

Required Report: Required - Public Distribution

Date: December 01, 2021

Report Number: SP2021-0031

Report Name: Agricultural Biotechnology Annual

Country: Spain

Post: Madrid

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

This report describes the agricultural biotechnology sector in Spain, covering production and trade, policy, and marketing aspects. It includes topics related to plant, animal, and microbial biotechnology. Spain is a powerhouse for agricultural biotechnology in the European Union, as the country remains the largest grower of biotech corn and a major consumer of feed ingredients. At the Member State level, there have been few changes affecting agricultural biotechnology as currently all eyes are set on the European Commission's future regulatory framework for genome editing.

Disclaimer: Spain, as a member of the European Union (EU), conforms to EU directives and regulations on agricultural biotechnology. It is therefore recommended that this report be read in conjunction with the [Agricultural Biotechnology Annual European Union](#).

EXECUTIVE SUMMARY

As an EU Member State (MS), Spain must abide by EU rules. However, Spain has traditionally taken a science-based approach to regulating biotechnology to defend farmers' access to agricultural innovation and avoid trade disruptions, despite the increasingly complicated European environment for biotechnology.

Spain is the largest grower of genetically engineered (GE) crops (96,606 Hectares [Ha] of Bt corn in 2021) in the EU. MON810 corn has been commercially grown in Spain uninterrupted since 1998. The country's regulatory framework allows confined research and field trials for GE and Innovative Biotechnologies (IB), although these are subject to prior notice and authorization.

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, as opposed to other EU Member States that only have a structural shortfall of protein feed ingredients (i.e., soybean and soybean meal).

Spain responded constructively to the EU Commission (EC) enquiry on new genomic techniques and welcomed the EC study that acknowledged the potential of gene editing to meet global challenges. The study recommends an update of the EU's legislation so that crops that are developed by modern plant breeding techniques but do not involve the introduction of genes from other species should be excluded from the genetically modified organism (GMO) regulatory package.

As for GE animals, research is permitted subject to prior notice and authorization and abides by the same rules as 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.

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

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Definitions and 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 |

“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).

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

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](#)). The same provisions apply to confined research and deliberate release of plants obtained through IBs.

Even though confined research and deliberate release can be carried out in the country, the current restrictive regulatory framework discourages domestic research and development as there is little certainty regarding development being able to achieve full potential at the commercial level. No new GE or IBs development are anticipated to reach the market within the next five years.

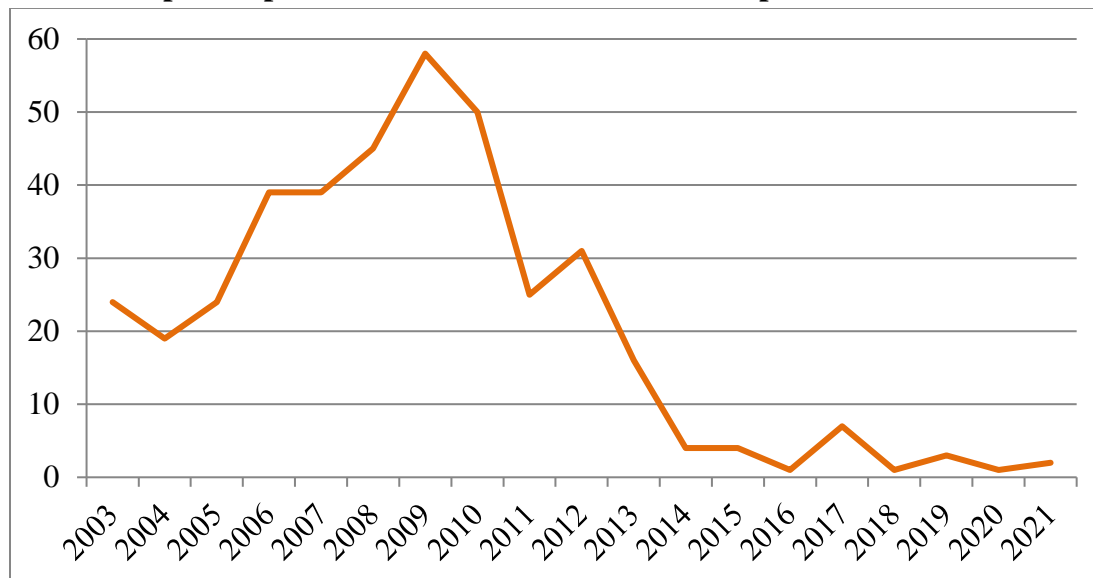
- **Confined Research¹:** In 2020, confined research activities on GE plants communicated to competent authorities included research tomatoes with high anthocyanin expression by [Universidad Islas Baleares \(in Spanish\)](#), GE petunias by Barberet & Blanc, and other non-specified plants by [Semillas Fitó](#).

In 2021 up to the date of this report, notifications on GE plant research in Spain included **corn** plants for pollination studies by [Eurofins Trialcamp](#), **strawberry plants** for fungal diseases control by [Viveros California](#), and crop development and pathogen resistance in **strawberry plants** by the [Universidad de Malaga](#).

- **Field testing:** Notifications to competent authorities for open field testing remain very low (**Graph 1**). 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 2021 according to the [Joint Research Center](#), the Spanish National Research Council ([CSIC](#)) presented two notifications for a field tests with **tobacco** plants.

