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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 the EU's largest grower of biotech corn and a major consumer of biotech feed ingredients.

Executive Summary

Spain is a leading player in agricultural biotechnology within the European Union (EU), particularly in the cultivation of genetically engineered (GE) crops. The country is the EU's largest producer of Bt corn, accounting for approximately 95 percent of the EU's total GE crop area. Bt corn has been cultivated in Spain since 1998, with MON810 being the only GE event approved for cultivation in the EU. Despite its dominance in GE corn production, Spain's total corn planting area has faced challenges due to water scarcity and competition from less water-intensive crops like sunflowers, or more profitable tree crops such as tree nuts.

Spain is heavily reliant on imports of GE products to meet the demands of its robust livestock sector. The country imports significant quantities of GE soybeans and soybean meal, as well as corn and corn by-products, primarily for feed purposes. The soybean imports are sourced from major agricultural biotechnology-producing countries such as the United States, Brazil, and Argentina. Spain's science-based approach to GE crops has contributed to high acceptance of these imports among feed-chain stakeholders.

At the same time, Spain's agricultural biotechnology sector faces trade barriers due to asynchronous GE event approvals between the EU and major trading partners like the United States. Additionally, the lack of coexistence regulations and labeling requirements for GE products create challenges for market expansion. Despite these obstacles, Spain's feed and livestock industries remain strong supporters of agricultural biotechnology, emphasizing its importance for competitiveness and food security. Farmers and livestock producers widely accept GE crops and feed, particularly in regions where pests like the corn borer are endemic.

Spain's regulatory framework for agricultural biotechnology is aligned with EU legislation, with oversight provided by the National Biosafety Commission (CNB) and the Inter-Ministerial Council for Genetically Modified Organisms (CIOMG). These bodies assess risks and manage approvals for GE crops, animals, and microorganisms. While Spain supports science-based regulations, the restrictive EU framework limits the development and commercialization of new GE traits and innovative biotechnologies (IBs) like genome editing. Spain has actively participated in EU discussions on new genomic techniques (NGTs), but the bloc has yet to achieve consensus on regulatory proposals.

In the animal biotechnology sector, research is primarily focused on pharmaceutical applications, with confined studies conducted on rodents, zebra fish, and farm animals. Spain has also made advancements in cloning and genome editing, including the creation of its first genetically modified lamb in 2024. However, there is no commercial production of GE or cloned animals for food purposes.

Microbial biotechnology is widely used in Spain for food production processes such as fermentation and bioethanol production. Research activities include developing vaccines, studying plant pathogens, and optimizing biofuel production. While microbial biotechnology is integral to food processing, public awareness of its applications remains limited.

The presence of GE-labeled consumer products in the Spanish market is minimal, as most food manufacturers have eliminated GE ingredients to avoid labeling requirements. Public perception of GE products in Spain is generally pragmatic, with limited concerns about genetically modified organisms (GMOs). According to public surveys' results, pesticide residues and food safety issues are more prominent concerns among Spanish consumers.

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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 Digital Transformation
MITERD	Ministry for the Ecological Transition and Demographic Challenge
MOC	Ministry of Consumption
MOH	Ministry of Health
MS	Member State(s)
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

Spain permits confined research and deliberate release of genetically engineered (GE) plants to the environment, including field trials, subject to prior notice, public information, and authorization (Law 9/2003) (available in Spanish language only). The same provisions apply to plants developed through innovative biotechnologies (IBs). Despite these allowances, Spain's current restrictive regulatory framework discourages domestic research and development as there is little certainty regarding potential for commercialization for GE plants. No new GE developments are expected to reach the market within the next five years. Similarly, the development and market potential for IB derived products remain contingent on the ongoing regulatory debates at the EU level. For additional information, see Section e) within Part B: Policy.

- **Confined Research:**

Under **Law 9/2003**, entities planning to use specific facilities for the first time to conduct confined activities involving genetically modified organisms (GMOs) must notify the competent authorities in advance. However, for subsequent trials by the same entities, notification is not required if the activities are deemed to pose zero or negligible risk. As a result, it is possible that additional confined research activities with minimal or no risk are occurring beyond those officially reported and noted below.

In 2025, GMC Citrus reported research on new **citrus** varieties. Similarly, Pioneer Hi-Breed Spain reported storage and preparation of **corn** seeds for field testing.

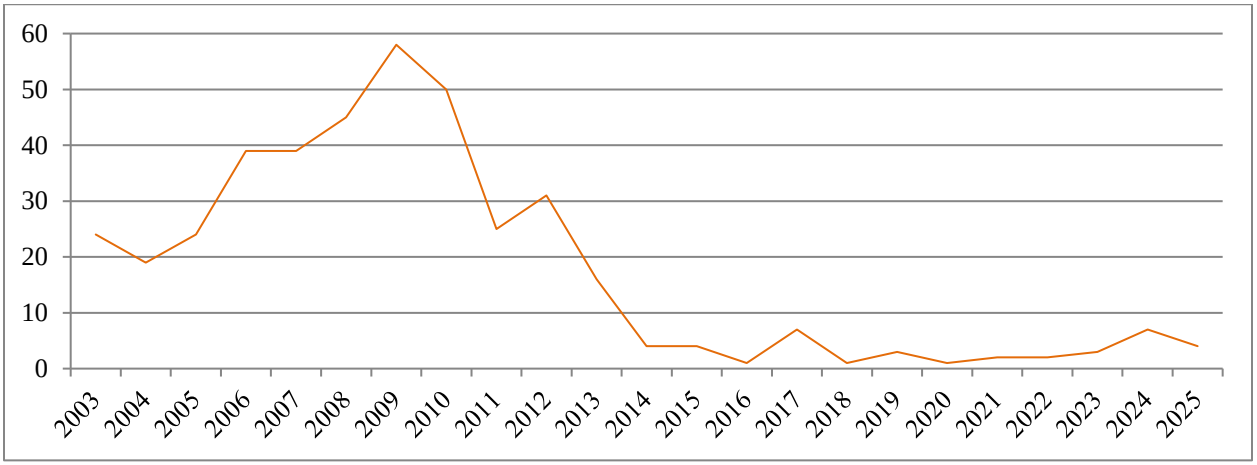
In 2024, the company Olivos de Badajoz reported research on GE **tobacco** plants as bio-factories for protein production. Eurofins Trialcamp (Valencia) is working on GE **corn seeds** research. Merlet Fruits (Lleida) and the Institute for Subtropical and Mediterranean Horticulture "La Mayora" (IHSM-UAM-CSIC) research on tomato plants too. Cambrico Biotech reported research on new citrus varieties. The National Agrifood Technology Center (CTAEX) in Extremadura notified research activities on transgenic **tobacco** plants as bio factories to produce the sweetener protein thaumatin-2 AVA-ASAJA reported research in *Nicotiana tabacum* for the use of **tobacco** as biofactory to produce anatabine.

