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Report Highlights:

Spain remains the largest grower of biotech corn in the European Union and a major consumer of genetically engineered soybean meal in animal feed. The country has traditionally defended a science-based approach to agricultural biotechnology. Technical experts ascribed to National Regulatory bodies have expressed their concerns regarding the difficulties of implementing the European Court of Justice (ECJ)'s decision on regulating new breeding techniques (NBTs). Stakeholders remain preoccupied over the negative impact the ECJ ruling may 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 [EU-28 Biotechnology Annual Report](#).

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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 Economic Affairs and Digital Transformation
MITECO	Ministry for Ecological Transition and Demographic Transition
MS	Member State(s)
MSCBS	Ministry of Health, Consumption and Social Welfare
MT	Metric ton (1,000 kg)
OEVV	Spanish Office for Plant Varieties

Glossary:

“Genetic Engineering” means transgenesis.

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

EXECUTIVE SUMMARY

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

Spain, along with Portugal, is one of the only two growers of GE crops in the EU. Spain is also the largest grower with Spanish GE corn planted area representing 95 percent of the total EU GE planted area. Spain’s total planted area for corn varies every year based on water availability, irrigation costs, prices paid to farmers, pest presence, and competition from alternative crops. In Spain, GE corn and conventional corn plantings coexist. Although, seed companies report similar levels of GE seeds sales, the new plant density considered for area calculation (95,000 seeds per hectare since 2009) has resulted in a statistical GE area decline.

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

With the country holding continuous general elections, little progress has been made to change its regulatory framework. However, Spain’s two main regulatory bodies for biotechnology (National Biosafety Commission and Inter-Ministerial Council for Biotechnology) have issued reports expressing their concerns on the difficulties of implementing the ruling by the European Court of Justice (ECJ) on new breeding techniques (NBTs). In addition, stakeholders remain preoccupied by the negative impact the ECJ ruling will have on Spain’s research, and agricultural competitiveness.

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. As for GE animals, subject to prior notice and authorization, research is permitted and abides by the same rules as those for GE plant research. Most of the notifications in this area consist of basic research for pharmaceutical purposes carried out by public institutions.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

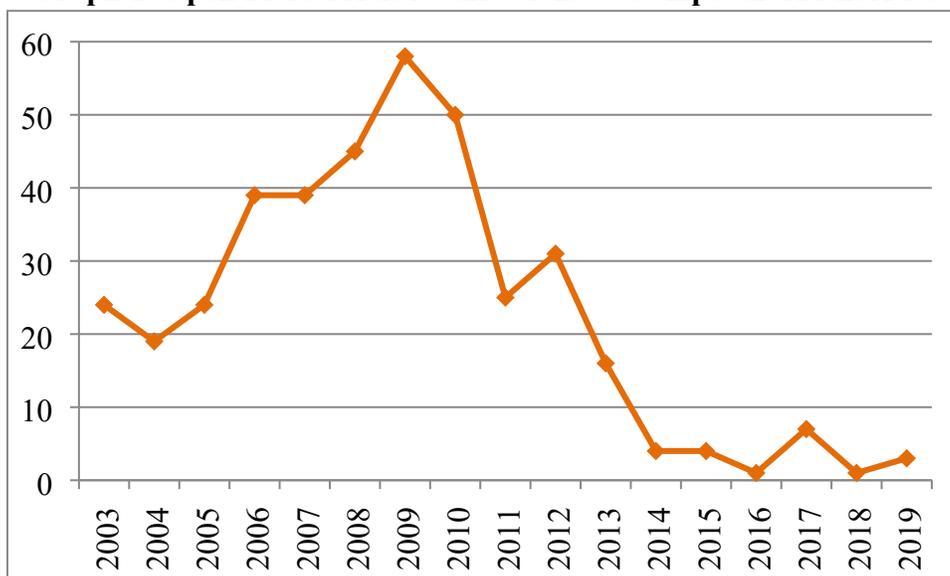
Both confined research and deliberate release to the environment of GE plants (field trials) are permitted in Spain subject to prior notice, public information, and authorization ([Law 9/2003 – in Spanish](#)). Confined research on IBs, is also subject of prior notice, public information and authorization.

The restrictive regulatory framework discourages domestic research and development. It also prevents these technologies from achieving 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. However, in 2019 field tests of plants obtained by using IB have been notified to competent authorities.

- **Confined Research:** In 2018, confined research activities on GE plants communicated to competent authorities include research with early-flowering and long crop cycle rapeseed plants by the company [Ideagro](#), as well as research with arabidopsis and tomato plants, where resistance to abiotic factors is been studied, by the [University Jaume I](#) (Castellón). This activity later activity continued in 2019. In 2019, the Center for Research in Agricultural Genomics ([CRAG](#)) communicated research on GE plants. An interesting piece of EU-funded research by CRAG, is the [importance of drought-resistant plants](#) by modifying the signaling process of a group of plant hormones called brassinosteroids.
- **Field testing:** Notifications to competent authorities for open field testing remain very low, reflecting public and private sector limited interest in developing crops adapted to Spain's conditions using GE or IBs given the uncertain regulatory environment. In 2018, according to the [Joint Research Center](#), notifications for deliberate environmental release of GE plants for any other purposes than market-placing come down to a biomass production assay in tobacco genetically modified with the *adrenomedullin* gene. In 2019, up to date, two notifications of deliberate release to the environment have been registered:
 - Field production (under net confinement) of **rice** plants accumulating three microbicide components in the endosperm by the [University of Lleida](#).
 - Propagation and evaluation in field productivity of **potato** lines (variety Atlantic) modified genetically by the over expression of the endogenous gene Susy of *Solanum tuberosum* by the company [Iden Biotechnology](#). However, this notification was withdrawn by the company.

- Field test of the development of **tobacco** plants with mutations in the sequence of SPL transcription factors, generated by CRISPR / Cas9. This notification was presented by the Spanish National Research Council ([CSIC](#)).

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**).

In MY2019/20¹, for the first time since MY2014/15, the long-term decline in total corn area reversed. Factors driving the area recovery include the reduction in area of alternative crops such as sugar beets, plus the increase in second crop corn plantings after the early winter grains harvest, this is particularly true in the case of the Ebro Valley area.

Table 1. Spain’s Corn Area and Production*

Marketing Year	MY2014/15	MY2015/16	MY2016/17	MY2017/18	MY2018/19	MY2019/20e
Area (1,000 Hectares [Ha])	421.6	398.2	359.3	333.6	322.4	359.0
Production (1,000 MT)	4,811.5	4,565.1	4,069.5	3,775.6	3,842.5	4,111.7

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

¹ Corn Marketing Year is October- September.