¹ According to Law 9/2003, all entities that intend to use specific facilities for the confined uses of genetically modified organisms for the first time are obliged to notify the competent authorities in advance. However, subsequent trials by the same entities are not required to be communicated to competent authorities in the case of activities of zero or negligible risk. Consequently, additional zero or negligible confined research activities beyond those listed may be taking place.

Graph 1. Open Field Trial Notifications to Competent Authorities



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

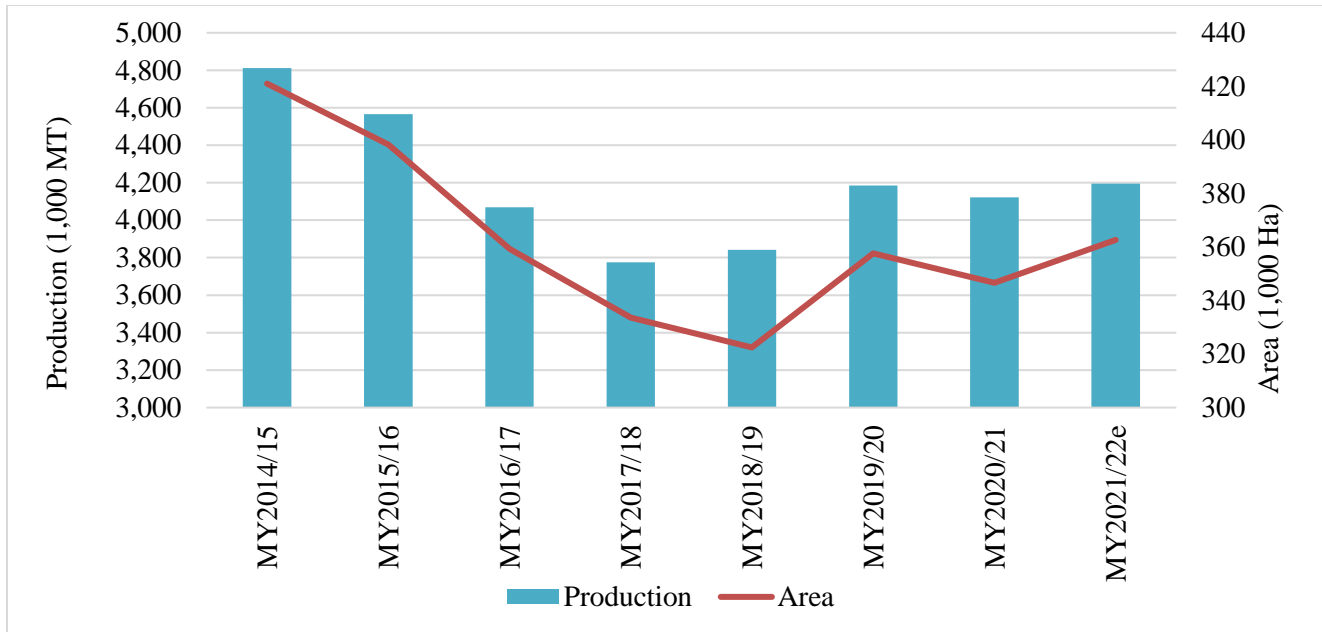
b) COMMERCIAL PRODUCTION

Spain is the largest EU producer of Bt corn. Spain's Bt corn area represents about 95 percent of the EU's total GE crops area, and the remaining five percent corresponds to Portugal, the only other EU Member State that grows GE crops. In 2021, area planted to Bt corn in Spain amounted to 96,606 Hectares. MON810 corn has been commercially grown in Spain uninterruptedly since 1998. Bt corn is grown in twelve of the seventeen Spanish autonomous regions. However, MON180 cultivation is concentrated in Ebro River basin (autonomous regions of Aragon, Catalonia and Navarra), where the corn borer is endemic. Spain was among the nine² EU Members that decided not to opt-out when [Directive 412/2015](#) was issued, which gave flexibility for Member States to restrict or prohibit biotech cultivation within their borders.

Total Corn Plantings: Total corn area in Spain has been declining since Marketing Year (MY) 2013/14. However, since MY 2019/20 total corn area in Spain has stabilized around 355 thousand Hectares (**Graph 2**). The use of irrigation technology and GE corn in those areas where the corn borer is an issue result in very stable yields. Improved crop margins, good spring planting conditions, and the agronomic practice in regions such as the Ebro Valley of planting corn as a second crop once winter grains are harvested, justify the somewhat higher area planted for MY2021/22. Factors preventing total corn area from further expansion include crop diversification established under EU's greening measures and, in absence of other tools, the need to carry out crop rotation to manage pests and weeds infestation.

² The EU MS that decided not to opt out include Spain, Portugal, Ireland, Finland, Romania, Sweden, Estonia, Slovakia, Czech Republic, plus the Belgian Region of Flanders.

