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#### **Report Highlights:**

This report describes the agricultural biotechnology sector in Portugal, covering production and trade, policy, and marketing aspects. It includes topics related to plant, animal, and microbial biotechnology. Portugal is the European Union's (EU's) second largest grower of genetically engineered (GE) corn, and a major consumer of genetically engineered (GE) soybean meal in animal feed.

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY **Report Highlights:** This report describes the agricultural biotechnology sector in Portugal, covering production and trade, policy, and marketing aspects. It includes topics related to plant, animal, and microbial biotechnology. Portugal is the European Union's (EU's) second largest grower of genetically engineered (GE) corn, and a major consumer of genetically engineered (GE) soybean meal in animal feed.

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### **CHAPTER 1: PLANT BIOTECHNOLOGY**

### PART A: PRODUCTION AND TRADE

#### a) PRODUCT DEVELOPMENT

#### • Confined Research:

Confined research with Genetically Engineered (GE) organisms is regulated by <u>Decree Law 55/2015</u> (in Portuguese language only), which establishes prior notice and approval by competent authorities (see <u>Regulatory Framework Section</u> for additional information). The same provisions apply to confined research and deliberate release of plants obtained through Innovative Biotechnology (IB) and Genetic Engineering (GE). Even though confined research and deliberate release can be carried out in the country, the current restrictive regulatory framework discourages domestic research and development as there is little certainty regarding development being able to reach full potential at the commercial level for GE plants. No new GE developments are anticipated to reach the market within the next five years. Regarding IB development, its evolution in terms of product development and market potential will be conditioned by the regulatory framework, which is currently being debated at the EU level.

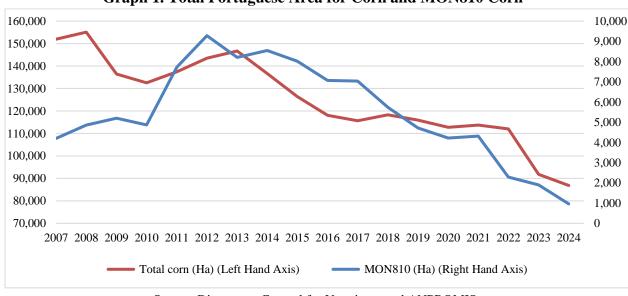
In 2022, the Facultade de Ciencias da Universidade de Lisboa (FCUL) reported to the Portuguese Agency for Environment (<u>APA</u>) confined research activity in vines (*Vitis vinifera*), Norway spruce (*Picea abies*), hybrid aspen (*Populus tremula x P. tremuloides*), tomato plants (*Solanum lycopersicum*) and potato plants (*Solanum tuberosum*). The full list of confined activities authorized in Portugal can be found in <u>APA's website</u>.

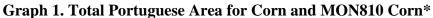
### • Field Testing:

Decree-Law 72/2003 (in Portuguese), as amended by Decree-Law 164/2004 (in Portuguese), regulates the deliberate release in the environment of a Genetically Modified Organism (GMO). Prior notice and authorization are required to carry out field tests. Those companies that intend to carry out field trials must submit a notification to the Portuguese Agency of Environment (APA) for its assessment. Risks for the environment and for human health are considered in the assessment. The Ministerial Departments that weigh in prior to APA's opinion include the Directorate General of Health (DGS) and the Directorate General for Food and Veterinary Affairs (DGAV). To date, according to the Joint <u>Research Center</u>, no notifications for deliberate environmental release of GE plants for any other purpose than market placement were submitted in Portugal since 2010. As in other European Member States, the limited ability for GE crops to be commercially available discourages investment in GE crop research in Portugal. An uncertain investment environment for seed companies has caused the private sector to limit their interest in the development of GE crops adapted to Portugal-specific conditions. EU seed breeding companies have concentrated their efforts in non-European markets, and most of their research in plant biotechnology is conducted outside Europe.

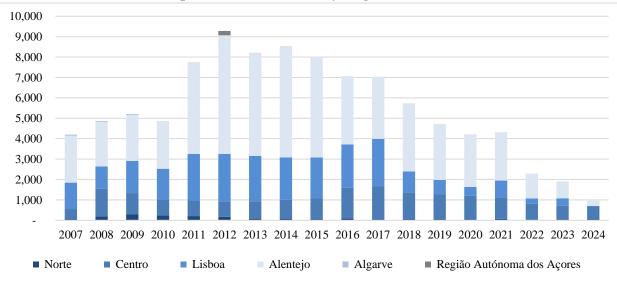
### **b) COMMERCIAL PRODUCTION**

Portugal is the European Union's second largest grower of Bt corn, after Spain. Portugal's Bt corn area represents on average about 5 percent of the EU's total GE crops area, and the remaining 95 percent is located in Spain. MON810 corn has been commercially grown in Portugal since 2005. Area planted for Bt corn in Portugal has decreased steadily since 2014 and hit its lowest level in 2024 when only 963 Ha of Bt corn were planted in Portugal.