Planted area for Bt corn in Spain grew steadily until 2013 (**Graph 2** and **Table 2**) driven by an increased use of the technology that expanded to non-traditional areas. Since then, Bt corn area declined driven by the total corn area decline. While normally, a year with low corn borer incidence is followed by a year with lower share of Bt corn, in the past four years (2016 to 2018) the GE corn share has stabilized around the 35 percent (**Graph 3**).

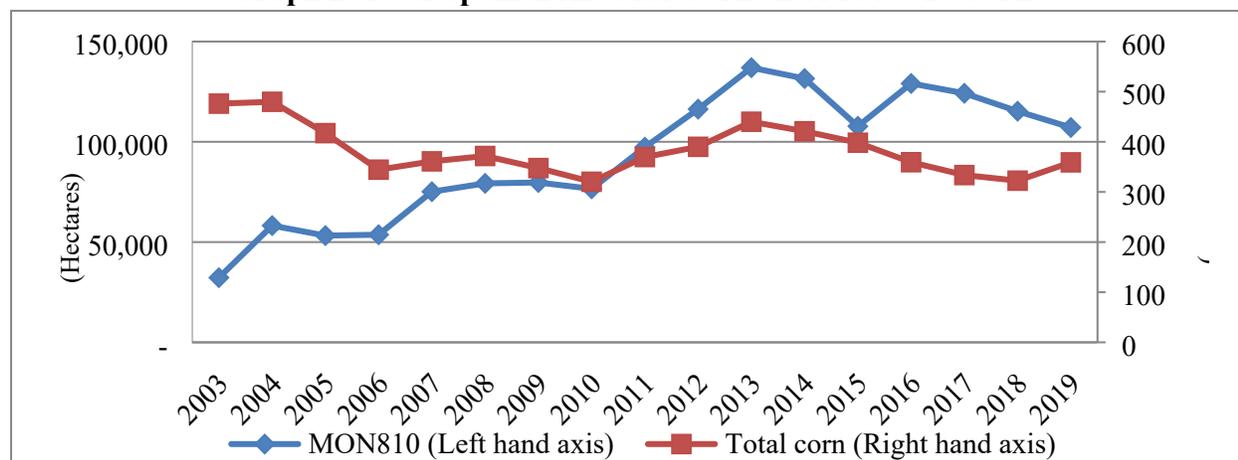
Until 2018, GE corn area estimates released by the Ministry of Agriculture are calculated considering the companies’ seed sales declaration and assuming an average planting density of 85,000 seeds per hectare. In 2019, GE corn area in Spain was calculated considering an average planting density of 95,000 seeds per hectare. Industry sources report similar seed sales compared to last season. Hence, it is Post’s understanding that what is driving the GE area decline is new planting density considered for area calculation.

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

Region	2013	2014	2015	2016	2017	2018	2019
Aragon	54,451	54,041	42,612	46,546	49,608	44,932	42,646
Catalonia	33,996	36,381	30,790	41,567	39,092	38,752	36,430
Extremadura	16,979	13,815	9,827	15,039	13,976	14,138	12,255
Navarra	7,013	7,264	6,621	8,066	7,778	8,101	8,253
Castile-La Mancha	8,766	7,973	5,734	5,932	5,039	3,805	3,101
Andalusia	12,862	10,692	11,471	10,919	8,013	4,972	3,795
Others	2,895	1,371	695	1,011	691	547	650
Total	136,962	131,538	107,749	129,081	124,197	115,246	107,130

Source: MITECO.

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



Source: FAS Madrid based on MAPA data².

² Since 2009, the Spanish Ministry of Agriculture, Fisheries and Food (MAPA) publishes GE crop area including not only corn varieties in the national register in the EU common catalogue, but also those varieties granted with a provisional authorization. Figures from 2009 up to present in the chart above have been updated accordingly.

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



Source: FAS Madrid based on MAPA data.

Factors Limiting Further Expansion of Spanish GE corn area:

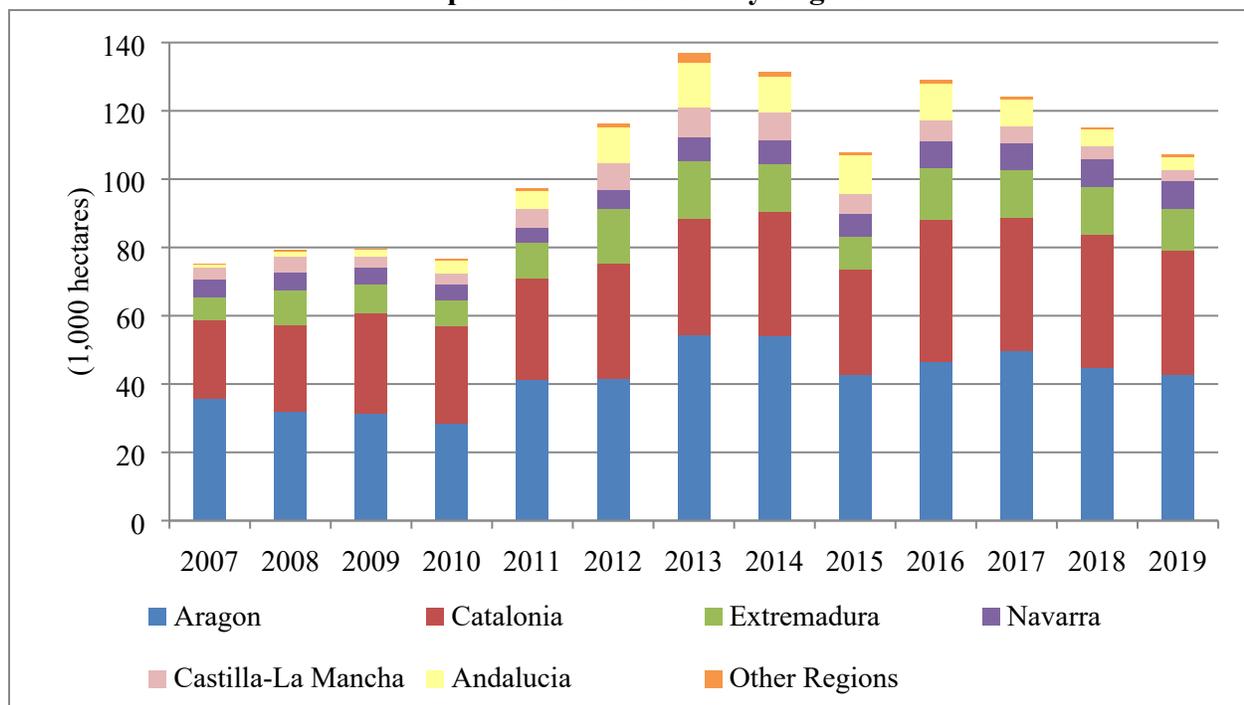
- **Total corn area registers a long-term decline:** Poor crop margins, competition by other crops, crop diversification established by greening³, and limited amounts of water for irrigation purposes in certain areas continues to force total corn area down. Despite the total corn area spike in MY2019/20, there is an overall long-term trend of increasing the area for tree crops, at the expense of arable crops and/or fallow land. However, some corn growing areas have few other planting options, so farmers continue to grow corn.
- **GE corn use is limited to areas where the corn borer represents a threat:** As MON810 is the only GE event approved for cultivation in the EU, possibilities of growth are limited to those areas where the corn borer represents a problem. Approvals of new traits could raise the interest in GE crops by other growers.
- **Feed compounders are the only users of GE corn:** Most Spain-based feed grain elevators, except for those devoted to special market niches, do not keep separate production lines for GE and non-GE corn. Practically all marketed feed contains GE soybean as a source of protein, and consequently 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