Graph 2. Spain's Total Corn Area and Production*

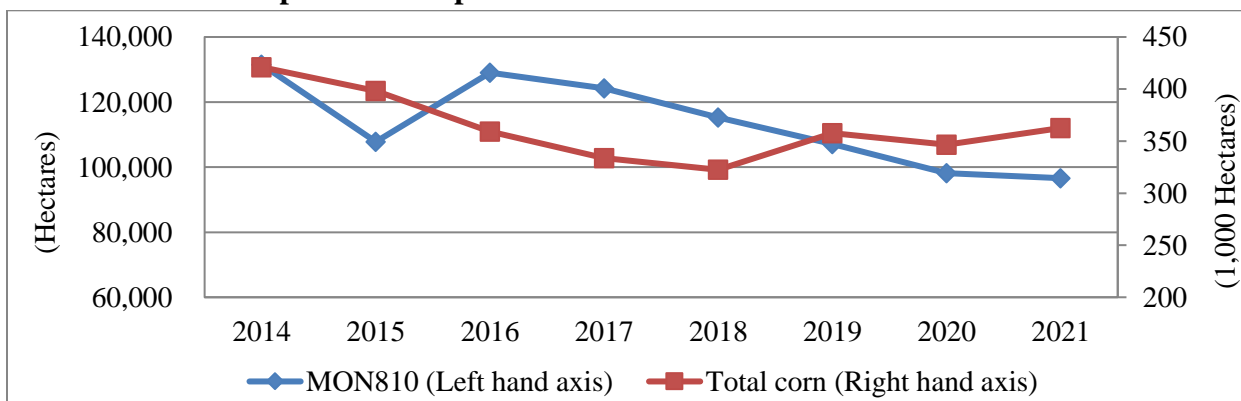


Source: MAPA and FAS Madrid estimates. *Includes GE and non-GE corn

Bt Corn Plantings: With the exception of 2015, the share of Bt corn has continuously expanded, reaching its highest point in 2016 (**Graph 4**). Since 2019³, a change in methodology for Bt corn planted area calculation has altered the absolute value of area planted to Bt corn.

Data available for 2021 indicates that Bt corn plantings declined by two percent, while total corn area grew by nearly five percent in the same period. The drop in Bt corn share (**Graph 4**) can be partially explained by the limited supply in the market of long-cycle corn seeds that were replaced by conventional corn plantings.

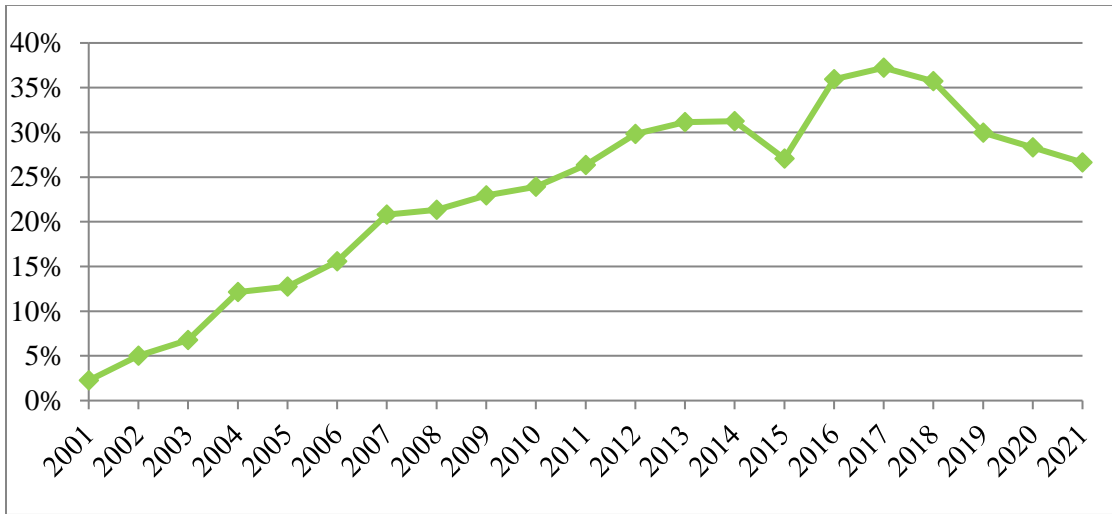
Graph 3. Total Spanish Area for Corn and MON 810 Corn



Source: FAS Madrid based on MAPA data⁴.

³ 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.

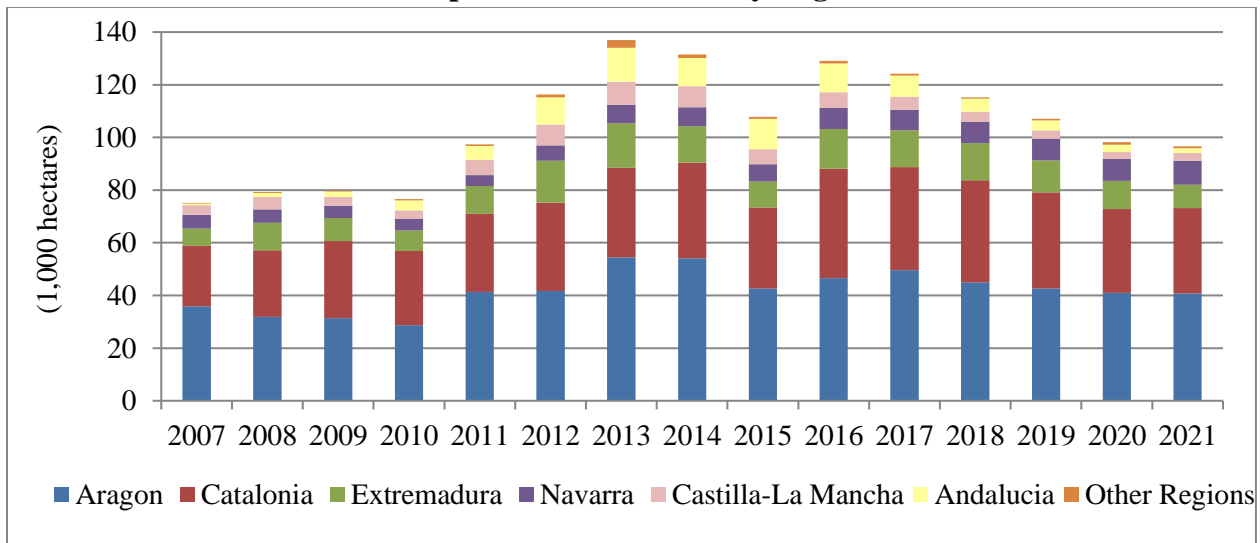
Graph 4. MON 810 Area Share in Spain (%)



Source: FAS Madrid based on MAPA data.