- **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 2025, notifications of open field trials of GE rice were reported by University of Lleida, soybean plants by INARI Agriculture, and corn plants by VIB (Vlaams Interuniversitair Instituut voor Biotechnologie).

In 2024, the company Olivos de Badajoz and National Agrifood Technology Center (CTAEX) reported open field research on GE tobacco. Pioneer Hi-Breed Spain reported CRISPR-Cas9 corn field testing. Similarly in 2024, CEBAS CSIC in Murcia submitted a request to use transgenic commercial varieties of stone fruits.

Graph 1. Open Field Trial Notifications to Competent Authorities*



Source: Foreign Agricultural Service (FAS) Madrid based on EU's Food and Feed Information Portal Database.
*Data up to September 30, 2025.

b) COMMERCIAL PRODUCTION

At present, there are 82 commercial GE corn varieties approved for cultivation in Spain. Spain is the largest EU producer of Bt corn, accounting approximately for 95 percent of the EU's total GE crops area. The remaining five percent corresponds to Portugal, the only other EU Member State that grows GE crops.

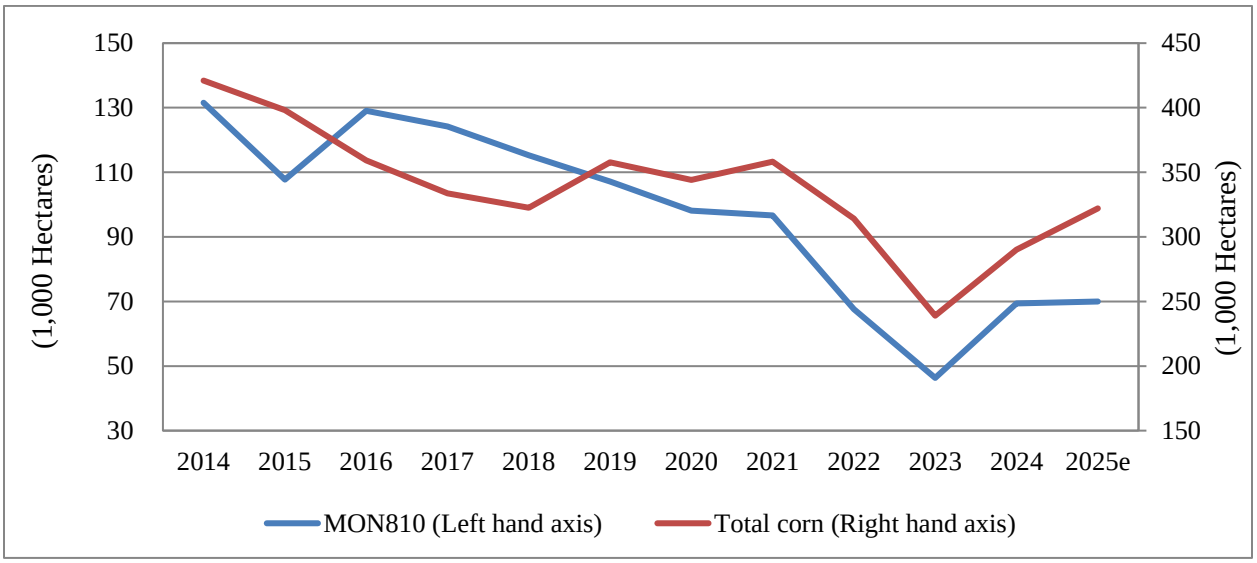
In 2025, area planted to Bt corn in Spain is expected to amount to almost 70,000 Hectares. MON810 corn – commonly referred to as Bt corn - has been commercially grown in Spain uninterruptedly since 1998. Bt corn is grown in twelve of the seventeen Spanish autonomous regions. However, MON180 cultivation is concentrated in Ebro River basin -autonomous regions of Aragon, Catalonia, and Navarra- where the corn borer is endemic. Spain was among the nine[1] EU Members that decided not to opt-out of biotech cultivation under the Directive 412/2015, which gave flexibility for Member States to restrict or prohibit biotech cultivation within their borders.

Total Corn Plantings: Spain's total corn area (Graph 2) hit bottom in MY 2023/24, because of the long-term decline in area planted to corn, and the low water storage levels for irrigation purposes which disincentivized corn plantings in favor of less water-demanding crops such as sunflower and the expansion of more profitable tree crops (such as tree nuts or olive trees). However, in MY 2024/25 and MY 2025/26, the significant recovery of water reservoirs has allowed for an area expansion of both first

[1] 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.