³ A large part of the support received by farmers (30%) is linked to greening measures. To comply with greening measures, crop diversification must be observed. Farms between 10 and 30 ha must grow at least two different crops, and farms over 30 ha must grow at least three different crops in their arable land, which ultimately introduces slight variations in areas where monoculture is carried out.

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. Better prices in the food corn processing industry along with limitations on water irrigation have resulted in a shift towards forage corn production. This may also have contributed to farmers switching to planting conventional corn varieties.

Data available for 2019 indicates that the Ebro River basin (autonomous regions of Aragon, Catalonia and Navarra) has the largest share of GE corn, accounting for nearly 75 percent of Spain’s total GE corn plantings, as the corn borer is endemic in this area.

Graph 4. GE Corn Area by Region



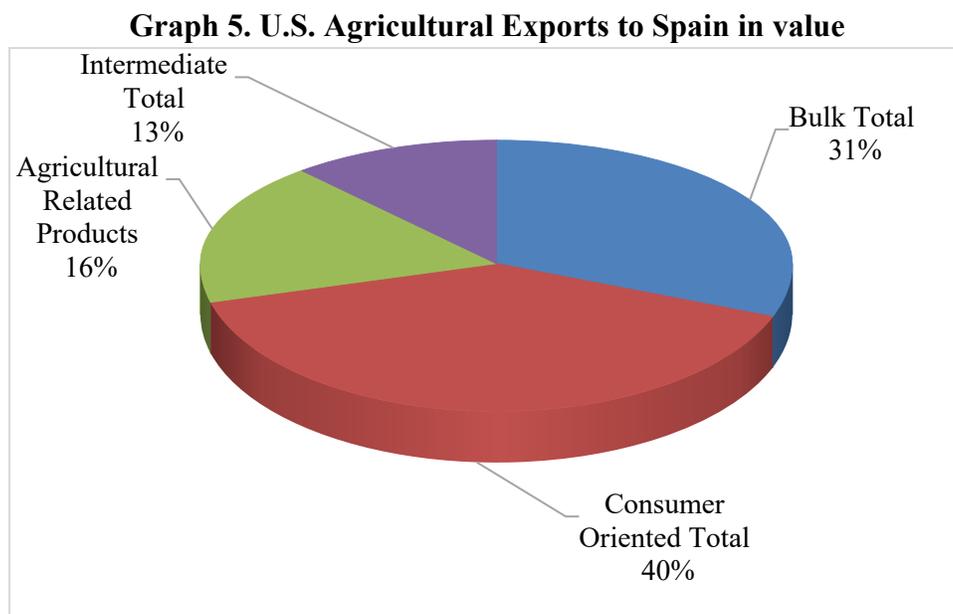
Source: FAS Madrid based on MITECO data.

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 largest producer of GE crops, Spanish exports of GE product 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 31 and 40 percent of the U.S. exports value during 2014-2018. Soybeans and tree nuts are the largest categories within these groups representing 26 and 36 percent of total agricultural trade, respectively (**Graph 5**).

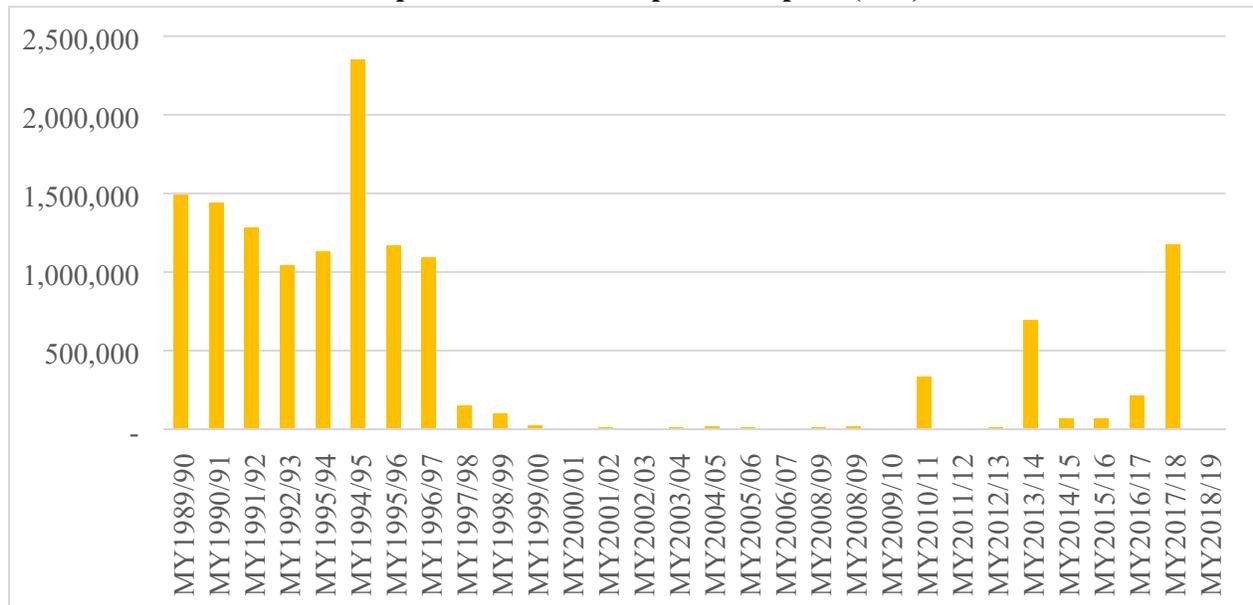


Source: FAS Madrid based on Trade Data Monitor, LLC data.