Nevertheless, the use of Bt corn in the Ebro River basin remains strong. Aragon and Catalonia (**Graph 5**) represent 42 and 34 percent, respectively, of the country’s GE area. In these areas, the corn borer is endemic, and the use of GE corn contributes to reduce pest incidence in the second crop⁵, allowing farmers to obtain and profit from two grain crops on the same plot.

Graph 5. GE Corn Area by Region



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.

⁵ Planting corn as a second crop is a fairly widespread agronomic practice 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.

In July 2021, Catalonia's Regional Plant Health Services [alerted](#) (Catalan language only) farmers about the presence of corn root worm (*Diabrotica virgifera*) in the Pla d'Urgell County (Lleida, Catalonia). This is the first time that the corn root worm has been detected in Spain. The zone that presented evidence of infestation is an area with a high density of feed compound factories, and where MON-810 is extensively cultivated.

Since 2014, with [Decision 2014/62/EU](#), this pest is no longer considered as a harmful quarantine organism, however, it can cause significant damage to the corn crop, so maximum attention should be paid to its presence and take measures to prevent their spread. The regional health services recommend crop rotation as a tool to mitigate the damage of this new plant pest.

Factors limiting expansion of Spanish GE crops:

- **Total corn area is stable:** Spain's total corn area has stabilized around 355 thousand MT. Crop rotation for pest control management, crop diversification established by EU greening measures⁶, and competition by other crops limit corn area from expanding further. At the same time, the expansion of corn as a second crop, together with the limited alternative crops in some regions prevent total corn area from falling.
- **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 an issue. Approvals of new traits could raise growers' interest in planting other GE corn events, or new 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.

⁶ 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

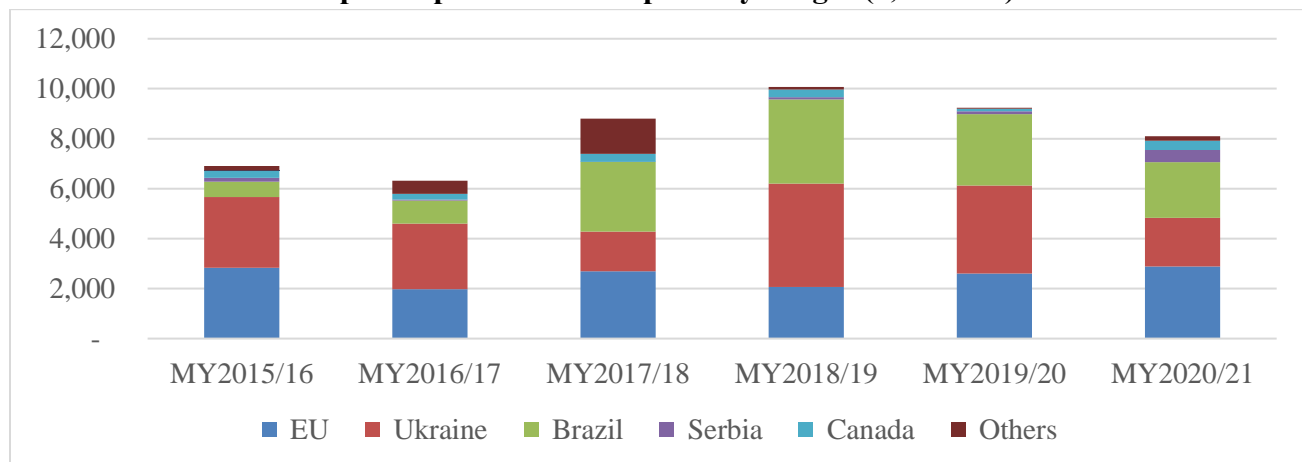
Spain is a net importer of grains and oilseeds as domestic production is not enough to meet the demand of Spain’s robust export-oriented livestock sector. Despite being the EU’s Bt corn production powerhouse, Spanish exports of GE products are negligible as production is fully utilized by the robust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

d) IMPORTS

Spain is the EU’s largest feed ingredient importer as the country’s dependency on imported feedstuffs affects both grains and oilseeds. The country’s strong reliance on imports and its 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 to the expansion of GE crop cultivation and imports. Moreover, Spain imports a large amount of GE products. Products derived from agricultural biotechnology shipped to Spain consist mainly of soybeans and products, and corn and corn processing by-products.

Grains: The amount of grains imports depends on the size of the highly variable domestic crop, the pasture availability, and the evolution of demand from the livestock sector. Spanish total annual grain imports range from 12 million MT to 17 million, out of which between 6 and 10 million are corn imports. 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. The progressive adoption of agricultural biotechnology in countries such as the United States, Argentina, and Brazil, has forced Spain-based commodity trading companies to source most of the country’s extra EU corn import needs from Ukraine (Graph 6).