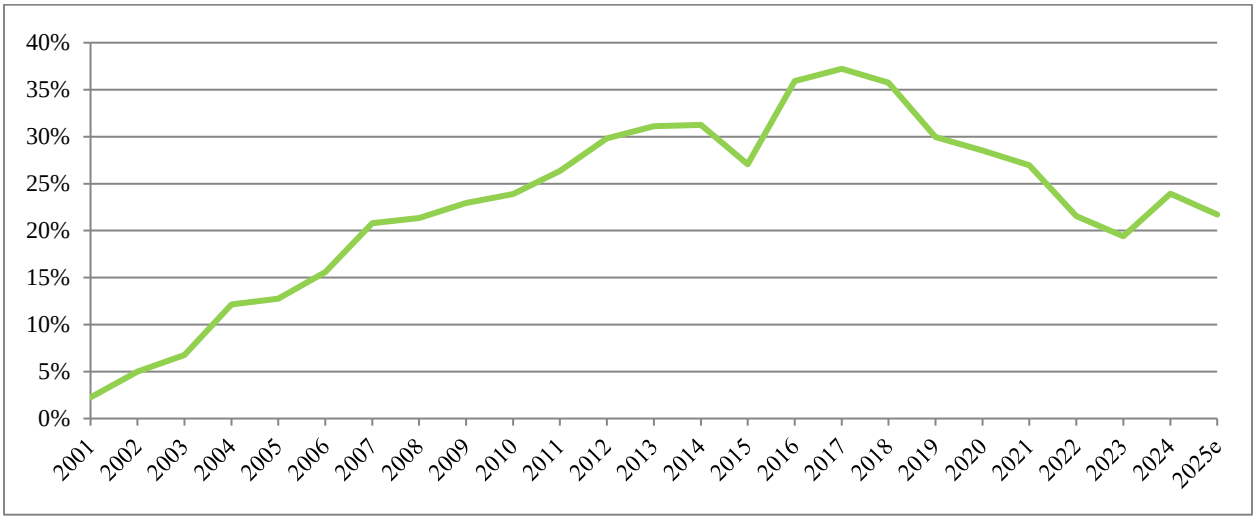
crop corn and second crop[2] corn (after barley), typically grown in the Ebro Valley (regions of Aragon and Catalonia). Corn borer is endemic in these areas, hence Bt corn has a larger presence to counter its impact, accounting for the large majority of the country's GE corn area (75 percent on average).

Graph 2. Total Spanish Area for Corn and MON810 Corn



Source: FAS Madrid based on MAPA data[3] and FAS Madrid estimates.

Graph 3. MON810 Area Share in Spain (%)

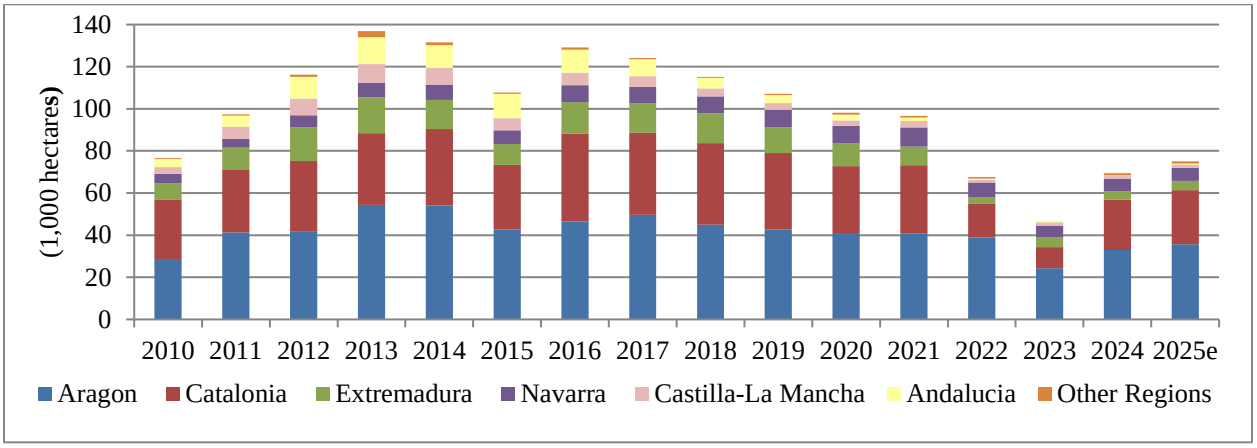


Source: FAS Madrid based on MAPA data and FAS Madrid estimates.

[2] Planting corn as a second crop is a 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 the fall. This agronomic practice allows farmers to obtain and profit from two grain crops on the same plot.

[3] 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 4. GE Corn Area by Region



Source: FAS Madrid based on MAPA data and FAS Madrid estimates.

Bt Corn Plantings: Data available for 2025 indicates that Bt corn plantings in Spain have stabilized after reaching their lowest point in 2023. However there are still factors that limit further expansion:

- **Total corn area expansion possibilities are limited:** Input costs and irrigation water requirements limit corn area expansion, favoring less input-intensive crops. At the same time, the expansion of corn as a second crop, together with the limited alternative crops in some regions, prevents decline of total corn area.
- **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, its use is concentrated in those areas where the corn borer poses an issue. Expanding GE corn cultivation beyond these regions would require the approval of new GE corn traits could raise other farmers' interest beyond the corn-borer affected areas.
- **MON810 is an obsolete corn event:** Seed companies' incentive to continue to supply this market is eroding as it has become a niche market.
- **Feed compounders are the only users of GE corn:** In Spain, most 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.
- **Food grade corn receives better prices:** Farmers are increasingly opting for a larger share of conventional corn in their planting plans. Whereas GE corn is approved for food consumption purposes across the EU, most food manufacturers have eliminated GE products from their food product composition to avoid GE labeling requirements, which ultimately restricts GE crop supplies to the animal feed industry.
- **Bt corn is the only GE crop approved for cultivation in the EU:** Approvals of new GE crops could raise growers' interest in planting other GE crops.

In summary, while Bt corn plantings have stabilized, the combination of regulatory, economic, and market factors continues to limit its expansion in Spain. Addressing these challenges—such as approving new GE traits and improving market incentives—could help unlock further growth in GE crop cultivation.

c) EXPORTS

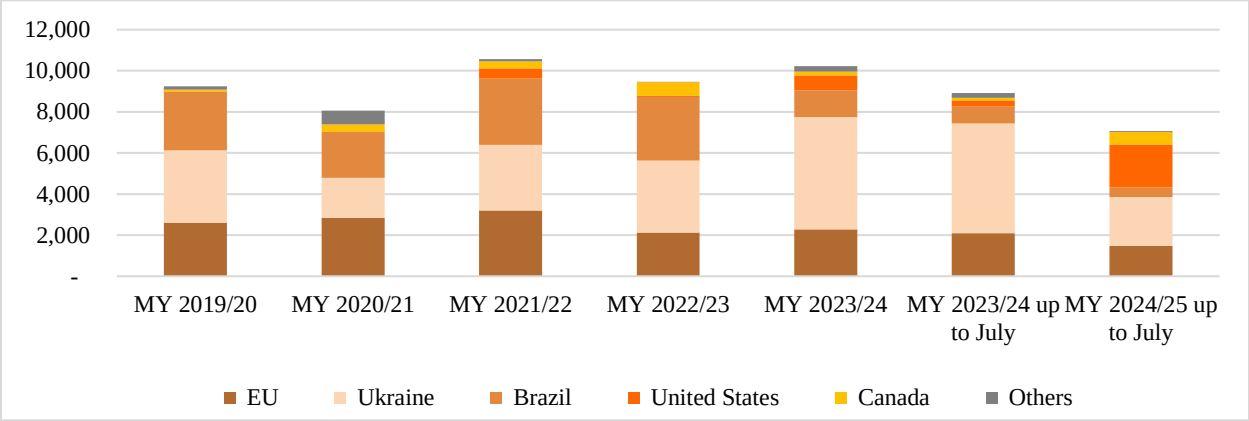
Spain is a net importer of grains and oilseeds as domestic production is not enough to meet the demand for its robust export-oriented livestock sector. Despite being the EU's Bt corn production powerhouse, Spanish exports of GE products are negligible, as production is fully utilized by the domestic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