Spain imports a large amount of GE products. The country's dependency on imported feedstuffs and the science-based approach to GE crops have contributed to a high acceptance of the technology among feed-chain stakeholders. Over the years, these factors have led the expansion of GE crop cultivation and imports. Products derived from agricultural biotechnology imported to Spain consist mainly of corn and corn processing by-products, soybeans and products originating from countries such as in Brazil, Argentina, and the United States. Spanish total annual grain imports range from 9 to 18 million MT. Over the past ten years, Spain's total corn imports have followed an upward trend due to increased price competitiveness compared to other feed grains, and the steady demand by the Spanish livestock sector.

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.

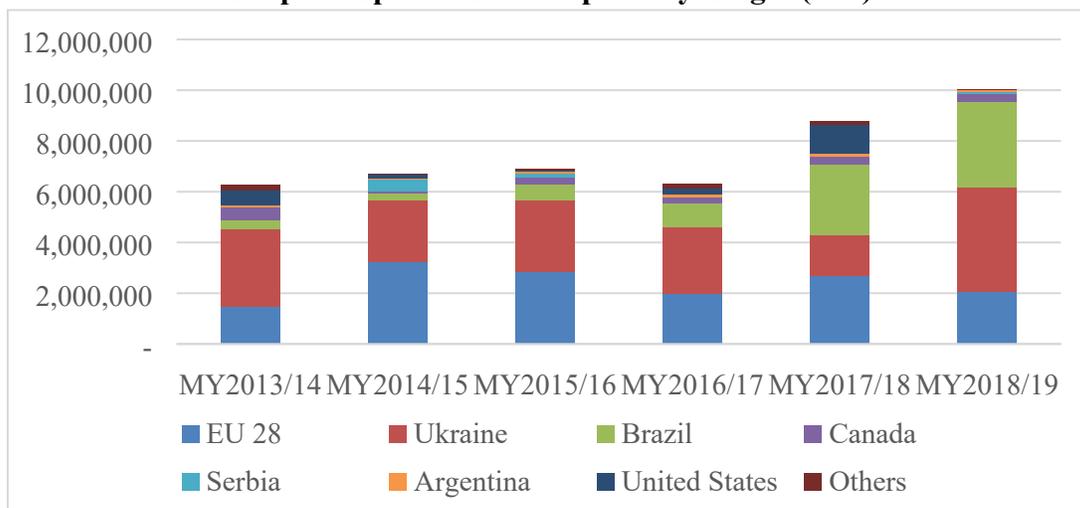
Graph 6. U.S. Corn Exports to Spain (MT)



Source: Trade Data Monitor, LLC data.

Initially, agricultural biotechnology adoption in Argentina and Brazil forced Spain-based feedstuff importers to find alternative corn providers, such as Ukraine. However, in MY2017/18 both the United States and Brazil increased their share of the Spanish corn import market (**Graph 7**), representing a combined 45 percent of the country’s corn imports. During MY2017/18, Spanish imports of U.S. corn recovered to significant levels since MY1996/97. However, in MY2018/19, Spain’s imports of U.S. corn were virtually zero and are anticipated to stay at the same level during MY2019/20, as a result of EU retaliatory duties imposed on U.S.- sourced corn since June 2018.

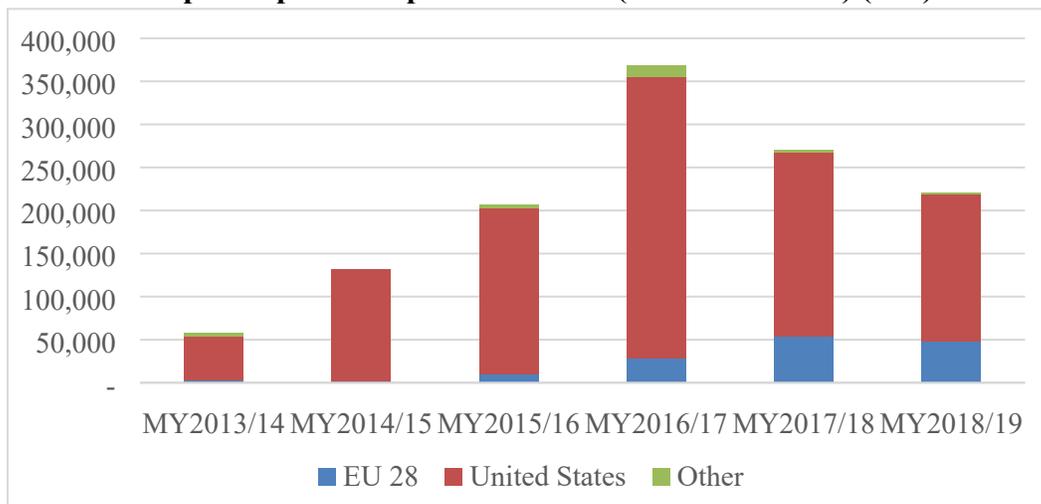
Graph 7. Spain’s Corn Imports by Origin (MT)



Source: Trade Data Monitor, LLC data.