Graph 6. Spain’s Corn Imports by Origin (1,000 MT)⁷

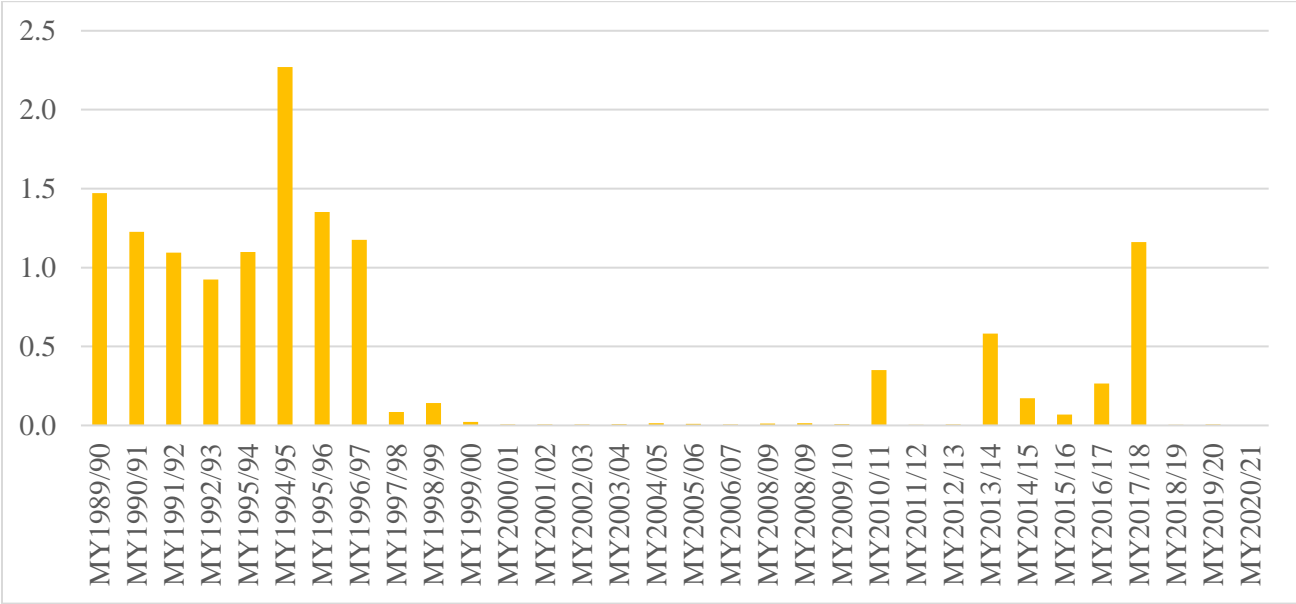


Source: Trade Data Monitor, LLC data.

⁷ Corn Marketing Year is October September.

Graph 7 illustrates the drastic decline of U.S. corn exports to Spain starting in 1998, when GE corn was first planted in the United States, as a direct consequence of the asynchronous GE events approvals between the United States and the EU. The recovery in Spanish imports of U.S. corn that occurred in MY 2017/18 came to an end in June 2018, when U.S. corn imports were discontinued due to an EU 25 percent retaliatory tariff against U.S. steel and aluminum tariffs.

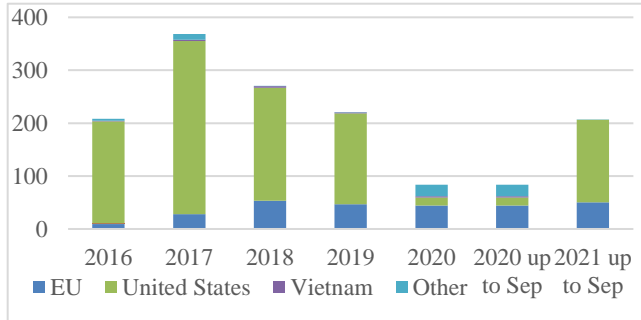
Graph 7. U.S. Corn Exports to Spain (Million MT)⁷



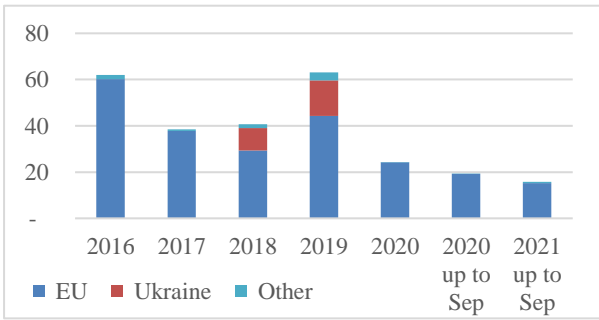
Source: Trade Data Monitor, LLC data.

Regarding corn processing by-products, **Graph 8** shows how in 2021 soaring feed ingredient prices opened opportunities for imports of U.S. Distiller’s Dried Grains with Solubles (DDGS). In the case of Corn Gluten Feed (CGF) (**Graph 9**), trade within the EU (mostly non-GE) satisfies virtually all the Spanish demand.