Grains: The volume 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. Spain's total annual grain imports range from 12 to 17 million metric tons (MMT), out of which between 6 and 10 MMT correspond to corn imports largely intended to supply the steady demand from Spain's export-driven livestock sector. The progressive adoption globally of agricultural biotechnology since 1998 coupled with the asynchronicity of biotechnology events approval for cultivation and import in the EU forced Spain-based commodity trading companies to switch away from its traditional corn suppliers from North America, and rely in sourcing most of the corn from other EU countries, Brazil and Ukraine (Graph 5).

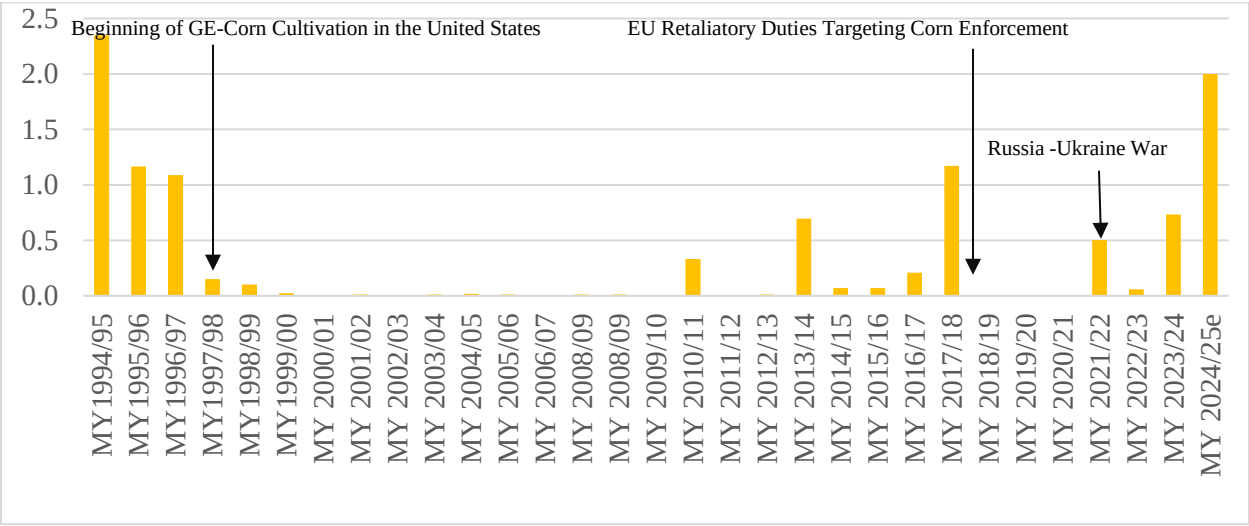
Graph 5. Spain's Corn Imports by Origin (1,000 MT)[4]



Source: Trade Data Monitor, LLC data.

Graph 6 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 where discontinued due to an EU 25 percent retaliatory tariff against U.S. steel and aluminum tariffs. In MY 2021/22, U.S. corn exports to Spain resumed after the retaliatory duties were phased-out and the need for alternative corn suppliers following Russia's invasion of Ukraine. Access to Ukrainian corn and ample supplies of Brazilian corn reverted U.S. corn exports in MY 2022/23 to negligible volumes. In MY 2023/24 U.S. corn exports to Spain amounted to nearly 800,000 MT driven by the poor crop anticipated in Brazil. In MY 2024/25 U.S. corn price competitiveness against alternative origins is expected to push this volume to exceed 2 million MT.

Graph 6. U.S. Corn Exports to Spain (Million MT)[5]

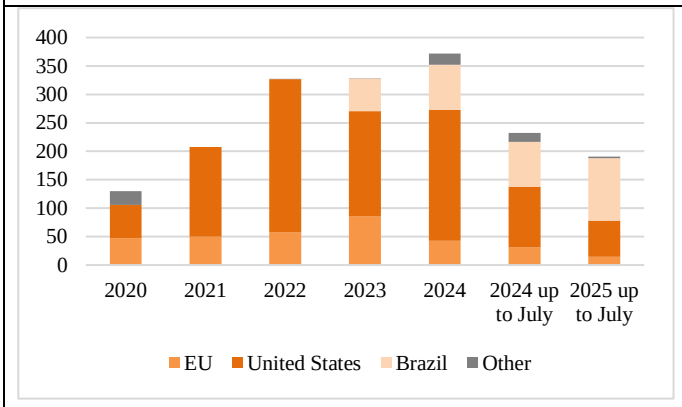


Source: Trade Data Monitor, LLC data and Exports Sales Report.

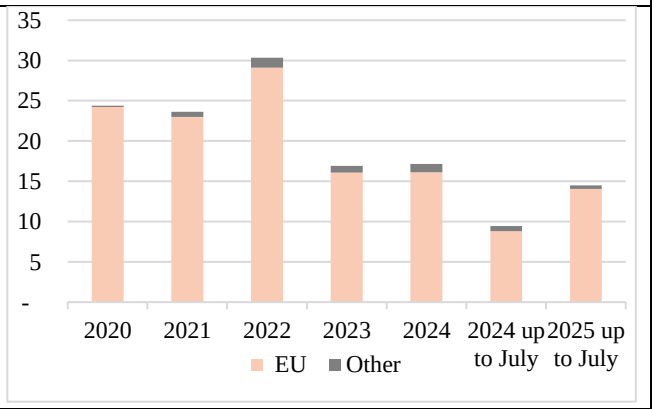
[4] Corn Marketing Year is October September.
[5] Corn Marketing Year is October September.