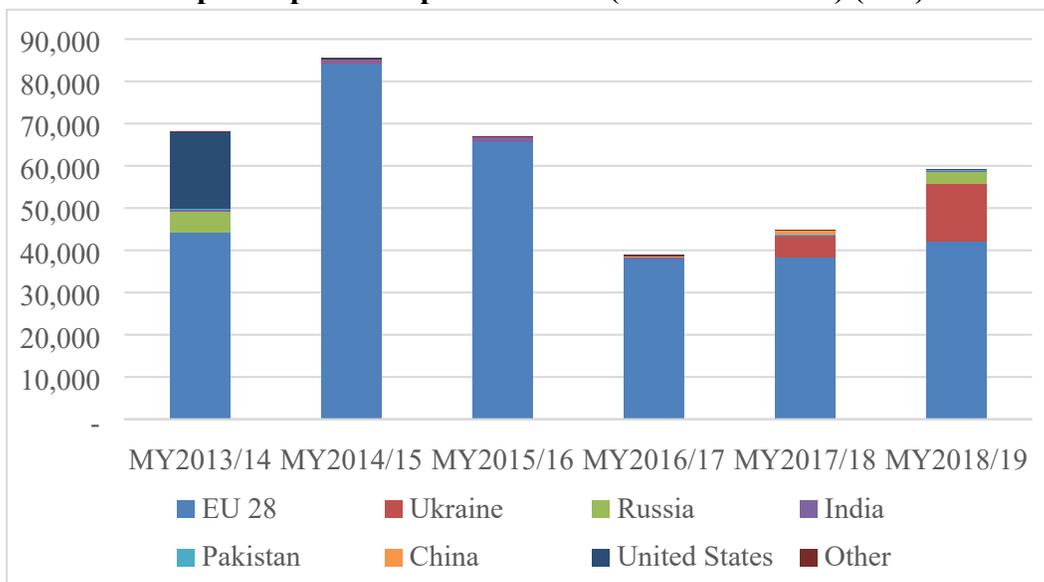
Regarding corn processing by-products, **Graph 8** below shows that in 2016 and 2017, lower domestic bioethanol production, along with competitive prices, opened new opportunities for Distiller’s Dried Grains with Solubles (DDGS) imports. However, ample domestic DDGS supplies and competitively priced soybean meal have resulted in a reduction of Spain’s imports of DDGS in 2018. Data available for 2019 indicate that DDGS imports are somewhat lower than during the previous year. Most of these imports originated from the United States. In the case of Corn Gluten Feed (CGF) (**Graph 9**), intra-EU trade satisfies virtually all the Spanish demand. According to trade statistics, in 2019, Spain increased purchases of Ukrainian CGF.

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



Source: Trade Data Monitor, LLC data.

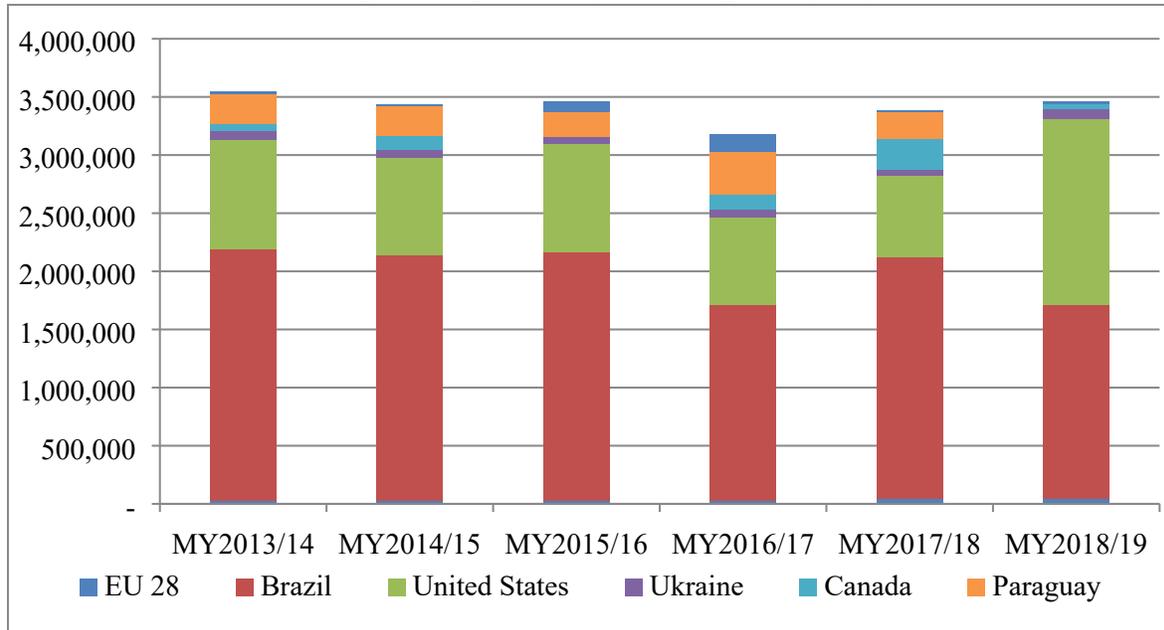
Graph 9. Spain’s Imports of CGF (HS code 230310) (MT)



Source: Trade Data Monitor, LLC data.

On average, Spain’s annual combined imports of soybean and soybean meal amount to nearly 6 million MT. 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 MY2018/19⁴, competitively priced U.S. soybeans allowed the United States to increase its market share. Virtually all Spanish imports of soybean products are GE, except for those devoted to niche special markets. Post estimates non-GE soybean meal demand in Spain is less than 5 percent of total. The impact of the slower approval pace has been less significant in the imports of protein feed ingredients than in the grain sector.

Graph 10. Spain’s Soybean Imports (MT)

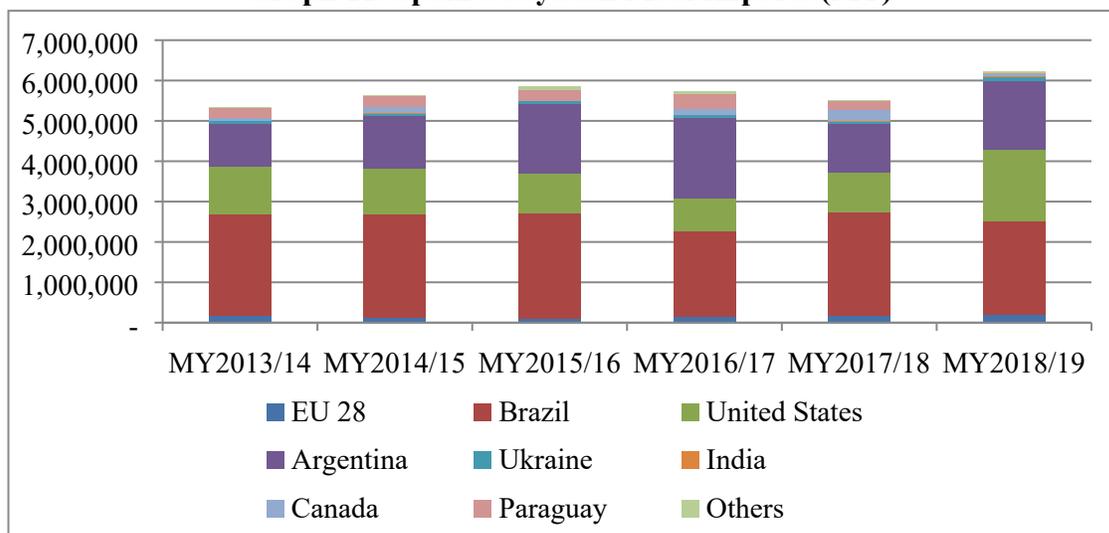


Source: Trade Data Monitor, LLC data.