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



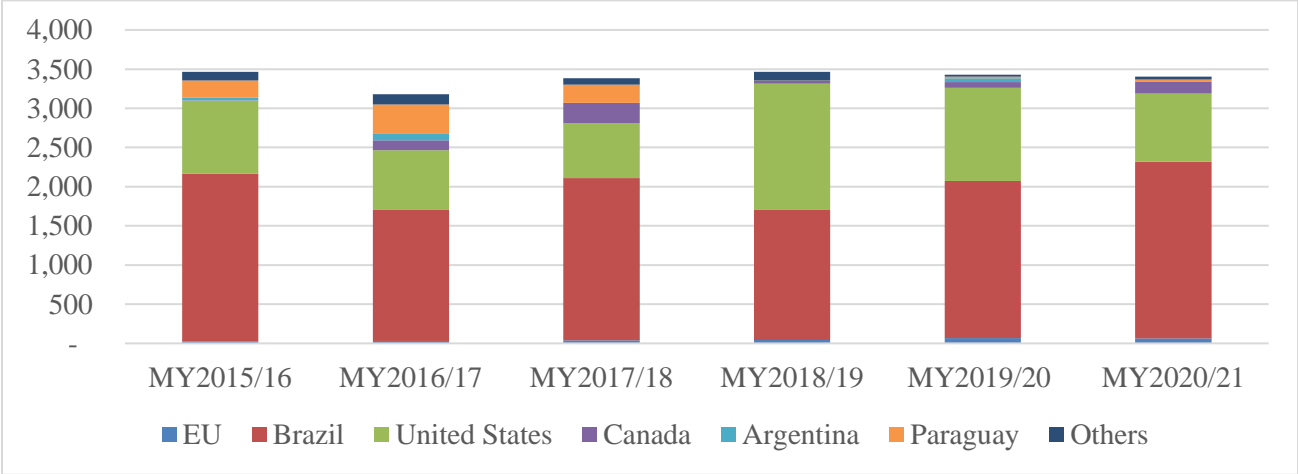
Graph 9. Spain’s Imports of CGF (HS code 230310) (1,000 MT)



Source: Trade Data Monitor, LLC data.

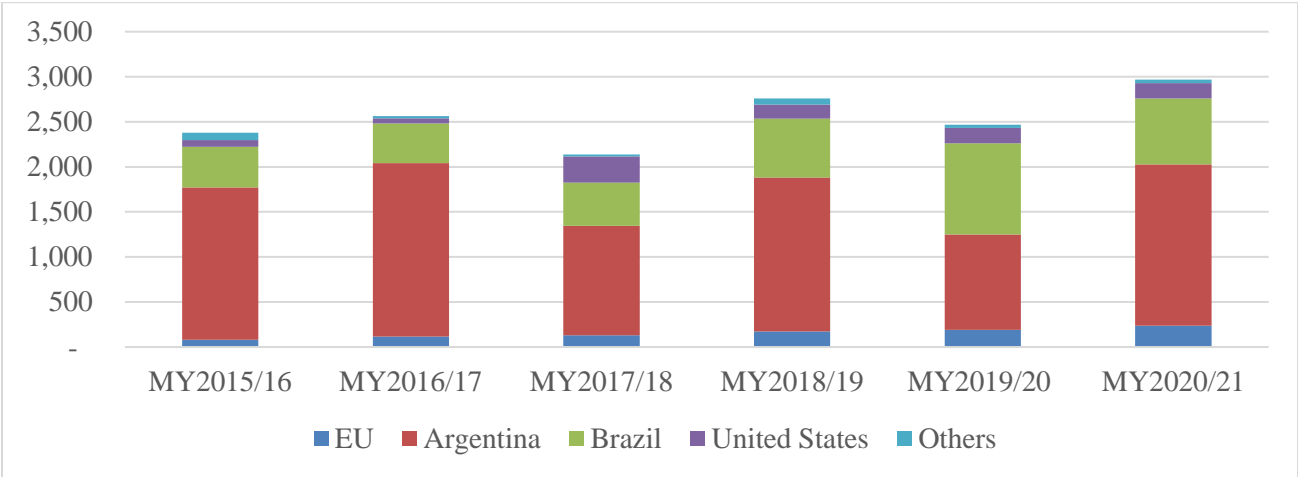
Oilseeds: Spanish oilseed production is comprised of olives and sunflower, both primarily intended for the food market. Rapeseed production is small and normally exported to neighboring Portugal or France. Hence, Spain needs to import most of the protein feed ingredients. On average, Spain’s annual combined imports of soybean and soybean meal amount to nearly six million MT. 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 at nearly 2 percent of total sales and partially satisfied by Spanish beans (4,900 MT in 2021), and primarily intended for food uses and aquaculture feed. 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. In MY 2020/21 Spain’s soybean seed imports remained unchanged (**Graph 10**), with U.S. soybeans losing market share to Brazil and Canada to a lesser extent. Data available for MY 2020/21 show a post-COVID recovery of soybean meal import (**Graph 11**), mainly originating from Argentina.

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



Source: Trade Data Monitor, LLC data.

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.

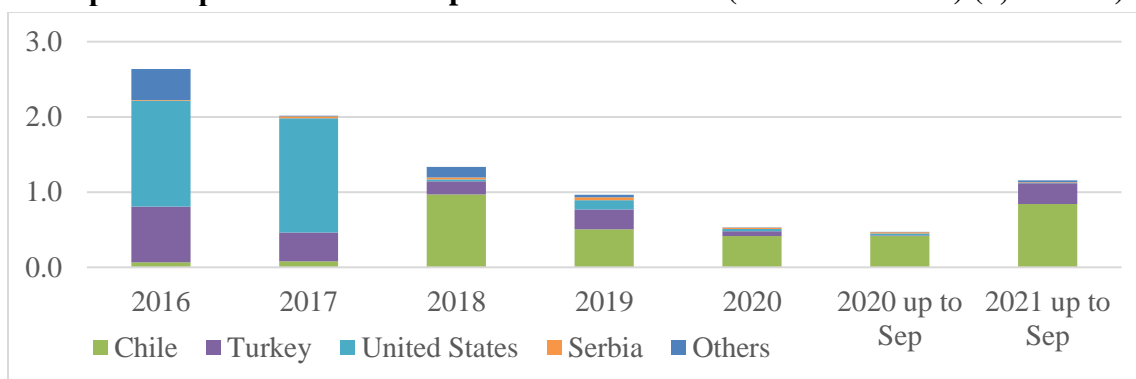
f) TRADE BARRIERS

- **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 6**). Additionally, the limited allowance for adventitious presence⁸ for non-approved events continues to constrain 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, 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 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. The unfavorable seed-corn growing conditions in the Northern Hemisphere have resulted in increased seed-corn imports from Chile in 2021 (**Graph 12**).