The sharp rise in feed ingredient prices in 2022, followed by elevated protein meal costs in 2023 and 2024, fueled the surge in Spain's import Distiller's Dried Grains with Solubles (DDGS) from the United States and Brazil (Graph 7). In the case of Corn Gluten Feed (CGF), trade within the EU (mostly non-GE) satisfies virtually all the Spanish demand (Graph 8).

Graph 7. Spain Imports of DDGS (HS code 230330) (1,000 MT)



Graph 8. Spain Imports of CGF (HS code 230310) (1,000 MT)



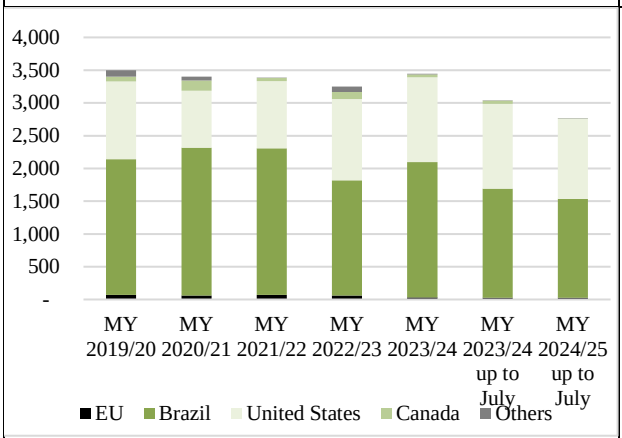
Source: Trade Data Monitor, LLC data.

Oilseeds: Span's 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. Consequently, Spain needs to import virtually all its protein feed ingredients.

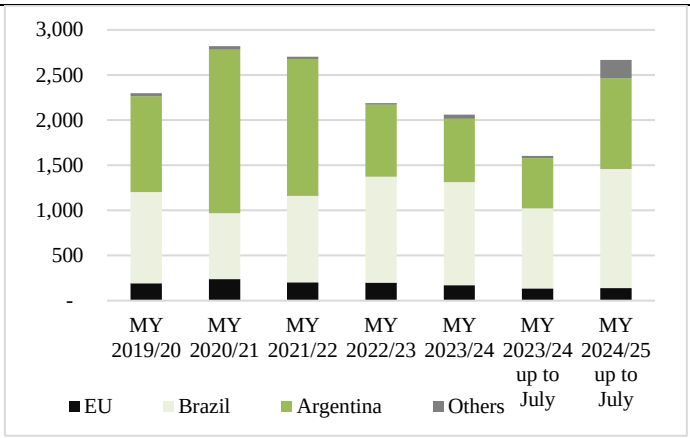
On average, Spain's annual combined imports of soybean and soybean meal amount to nearly six MMT. Almost all Spanish imports of soybean products are GE, except for those devoted to niche specialty markets. The impact of the slow EU approval rate of GE products has had less impact on the import of protein feed ingredients (primarily soy) than on grain imports. Post estimates Spanish non-GE soybean meal demand at barely 2 percent of total sales and partially satisfied by Spanish beans (9,900 MT in 2024, significantly up from the 7,500 MT produced in 2023). In 2025, production of soybeans in Spain is expected to remain strong, driven by area increases in the Ebro Valley (Aragon and Catalonia). Domestic soybean production is primarily intended for food use, and aquaculture feed.

For additional details, see GAIN Report entitled: Spain Soybean and Products Market.

Graph 9. Spain Soybean Imports (1,000 MT)



Graph 10. Spain 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

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 has progressively increased their market share over the years at the expense of imports from North America. Despite the limited allowance for adventitious presence[6] for non-approved events continues, the larger synchronicity of events has allowed EU imports of U.S. corn to be resumed by trading companies, with the notable exception of those carrying out a no-risk policy in their purchases.

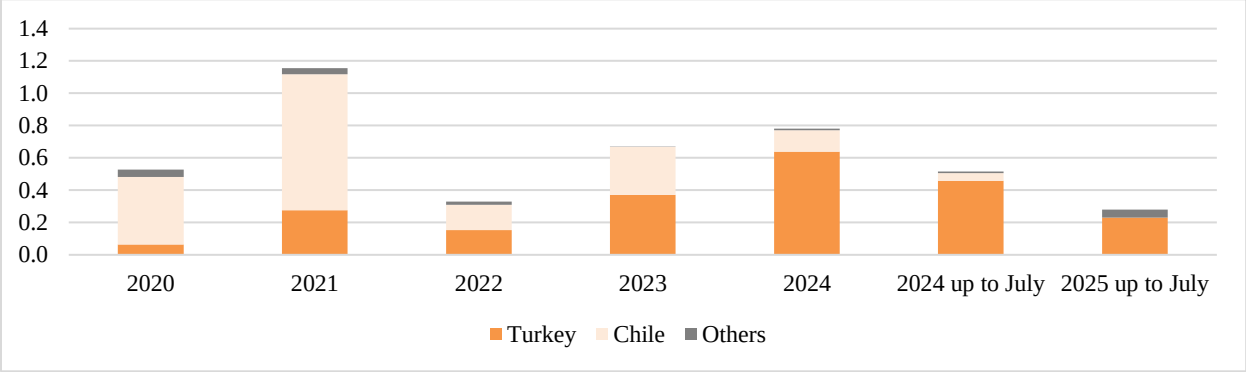
Consumer-oriented products: The presence of GE labels on consumer-oriented products is very limited in the Spanish market. Most of the food manufacturers and processed food importers have either eliminated GE ingredients from food manufacturing or switched to GE-free suppliers to avoid labeling and marketing food products with the claim "Contains GMOs."

Seed: Seed trade is affected by the zero tolerance of adventitious presence. The fact that the EU only allows cultivation of MON810 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 in 2024 contributed over 99 percent of Spanish imports of corn seed. Non-EU corn seed suppliers increasingly see their market share reduced due to the restrictive conditions to prevent adventitious levels of seed from unapproved GE events (Graph 11).

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

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

Graph 11. 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). As noted in the first section, Law 9/2003 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.