After hitting rock bottom levels in MY2011/12, Spain’s soybean meal imports grew until MY2017/18, when total meal imports declined in favor of increased soybean seed imports for crushing (**Graph 10**). In MY2018/19, favorable U.S. soybean prices led to an increase in the U.S. share of Spain’s soybean meal and soybean seed markets. However, during average years, Argentina with a nearly 70 percent share, and Brazil, covering over 20 percent, traditionally supply most of the Spanish soybean meal market (See **Graph 11**). In MY2018/19, Argentina recovered its market. The growth in Spanish livestock production fueled Spain’s demand for soybean meal and the full use of the country’s soybean crushing capacity.

⁴ Soybeans Marketing Year is October September.

Graph 11. Spain's Soybean Meal Imports (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 in-kind food aid may be provided. This avoids pushing local prices down and discouraging domestic production in recipient countries. Hence, local purchases in recipient countries are preferred. Spain is a founding member of IFAD (International Fund for Agricultural Development), the 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. Within Spain's Ministry of Foreign Affairs, EU and International Cooperation, the Spanish Agency for International Development Cooperation (AECID), created in 1988, is responsible for elaboration, execution and management of the cooperation programs and project. This is whether working directly, either through its own resources, or through collaboration with other national or international organizations and Non-Government Organizations (NGOs). This Agency, ascribed to the Under-Secretariat for International Cooperation (SECI), has an extensive structure overseas.

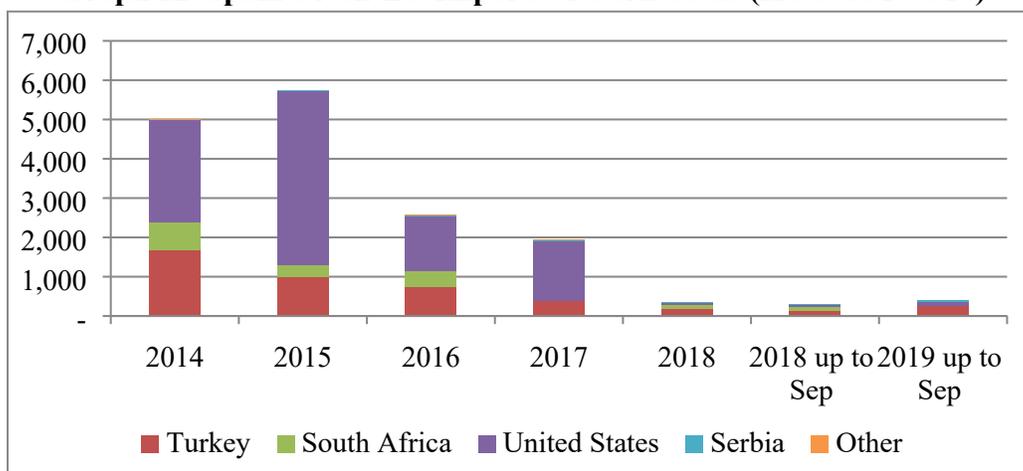
f) TRADE BARRIERS

- **For bulk commodities:** The asynchronous approval of GE events cultivated in the United States yet not authorized for import to the EU remains the main trade barrier. The expansion of GE crop production in traditional grain supplying countries had a significant impact on trade flows to Spain. For instance, in the corn market, Ukraine, Serbia and Russia have progressively increased their market share over the years at the expenses of lower imports from the United States, Argentina and Brazil (See **Graph 7**). Additionally,

the limited allowance for adventitious presence⁵ 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. A threshold level for adventitious GE material presence in seed has not yet been set. Therefore, Spain is forced to source its corn seeds from other EU Member States (mainly France), which constitute 95 percent of Spain seed corn imports. Non-EU suppliers of corn seed, accounting for five percent of the seed import market, include the United States, Turkey, South Africa and Chile. 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)



Source: Trade Data Monitor, LLC data.

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

⁵ Refers to the detection of unintentional presence of GE crops.

The EU [Directive 2001/18](#) on the deliberate release into the environment of “genetically modified organisms (GMOs)” was transposed to national regulation by [Law 9/2003 \(in Spanish\)](#). This applies to both the confined use and environmental release. This same piece of regulation created and defined the responsibilities of the two relevant authorities that weigh in on Spain’s agricultural biotechnology decision-making process. These are the National Biosafety Commission (CNB) and the Inter-Ministerial Council for Genetically Modified Organisms (CIOMG). Under this two-tier system, the CNB carries out the risk assessment and the CIOMG decides the country’s position taking into consideration CNB’s assessment. Since June 2018, following a new Spanish government and following Cabinet-Level reorganization, agricultural and environmental affairs were separated into two different Ministries: The Ministry of Agriculture, Fisheries and Food (MAPA) and the Ministry for Ecological Transition (MITECO). The CNB is ascribed to the Ministry for Ecological Transition, and the CIOMG to the Ministry of Agriculture, Fisheries and Food.

National Biosafety Commission (CNB): The National Biosafety Commission is an advisory body, ascribed to the MITECO, whose role is to scientifically assess the requests for cultivation, confined use and marketing of GE products submitted at either the national or regional level. The CNB is comprised of representatives from different ministerial departments, representatives of the autonomous regions and experts in agricultural biotechnology. This Commission is chaired by the Director General of Environmental Quality and Assessment and Natural Environment. The composition of the CNB is available in the [link \(in Spanish\)](#).