For additional information, see Section h) Monitoring and Testing within **Part B: Policy**.

⁸ Refers to the detection of unintentional presence of GE crops.

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



Source: Trade Data Monitor, LLC data.

PART B: POLICY

a) REGULATORY FRAMEWORK

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 the 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 GMOs was transposed to national regulation by [Law 9/2003 \(in Spanish\)](#). This applies to both 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 and manages risk taking into consideration CNB's assessment.

Since June 2018, following a new Spanish government and a 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 manages risk. 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 82 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 GMOs (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, central⁹ and regional¹⁰ governments in Spain hold different responsibilities.

⁹ 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.

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.

¹⁰ 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).

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. Member States replies, including Spain's, are publicly available in the [EC's website](#). Spain responded very constructively to the EU Commission enquiry, and after reviewing different sources of information, the Inter-Ministerial Council for GMO the (CIOMG) identified the main problems in applying conventional biotechnology regulation to innovative biotechnologies, such as identifying the technology used, how to obtain solid evidence to impose fines for non-compliance and ensuring efficiency in control systems. The CIOMG also identified opportunities for innovative biotechnologies in the agri-food sector to meet targets under [Common Agricultural Policy](#), [Climate Change mitigation](#), and [Green Deal and Farm to Fork Strategy](#), for medical purposes, small and Medium Enterprises as well as to [new societal demands](#) (all of these links are in Spanish). In terms of research and development, CIOMG conveyed that applying conventional biotechnology regulation to innovative biotechnologies will stifle the number of publications on the subject and reduce the possibilities of carrying out technology transfer.

The EC's "[Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16](#)." was released in April 2021. The study acknowledged the potential of gene editing to meet global challenges, and notes that most research into commercial

applications is taking place outside the EU. The study recommends an update of the EU's legislation so that crops developed by modern plant breeding techniques that do not involve the introduction of genes from other species are excluded from the GMO regulatory package. Spain's competent authorities welcomed EC Study's conclusions and are supportive of the Commission's initiative to adapt the current regulatory framework to the latest scientific developments.

For additional information, see GAIN Report entitled [European Commission Publishes Biotechnology Study](#).

In September 2021 the Commission published an [inception impact assessment](#) on plants derived from certain applications of genome editing along with a roadmap for a legal framework for plants obtained by targeted mutagenesis and cisgenesis, and for their food and feed products. Commission adoption is only planned for the second quarter of 2023, which will likely translate into regulation not earlier than 2024. For additional information see GAIN Report entitled [European Commission Publishes Roadmap on Legislative Initiative for Plants Produced by Certain Genome Editing Techniques](#).

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

f) COEXISTENCE

Spain is the EU's largest GE crop grower; however, the country has not yet implemented a coexistence regulation. Despite the lack of coexistence measures, Spanish farmers continue to grow GE corn without any incident between farmers.

A first draft of a coexistence decree was made public in 2004 but abandoned due to the lack of consensus among the interested parties. 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). 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 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. 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. 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. 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. 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.

Since January 1, 2021, the fourth Control Plan, called "National Plan for Official Control of the Food Chain 2021-2025", is in place. This plan includes within of its scope the official controls in the field of deliberate release into the environment of GE products for food and feed uses and aims to ensure that such release complies with the requirements established in current regulations. For this purpose, official controls are carried out in three areas:

- GE crops in commercial fields. Details on the official control program for GE crops production are available in the [link](#) (Spanish language only).
- Field trials of GE crops.
- Seed for GE food and feed production. Requirements for control, sampling and analysis for detection of GE presence are established by a [Ministry of Agriculture Resolution](#) (Spanish Language only).

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 percent¹¹ '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 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, as mandated by [Royal Decree 1378/2018](#) (Spanish language only), since 2019 Spanish farmers, when submitting the CAP payment application form, must declare all the agricultural plots on their holding, and for statistical and control and surveillance purposes, whether they are growing GE corn varieties, including those planning to grow GE corn as a second crop. 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

¹¹ 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.

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 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.

1) 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. Spanish Competent Authorities maintain science is an important component in the decision-making process and defend the role of the European Scientific institutions. The promises that IBs offer to counter climate change, and its adverse effects in agriculture, back up Spain's competent authorities in their support of the Commission's initiative to adapt the current regulatory framework to the latest scientific developments.

Agricultural Stakeholders: Within the agricultural sector, agricultural biotechnology is perceived as a tool to improve the competitiveness of farms through higher yields and lower use of inputs. Most of Spain's farmers associations are in favor of planting GE crops or crops obtained using IBs. 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.

Founded in 2016, [the Spanish Alliance for Sustainable Farming \(ALAS\)](#) gathers a group of Spanish agricultural stakeholders with the aim to support for all models of sustainable productive agriculture, based on scientific evidence. Given the country's variable yields and dependency on imported feed ingredients, it is critical to improve domestic production through the deployment of technology. In areas where the corn borer represents a problem, corn growers widely accept and adopt the technology.

