – the production organism – must be absent in the final product, only general EU food labeling rules apply. Additional information regarding the legal EU framework and Spain's specific requirements for food labeling is available at the latest EU FAIRS Country Report and Spain FAIRS Country Report.

d) MONITORING AND TESTING

Like is the case with plant biotechnology, the Spanish Food Safety and Nutrition Agency (AESAN), ascribed to the Ministry of Consumption coordinates the food chain control. The Autonomous Regions establish their own monitoring and sampling plans throughout the food and feed chain. For more information see Section h) Monitoring and Testing within **Plant Biotechnology Chapter. Part B: Policy.**

e) ADDITIONAL REGULATORY REQUIREMENTS

Spain applies EU-harmonized legislation regarding food additives and flavorings and processing aids. Information regarding the legal EU framework and Spain's specific requirements is available at the latest EU FAIRS Country Report and Spain FAIRS Country Report.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

The biotechnology sector can opt for protecting its innovations internationally through the European Patent Office or the Patent Cooperation Treaty, or at the national level through the Spanish Office for Patents and Brands. The Spanish Office for Patents and Brands (in Spanish) ascribed to the Ministry of Industry, Trade and Tourism, is the public body responsible for the registration and granting the different types of Industrial Property ranking from industrial property titles, including brands and commercial names (or distinctive signs), inventions, and industrial designs.

g) RELATED ISSUES

N/A

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Food ingredients derived from microbial biotechnology are not widely discussed in Spain.

b) MARKET ACCEPTANCE/STUDIES

There is little public awareness of food ingredients derived from microbial biotechnology being used in Spain.

Attachments:

No Attachments