- **Inter-ministerial Council for GMOs (CIOMG):** The CIOMG takes a technical approach, and it is the competent authority to grant nationwide authorizations for confined use, voluntary release and marketing of products derived from biotechnology. The CIOMG coordinates with the CNB and liaises with the European Commission (EC) and the Autonomous Communities. This Council is chaired by the Secretary General for Agriculture and it is comprised by representatives of the Ministries that are somehow related to agricultural biotechnology. It includes representatives from the Ministry of Agriculture, Fisheries and Food (MAPA), the Ministry of Health, Consumption and Social Welfare (MSCBS), Ministry of Economy and Enterprises (MINECO), and the Ministry of Internal Affairs. The composition of the CIOMG is available in the [link \(in Spanish\)](#).
- **Other Ministerial departments involved:** The Spanish Office of Vegetal Varieties, belonging to the Directorate General for Agricultural Productions and Markets, is responsible for registering and monitoring of GE seed for planting. Information on the corn varieties registered for planting in Spain is available on this [link \(in Spanish\)](#). At present there are 90 GE corn varieties approved for commercial cultivation. Within MAPA, the Sub-Directorate General for Animal Feed and Resources Preservation coordinates the National Plan in feedstuffs whereas the Spanish Food Safety and Nutrition Agency (AESAN), ascribed to the Ministry of Health, is in charge of the food chain control. Other Ministerial Departments weigh into the agricultural biotechnology decision-making process through their participation in the CIOGM or the CNB.

- **Civil Society Participation - Consultative Committee for GMO:** While the cultivation of GE crops is permitted, Spain is also strengthening public information and participation. The Consultative Committee for “GMO” (CPOGM) ascribed to the Inter-Ministerial Council was created in October 2010 [by Ministerial Order 2616/2010 \(in Spanish\)](#). This body’s main objective is to reassure public participation in agricultural biotechnology issues so that the Inter-Ministerial Council obtains first-hand information of civil society representatives. The CPOGM can express its opinion on upcoming decisions and it is entitled to prepare proposals for examination by the CIOMG. The CPOGM is comprised by representatives of farmers’ unions, agricultural cooperatives, consumers’ organizations, labor unions, conservation NGOs, food industry, pharmaceutical industry, the Entrepreneurial Organization, and the National Network for Rural Development. The seed breeding industry is not represented in this consultative group.

Due to the country’s decentralized structure, central⁶ and regional⁷ governments in Spain hold different responsibilities.

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 [EU-28 Biotechnology Report](#). With only a couple of exceptions, Spain has traditionally voted in favor of new events for imports within the Standing Committee on the Food Chain and Animal Health in Brussels.
- **For cultivation:** Spain’s position on renationalization of cultivation decisions has evolved through the years. When this debate was first launched, Spain reacted cautiously by putting forward concerns over common market implications and compliance with WTO rules. However, Spain voted in favor of the renationalization of cultivation decisions in what Post understood as an attempt to open the door to cultivation of new events. [Royal Decree 364/2017](#) amending [Law 9/2003 \(in Spanish\)](#) transposes [Directive \(EU\) 2015/412](#) into National Law. The National Law establishes that in those cases where GE corn cultivation takes place near to the borders, a 20 meters isolation distance must be observed. More information in Section e) Coexistence within **Part B: Policy**

⁶ *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.*

⁷ *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)*

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 in the [link](#), Spanish language only) Spanish authorities expressed their preference for a case-by-case approach for IBs and endorsed a product-focus basis. These approaches were preferred versus a process-focus, as the progress in science is outpacing updates in the regulatory framework. Spain has traditionally taken a science-based approach 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.

Spain was among the fourteen EU Member States that on the EU Farm Council held on May 14, 2019 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.

With the country holding continuous general elections⁸, Spain has made little regulatory progress. However, Spain's two main regulatory bodies overseeing biotechnology (National Biosafety Commission and Inter-Ministerial Council for Biotechnology) have issued reports expressing their concerns on the difficulties of implementing the ruling by the European Court of Justice (ECJ) on new breeding techniques (NBTs):

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. This [report](#) (available in the link Spanish language only) tackles three main aspects:

- Purposes for which genome editing tools are being used in the different biotechnology sectors.

⁸ On April 28, 2019 Spain celebrated National Elections coinciding with EU Parliament Elections, the lack of consensus for form a government led to calling for new elections, that were hold on November 10, 2019.

- Risk comparisons between genome editing tools and other biotechnology applications, used in plant or animal breeding programs, such as transgenesis or mutagenesis.
- Determinations from a scientific and compliance point of view the consequences of the ECJ ruling on genome edited products.

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, which prevents detection and limits ruling enforcement possibilities, when it comes for instance, to imports control. As previously noted in their [2015 report, the National Biosafety Commission](#) reiterates that a product-based approach would be preferred over a process-based approach. Hence, it is their recommendation to carry out a major overhaul of the Directive 2001/18/EC.

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. In this document, the CIOMG recognizes that the 2001 legislation is no longer adequate, and it needs to revise to eliminate inaccuracies and improve its applicability. The CIOMG recognizes the benefits of biotechnology in areas such as health, agriculture, food safety, the environment, or control and eradication of pests and diseases. They also state that any technology must be used responsibly, with "a prior risk assessment in order to guarantee the absence of risks". Based on their assessment, the CIOMG advocates freedom of choice for farmers, citizens, researchers and the different sectors in which biotechnology can be applied. The Spanish Ministry of Agriculture supports basing the risk assessment on the safety of the final product instead of which technique is used to obtain it. According to this document, the lack of adequacy in the regulations is reinforced by the inability to distinguish between certain spontaneous mutations and human-made mutations, as a large part of the new technologies leave no trace, and consequently hinder implementation of controls. The CIOMG concludes that the EU Court of Justice Ruling could have important consequences for the agro-food sector, international trade, research and innovation and control and inspection services.

Scientific Community: On September 5, 2018, two Spanish Scientist (Josep M. Casacuberta, Pere Puigdomènech) published an opinion at EMBO (European Molecular Biology Organization) site on [Proportionate and scientifically sound risk assessment of gene-edited plants](#). This article analyzes the consequences of the ECJ ruling on genome-edited products and discusses possible options for a scientifically sound and proportionate risk assessment of genetically engineered plants compatible with the Court's decision and the present GE legal framework. On July 25, 2019, one year after the CJEU ruling, the Spanish scientist adhered to an [open letter](#) authored by 126 European research institutes directed to European institutions in order to urge them to undertake legislative action to support innovative biotechnologies.

Agricultural Stakeholders: Spanish agricultural stakeholders, who support agricultural innovation as a tool to improve competitiveness, have expressed their concerns with repeating the same mistakes made with conventional biotechnology. They are particularly worried about having to continue facing competition from third countries without having access to the same tools. On April 23, 2019, Spanish stakeholders, through their European organizations, addressed an [open letter](#) to Member States encouraging them and the EU Commission to take action and initiate a legislative change that provides innovation-friendly rules.

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 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. In 2019 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 percent⁹ '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**.