The **Spanish feed ingredients supply chain, feed, and livestock industries** have been traditional supporters of agricultural biotechnology. Spain boasts of an export-oriented livestock sector. 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.

Some **farmers or food processors** that initially did not benefit from the GE technology are becoming more interested as they see their competitiveness affected. Moreover, additional tools to temper the impact that persistent droughts or plant pests have in yields would be welcomed by agricultural producers. 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.

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

Additional details about Spanish consumer preferences can be found in GAIN Report entitled [How COVID is Changing Consumer Behavior](#).

b) MARKET ACCEPTANCE / STUDIES

The presence of GE labeled consumer-oriented products is very limited in the Spanish market. Many 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 support GE food with 35 percent of respondents agreeing or totally agreeing that GE food should be encouraged.

In a [Eurobarometer 2011 survey](#), 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 about 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.

The [Eurobarometer 2020 survey](#) on making food fit for the future citizens’ main findings included that, when asked, Spaniards mention food safety, cost and nutrient content as main criteria when buying their food. The same opinion poll shows that for Spanish consumers, sustainable food implies affordable for all, nutritious and healthy, and with little or no use of pesticides.

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 farmers’ 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 funded by the Antama Foundation¹², 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 CO₂ 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 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

¹² 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.

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 crop 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.

In 2021, the Centre for Rural Economy within the School of Natural and Environmental Sciences in Newcastle University (United Kingdom) along with the Department of Economics, Universidad Pablo de Olavide (Spain) published a Study entitled: [EU Inspections of GM Content in Food and Feed: Are They Effective?](#). This study explores the effectiveness of inspecting regimes in controlling food and feed products containing GE content above established adventitious presence limits in food and feed.

CHAPTER 2: ANIMAL BIOTECHNOLOGY¹³

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 1998-2021 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.

¹³ 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 1. 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 | |
| 2021 | X | 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 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

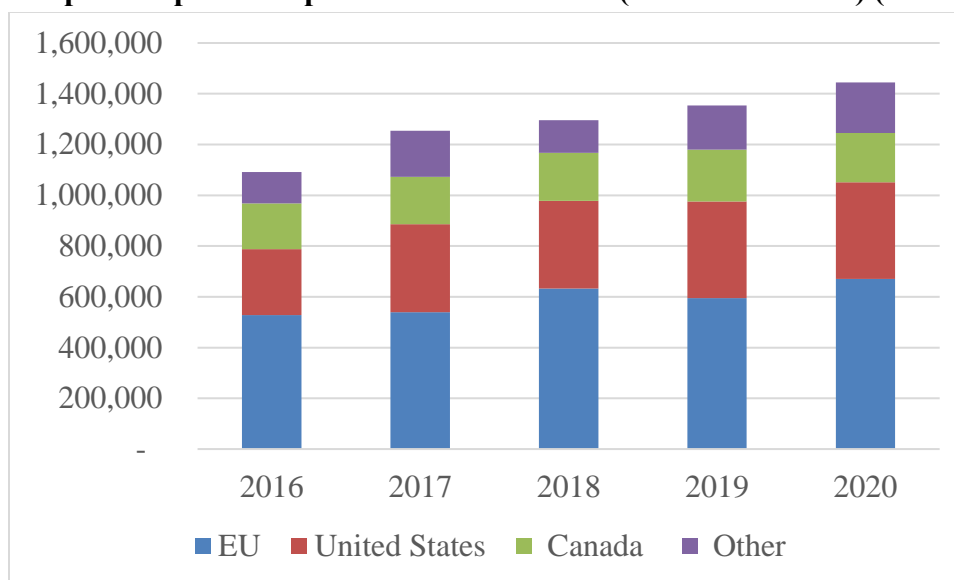
Spain does not produce commercial **GE animals, clones**, or products; hence there are no known exports within these categories.

d) IMPORTS

GE animals have been imported to Spain for research purposes. Genetically engineered animal imports are subject to notification requirements by customs authorities. Import requirements do not need to indicate whether embryos or semen is sourced from a cloned animal. Spanish livestock industry may have imported semen and embryos from cloned animals.

Spain's total imports of bovine semen have been recovering 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 2016-2020 period, the average U.S. market share represented over 27 percent of imports in quantity and nearly 50 percent of the import market in value. In 2020, 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 is an independent agency ascribed to the Ministry of Consumption, whose constituents are consumers, and 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. Similar 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 in 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 BIOTECHNOLOGY¹⁴

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 compiled 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 [2020 Annual Report](#) by ASEBIO, food applications biotechnology companies represented 43 percent of the biotechnology companies in Spain, holding the second largest group after human health biotechnology companies, which comprise 47 percent of Spain's biotechnology firms. In the case of companies working with food applications of biotechnology, 85 percent of them use biotechnology as a production tool.

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](#).

¹⁴ 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.

PART H: POLICY

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](#))¹⁵. 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](#)¹⁶.

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

¹⁵ 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.”

¹⁶ 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.

about these entities' role, see more information in Section a) Regulatory Framework within **Plant Biotechnology Chapter. Part B: Policy.**

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, hence it is hard to assess private or public perception.

b) MARKET ACCEPTANCE/STUDIES

There is little public awareness of food ingredients derived from microbial biotechnology being used in Spain. FAS Madrid is not aware of any study on microbial biotechnology acceptance.

Attachments:

No Attachments