As of June 2018, 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 (MITERD). 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 MITERD, 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 this 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 of representatives from the stakeholder Ministries: MAPA, the Ministry of Consumption (MOC), Ministry of Economy and Digital Transformation (MINECO), and the Ministry of Internal Affairs. The composition of the CIOMG is available in this 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 at 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:** In 2010, a consultative Committee for GMOs (CPOGM) ascribed to the Inter-Ministerial Council was created by Ministerial Order 2616/2010 (in Spanish). This body's main objective was to facilitate 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 may prepare proposals for examination by the CIOMG. The CPOGM is comprised of 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. In 2025, Ministerial Order APA/766/2025, included the seed breeding industry in the composition of this consultative group.

- **National Administration Responsibilities:** Spain's decentralized governance structure divides responsibilities between central and regional governments. The central administration is responsible for key aspects of GMOs including: 1) the marketing authorization for "GMOs" and products containing "GMOs," 2) authorizing confined use and deliberate release of "GMOs" for research and development (carried out under national programs), 3) authorizing pharmaceutical products for humans or animals containing "GMOs"; 4) monitoring and control of field trials before the registration in the Commercial Varieties Catalogue.

- **Regional Administration Responsibilities:** The autonomous regional 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).

Table of terms

Legal Term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Organismos Genéticamente Modificados	Genetically Modified Organisms (GMO)	Law 9/2003 (in Spanish).	Genetically modified organism: any organism, with the exception of humans, whose genetic material has been modified in a manner that does not occur naturally through mating or natural recombination, provided that the techniques established by regulation are used.

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 few exceptions, Spain has traditionally voted in favor of new events for imports within the EU Standing Committee on the Food Chain and Animal Health.
- **For cultivation:** Spain's position on renationalization of cultivation decisions has evolved through the years. Initially, Spain reacted cautiously noting concerns over potential implications on the EU's common market and compliance with WTO rules. However, Spain ultimately voted in favor of the decisions on renationalization of cultivation, which in Post's assessment is likely an effort to open the door for the cultivation of new events. 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 pyramid 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

After reaching an EU Council position on the regulatory proposal for new genomic techniques (NGTs) during the Polish presidency on March 14, 2025, all eyes are now in the trilogues launched under the Danish presidency in the second semester of 2025. Spain's agricultural administration and stakeholders continue to contribute constructively to this dialogue.

On May 12, 2025, MAPA organized a Seminar entitled "The Potential of IBs in the agricultural and food sector". This Seminar intended to present the Scientific Advisory Project on New genomic Techniques[7], a collaboration project between MAPA and the Center for Research in Agricultural Genomics (CRAG)[8]. This project consolidates MAPA's commitment to highlight scientific evidence in the negotiation of the European Commission's proposed regulation on plants obtained through new genomic techniques.

f) COEXISTENCE

Although Spain is the EU's largest GE crop grower, the country has not yet implemented a coexistence regulation at the national level. Despite the lack of coexistence measures, Spanish farmers continue to grow GE corn. The 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).

Royal Decree 364/2017 amending Law 9/2003 (in Spanish) and transposing Directive (EU) 2015/412 into National Law along with Ministerial Order APA/1083/2018 (Spanish language only) ensure coexistence with non-growing neighboring countries, namely France. According to Ministerial Order APA/1083/2018, farmers who grow GE corn must establish an isolation distance of 20 meters from the French border. Additional information can be found in Section a) on Approvals.

[7] Launched on April 15, 2025, the project is a beneficiary of the 2024 Call for the Promotion of a Culture of Public Innovation from the Spanish Foundation for Science and Technology (FECYT) and will last two years. During this period, the MAPA and the CRAG will collaborate on several activities aimed at improving scientific knowledge about the state of development of NGT, their potential for the Spanish agri-food sector, regulatory needs, and scientific dissemination. These activities will include workshops with the sectors involved, particularly the agri-food sector. Furthermore, transparency and knowledge will be promoted through a web platform with resources on these technologies.

[8] The CRAG is a consortium formed by the Spanish National Research Council (CSIC), the Institute for Agri-Food Research and Technology (IRTA), the Autonomous University of Barcelona (UAB), and the University of Barcelona (UB).

g) LABELING

Spain follows EU-harmonized legislation on labeling (Regulation European Commission (EC) 1829/2003 of 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 "adventitious," or accidental and technically unavoidable, presence of EU-authorized GE events 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 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, coordinates the food chain control. However, due to Spain's decentralized governmental structure, testing and control 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. 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 are primarily conducted at the wholesale and the processing level.

Since January 1, 2021, the fourth Control Plan, called the "National Plan for Official Control of the Food Chain 2021-2025," is in place. This plan includes within 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.
- 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 percent[9] '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 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 extra EU origins (Chile and Turkey.) 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 Section 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 on MAPA's website (in Spanish).

Since 2019, as mandated by Royal Decree 1378/2018 (Spanish language only), 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. This requirement also applies to those planning to grow GE corn as a second crop. However, the Spanish agricultural administration has been reluctant to publish information about the location of commercial GE crop plots, as the information could be misused.

[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.

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 protection for plant varieties across the EU. However, the European Patent Convention of October 1973 excludes patents for plant varieties. The CPVR enables breeders to obtain a single intellectual property right that is valid 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 that is harmonized with the EU regulations to ensure 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 rules of the Union for the Protection of New Varieties of Seeds. 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 to carry out the exclusive exploitation of a plant variety Spain.

To register a new plant variety in the Commercial Varieties Catalog, breeders must submit an application form. 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 important to note that 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 typically 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. 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), as 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.

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. Likewise, it is increasingly perceived as a tool to ensure food security and mitigate climatic challenges. Most of Spain's farmer 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 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 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 GE technology are becoming more interested as they see their competitiveness affected. Moreover, additional tools to temper the impact of persistent droughts or other adverse weather events, and plant pests on yields would be welcomed by agricultural producers. New traits developed by using IBs bring new stakeholders to the discussion as these technologies can bring positive traits to crops other than row crops, including 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.

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.

According to the Study released in May 2025: "Are consumers ready to accept gene-edited crops? Evidence from a choice experiment for CRISPR-edited tomatoes in Spain, published in the Spanish Journal of Agricultural Research main findings indicate that while Spanish consumers trust in EU food safety, the consumers show a marked neophobia. This is partially offset in those cases where new technology brings plant protection products use reduction.