⁹ *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.*

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 it 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 \(in Spanish\)](#) 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 years protection period for those varieties in the

Protected Plant Varieties Catalog. It is not possible to concurrently hold protection for the same plant variety under both the Community and a national system. When a variety is granted with the CPVR, the breeder 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, as with most of the corn cultivated in Spain, including GE varieties, it is a hybrid. IPR is not an issue for Spain's GE crops as hybrid seeds are not replanted.

l) CARTAGENA PROTOCOL RATIFICATION

The EU is a signatory to the Cartagena's Biosafety Protocol (Protocol), and so is Spain as a Member State of the EU. Spain ratified the Protocol on January 2002. At the national level, the Protocol is followed by the Ministry of Agriculture, Fisheries and Food and in particular, the Support Unit within Directorate General for Agricultural Production and Markets (protocolo.cartagena@mapa.es). Spain regularly attends the Cartagena Protocol Meeting of Parties.

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

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

n) RELATED ISSUES

GE-free Zones: Aside from the commercial production and research areas for GE crops, some Spanish municipalities/provinces have declared themselves GE free zones. These zones are created by political declaration at the municipality, province, or regional level. Most of these areas are 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 conventional agricultural biotechnology, 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 for the agricultural and food industry sector given the country's dependency on imported raw materials. Most of Spain's farmers associations are in favor of planting GE crops. The use of agricultural technologies such as biotechnology or irrigation systems to improve competitiveness and obtain consistent output levels are positively perceived and defended by a large majority of the farming sector. 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 and, in the case of the pork sector, exports nearly one third of the production to EU and third markets. Consequently, given that livestock producers face global competition and Spain's dependency on imported feedstuffs, the Spanish feed and livestock industry have repeatedly claimed that an increased access to GE products will help them compete equally in the global market. There is also an ample acceptance and adoption by corn growers in areas where the corn borer represents an issue.

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 in 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 product manufacturing to avoid labeling as “Contains GMOs.” In contrast, most livestock breeders use compound feed labeled as containing “Genetically Modified Organisms” and the GE-free feed market niche is rather small. Meat obtained from animals fed with GE feed does not have to be labeled so consumers cannot show a preference in their meat purchases. There are not many recent country-specific studies on marketing or acceptance of agricultural biotechnology in Spain.

In regard to public 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, 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 concludes that the current political situation in certain EU countries is an impediment to GE research in order 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 Foundation¹⁰, highlighted how the cultivation of Bt corn in Spain since 1998 has reduced total corn imports by more than 853,000 MT.

A study entitled [Genetically Modified Soy: an irreplaceable raw material in the EU. Assessment of Alternatives and Economic impact on the Spanish Feed and livestock farming sector](#), by Francisco J. Areal. University of Reading (United Kingdom) concludes that soybean products are key for feed production given its high protein content and its high protein price competitiveness. Genetically engineered soybean and products imports to Spain during the period 2000-2014 has meant 55,000 million euros in savings when compared to the alternative of importing conventional soybean and products during the same period. According to this study, the replacement of GE soybean products by conventional soybean products would mean a price increase of soybeans and soybean meal by 291% and 301%, respectively.

The study “[Economic, Social and Environmental Benefits of Bt corn cultivation in Spain \(1998-2015\)](#)” (in Spanish) by Francisco J. Areal. University of Reading (United Kingdom) released in 2016 highlights the benefits of biotech cultivation in Spain in terms of increased yields and crop margins, reduced import needs, improved corn health (lower mycotoxins incidence), and improved additional net CO₂ fixation.

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. In this study, Graham Brookes, Agricultural Economist in [PG Economics](#), 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.

¹⁰ *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.*

CHAPTER 2: ANIMAL BIOTECHNOLOGY¹¹

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 MAPA, notifications of confined research on GE animals throughout **1998-2016** was carried out with hogs, mice, flies, and zebra fish. Most of the notifications in this area consist of basic science research for pharmaceutical purposes carried out by public institutions. In **2017**, the Spanish Public Agricultural Research Institute (INIA), communicated activities on farm animals such as GE rabbits, goats, and sheep to study the molecular processes of reproduction. In 2018, there are reports of research in hogs for medical purposes. To date, animal biotechnology research official notifications in **2019** consists in rodents and flies.

¹¹ 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		

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.

e) TRADE BARRIERS

Trade barriers for GE or cloned animals in Spain are the same as those established at the EU level. For more information about the European framework, please see the latest [EU-28 Biotechnology Annual Report](#).

PART E: POLICY

a) REGULATORY FRAMEWORK

Genetically engineered animals are ruled by the same authorities as GE crops and notifications for confined use or release to the environment are regulated by the same provisions (See **Chapter 1. Part B: Policy. Regulatory Framework**). Additionally, specific regulations for animal research were introduced by [Royal Decree 53/2013 \(in Spanish\)](#). Regarding **cloning**, there are two ministerial departments involved in the position definition: The Ministry of Agriculture, Fisheries and Food, and the Ministry of Health.

- Ministry of Agriculture, Fisheries and Food (MAPA): Within MAPA, there are different units that play a role in the decision-making process in issues related to cloning. The Sub Directorate General for Livestock Resources coordinates cloning, and it has a technical approach to cloning as a breeding technology. The Sub Directorate General for Animal Health watches animal welfare implications. Additionally, the Sub Directorate General for Sanitary Agreements and Border Control has a role in enforcement if restrictions to trade were to be implemented.
- Ministry of Health: AESAN an independent agency ascribed to the Ministry of Health, whose constituents are consumers, is invited to weigh in food risk related aspects and pays particular attention to the placing on the market of food from animal clones.
- Domestic regulation applicable to GE plants also applies to GE animals. Spain has not specifically regulated GE animals or clones.

b) APPROVALS

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

c) INNOVATIVE BIOTECHNOLOGIES

Spain has not regulated the use of IBs in animals 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 [EU-28 Biotechnology Annual Report](#).

e) INTELLECTUAL PROPERTY RIGHTS

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

f) INTERNATIONAL TREATIES and FORUMS

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

g) RELATED ISSUES

Not available.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Spain is a country with a robust livestock sector and is pragmatic regarding the use of new technologies in the field of agriculture and livestock production. Similarly, to the situation in other countries, while the technical experts understand the technology and defend a science-based approach, fears about public opinion still weigh heavy in the decision-making process. Experts agree on the fact that cloning is not a food safety issue. However, there are concerns regarding implications 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 are 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 off 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](#).

Attachments: No Attachments