On June 17, 2025, the National Scientific Advice Office (ONAC) put forward a debate session tacking CRISPR gene editing technology in the context of the first edition of the Science and Policy Dialogues for Scientific Advice. The event was supported by the Spanish Foundation for Science and Technology (FECYT). It featured the participation of leading scientists specializing in the various aspects of this technology, from its potential for health to agricultural applications. The goal of the event was to promote connections between the scientific community and public officials on scientific issues with significant implications for public policy formulation.

On July 2025, a study conducted by researchers from the Universitat Rovira i Virgili, Complutense University of Madrid, and Rey Juan Carlos University was published in Food and Humanity. It reveals that in Spain, highlighting the nutritional and environmental benefits of GE food can enhance consumer acceptance, particularly among younger, more digitally connected populations.

On June 2023, as part of a larger study on Confidence Climate of the Agrifood Sector, the Spanish Ministry of Agriculture, Fisheries, and Food (MAPA) published two studies on the public perception of new genomic techniques (NGTs). These studies were conducted by Institut Cerdá and targeted producers, food industry, wholesalers and retailers, as well as consumers. The first study reveals that improving the capacity of adaptation to climate change is considered the most important attribute, whereas improving crop productivity is the least important one. The consumer-focused study shows that information on food safety is the most relevant attribute while there is little interest in knowing the exact name of the innovative technology applied.

CHAPTER 2: ANIMAL BIOTECHNOLOGY[10]

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 Ministry for Ecological Transition and Demographic Challenge (MITERD), notifications of confined research on GE animals between 1998-2025 was carried out with rodents[11], flies, zebra fish, and farm animals[12]. Most of the notifications in this area consist of basic science research for pharmaceutical purposes carried out by public institutions.

In 2025, the University of Cadiz reported research in rodents for animal health purposes. The Institute for Subtropical and Mediterranean Horticulture "La Mayora" (IHSM-UAM-CSIC) reported research with GE spider mites (family *Tetranychidae*) to assess effector-mediated plant defense suppression. Public institutions, such as the National Center for Biotechnology (CNB) and the National Center for Animal Research (CISA – INIA) are leading Spanish research on animal genome editing. Basic research with CRISPR-Cas9 in mice has been carried out since 2013. Additional information regarding research activity by the National Center for Biotechnology can be found in the link.

In 2024, media reported that researchers from the Animal Reproduction Department of the National Institute of Agricultural and Food Research and Technology (INIA-CSIC) generated the first genetically modified lamb in Spain. The lamb, named Teodoro, contained a mutation in a gene potentially involved in fertility and will be used as a model to study reproductive failures in farm animals and to understand fertility in humans. The researchers involved state that GE animal models are essential for advancing knowledge of any biological process, including those involved in reproduction.

As for cloned animals, in Spain, Somatic Cell Nuclear Transfer (SCNT) has taken place since 2003. There is no public register of research in cloning and notification on cloning research is not mandatory. According to information provided by the media, thus far, cloning 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.

[10] 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.
[11] Rats, mice and hamsters.
[12] Hogs, rabbits, sheep and goats,

- 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.
- As of 2024, the Spanish-based company Ovoclone laboratory provides cloning services for pet animals, particularly horses, but also cats and dogs.

No cloning or GE farm animals are currently being developed in Spain.

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

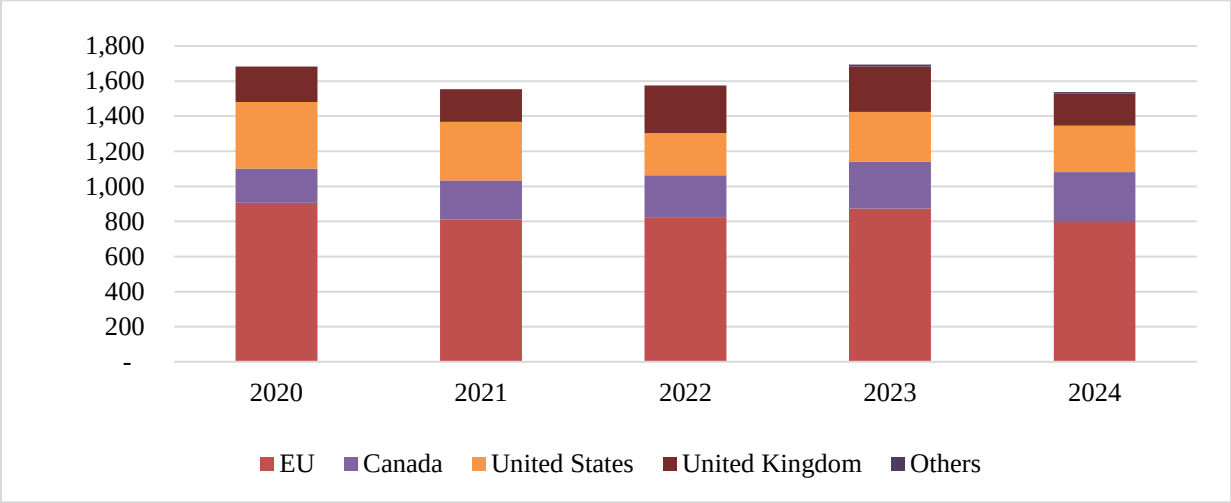
Spain does not produce commercial GE animals, clones, or products; hence there are no known exports within these categories.

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 continuously expanded between 2021 and 2023 (Graph 12). Data available for 2024 show that imported bovine doses have contracted. The United States as the largest extra EU supplier of bovine semen to Spain in value, however since 2024, Canada is the largest extra EU supplier in quantity. In the 2020-2024 period, average U.S. market share represented nearly 20 percent of imports quantity. In 2024, Spain's imports of bovine genetics from the United States accounted for $3.9 million.

Graph 12. Spain's Imports of Bovine Semen (HS Code 051110) (1,000 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 overseen 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 (MAPA) and the Ministry of Consumption.

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 trade restrictions 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 on 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.

In February 2025, the European Food Safety Authority (EFSA) launched a public consultation following the release of its draft scientific opinion on genome editing and synthetic biology in livestock. The consultation period ended in March 2025, and the final opinion, once released, is expected to impact future EU policies on genome-edited animals.

Table of terms

Legal Term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Organismos Genéticamente Modificados	Genetically Modified Organisms (GMO)	Law 9/2003 (in Spanish).	Genetically modified organism: any organism, with the exception of humans, whose genetic material has been modified in a manner that does not occur naturally through mating or natural recombination, provided that the techniques established by regulation are used.

b) APPROVALS/AUTHORIZATIONS

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) ADDITIONAL REGULATORY REQUIREMENTS

None.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

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

g) 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.

h) 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 heavily in the decision-making process. Experts agree on the fact that cloning is not a food safety issue. However, there are concerns regarding implications for animal welfare and ethical aspects.

To date, Spanish livestock breeders have shown very 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 about cloning overcome the benefits of the technology. This is down from the 42.6 percent registered in 2014. It is worth noting that since 2018, 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 on the Pyrenean Wild Goat, has recently been published in the Conservation Biology Magazine: The Arguments against Cloning the Pyrenean Wild Goat.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY[13]

PART G: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Confined research and deliberate release to the environment of GE microorganisms 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 microorganisms obtained through IBs.

In 2025, confined research activities in the field of agriculture on GE microorganisms communicated to competent authorities in Spain include research by Syva Laboratories on *Chlostridium perfringes* to elabortate a vaccine against porcine clostridiosis. Similarly, the National Center for Animal Research (CISA – INIA) reported research on Rift Valley Fever (RVF). The Center for Molecular Biology, Severo Ochoa (CBMSO-CSIC) IRTA CReSA and Veterinary Health Surveillance Center research on African Swine Fever (ASF) Virus vaccine, Calier research on *Salmonella infantis* for broiler production and Zoetis Manufacturing & Research research on *Parapoxvirus* vaccine for swine.

In 2024, the Botanical Institute University of Castilla-La Mancha is notified research with *E.coli*, *Agrobacterium* and *Fusairum fujikuroi* to check whether *Fusairum fujikuroi* accumulates carotenoid derivatives after transformation. The Institute of Sustainable Agriculture (IAS-CSIC) in Cordoba reports it is studying the infection processes, development, and pathogenicity of *Xylella fastidiosa*. The Institute for Integrative Systems Biology reports research on West Nile Virus. The Institute of Agrochemistry and Food Technology reports research on *Candida glabrata*. IRTA CReSA and National Center for Animal Research (CISA – INIA) report research on prion diseases. The Center of Research and Agrofood Research in Aragon (CITA) with GE *Brucella melitensis* to evaluate Immunogenicity of GMO vaccine prototypes in sheep. Zoetis Manufacturing & Research research on Equine herpesvirus (EHV) vaccine for horses. Biomar Institute notified research on *Komagataella phaffi* for production through fermentation and purification of a recombinant protein with interest in the food industry.

b) COMMERCIAL PRODUCTION

In Spain, microbes are largely used in food production processes such as fermentation (in bread, beer, dairy, and 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.

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

The Spanish Association of Bioindustries (ASEBIO in Spanish) maintains a weblog of product developments by its members in the biotechnology agrifood sector (Spanish Green Pipeline).

Based on the information compiled by the bioindustries organization, most of the research activities concentrate on veterinary products. Other categories of agrifood microbial biotechnology activities being developed include ingredients, additives, and probiotics, bioproducts and bioprocesses, feed applications and food safety and substance detection.

According to the 2024 Annual Report by ASEBIO, food application biotechnology companies represented 27 percent of the biotechnology companies in Spain, holding the second largest group after human health biotechnology companies, which comprise 58 percent of Spain's biotechnology firms. Agriculture and forest activities account for 16 percent of the biotechnology companies. The biotechnology companies related to environment; animal health and aquaculture represent 16 percent combined while industrial biotechnology accounts for 10 percent of the total number of companies active in biotechnology.

c) 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.

d) IMPORTS

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

e) TRADE BARRIERS

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

PART H: POLICY

a) REGULATORY FRAMEWORK

Separate EU legislation covers GE microorganisms depending on whether they are intended for deliberate release or contained use.

- Contained use is regulated by EU Directive (Directive 2009/41/EC).[14] To qualify for confined use, both the GE microbe – or the production organism – and the recombinant DNA (rDNA) used to genetically alter the organism must be absent from the final product.
- If criteria for contained use are not met, the product would fall under the scope of deliberate release to the environment, regulated by EU Directive 2001/18/EC[15].

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

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

Spain has not regulated the use of IBs in microbes and follows EU legislation.

Competent Authorities:
Law 9/2003 (in Spanish) created and defined the responsibilities of the two competent authorities that weigh in on Spain's microbial biotechnology decision-making process. These are the National Biosafety Commission (CNB) and the Inter-Ministerial Council for Genetically Modified Organisms (CIOMG). Under this two-tier system, the CNB carries out the risk assessment and the CIOMG decides the country's position taking into consideration CNB's assessment. For more information about these entities' roles, see more information in Section a) Regulatory Framework within Plant Biotechnology Chapter. Part B: Policy.

[14] This Directive defines "contained use" as "any activity in which microorganisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment."
[15] In case of falling under deliberate release category, the "GMM" must also comply with EU Regulation (EC) 1829/2003 regarding market access requirements and authorization procedure for "genetically modified" food and feed as well as with Regulation (EC) No 1830/2003 concerning the traceability and labelling of "genetically modified organisms" and the traceability of food and feed products produced from "genetically modified organisms".

Table of terms

Legal Term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Organismos Genéticamente Modificados	Genetically Modified Organisms (GMO)	Law 9/2003 (in Spanish).	Genetically modified organism: any organism, with the exception of humans, whose genetic material has been modified in a manner that does not occur naturally through mating or natural recombination, provided that the techniques established by regulation are used.

b) APPROVALS/AUTHORIZATIONS

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

c) INNOVATIVE BIOTECHNOLOGIES

For additional information, see Section a) within Part H: Policy.

d) 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.

e) 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.

f) 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.

g) 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.

h) RELATED ISSUES

None.

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. Broadly speaking, the public is not aware that microbial biotechnology is an essential part of today's food processing technology.

b) MARKET ACCEPTANCE/STUDIES

There is little public awareness of food ingredients derived from microbial biotechnology being used in Spain. FAS Madrid is unaware of any study on microbial biotechnology acceptance.

Attachments:

No Attachments