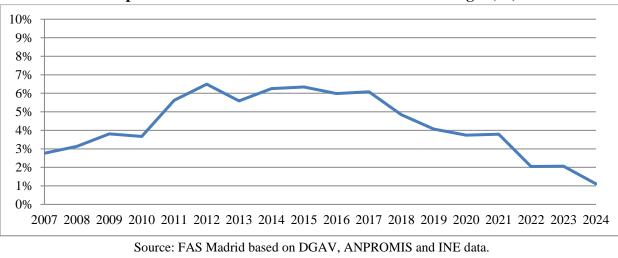


Source: Directorate General for Veterinary and ANPROMIS. \*Continental area of grain corn and silage corn is considered.



Graph 2. GE Corn Area by Region (Hectares)

Source: FAS Madrid based on DGAV data.



Graph 3. MON810 Share of Total Corn Area in Portugal (%)\*

Source: FAS Madrid based on DGAV, ANPROMIS and INE data. \*Continental area of grain corn and silage corn is considered.

The continued decline of GE corn area in Portugal is explained by several factors:

- Total corn plantings in Portugal are declining overall: Total area planted to GE corn is a factor of total area planted to corn. Portugal's total corn area varies every year depending on water availability, price, and competition from alternative crops. In MY 2024/25, total corn plantings decreased to just over 86,000 Ha in response to lower crop margins compared to alternative annual crops, such as tomatoes for processing, together with the steady long-term conversion from arable crops to tree crops (olives and tree nuts). To a lesser extent, EU's-greening measures are a factor.<sup>1</sup> Limited amounts of water available for irrigation purposes in certain areas also continue to push total corn area down. However, the decline registered in GE corn plantings since 2014 is sharper than decline registered in total corn plantings over the same period, resulting in a significantly lower share of Bt corn (**Graph 3**).
- **GE corn use is limited to areas where the corn borer is a threat:** As MON810 is the only GE event approved for cultivation in the EU, possibilities for expansion are limited to those areas were the corn borer presents a problem. When facing low crop margins, farmers tend to maximize their profit by investing in GE seed only if they see the corn borer as a real threat. Approvals of new traits could raise other growers' interest in GE crops.
- **MON810 is an obsolete corn event:** Seed companies' incentive to continue to supply this market is eroding as it has become a niche market.
- **GE corn is only consumed by feed compounders:** Most Portugal-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

<sup>&</sup>lt;sup>1</sup> 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.

consequently it is by default labeled as "contains GE products." Portuguese farmers generally accept the technology. However, some have switched back to conventional corn, as crop margins have proven to be more profitable when supplying product to food manufacturers. Food manufacturers prefer to use non-GE corn in processing to avoid the "Contains GMO" wording in the labeling of products intended for human consumption.

- Over one third of the Portuguese continental corn area is intended for silage production: The impact of corn borer attacks in final yields of silage corn is smaller, hence, the use of GE corn is rather limited.
- **Coexistence rules limit GE corn crop expansion:** Given the small average farm size that prevails throughout the country, to fulfill coexistence rules, smaller farmers must come to agreements with their neighbor farms to create GE areas. Bigger farmers can implement coexistence within their farm. In Alentejo, Lisboa, or Centro Regions, which are comparatively more oriented to grain-corn production and have larger farm sizes than in the Norte region, the share of GE corn is higher. (See <u>Coexistence</u> Section for additional information).

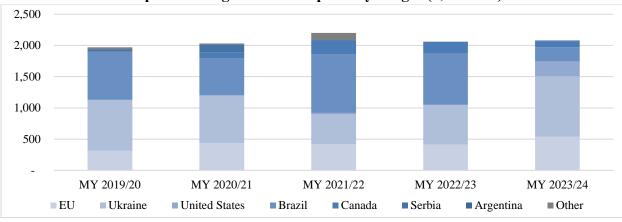
#### c) EXPORTS

Portugal is a net importer of grains and oilseeds as the domestic production is not sufficient to meet the demand of the domestic livestock sector. Exports of GE products are negligible, as the feed industry uses the domestic Bt corn production internally.

#### d) IMPORTS

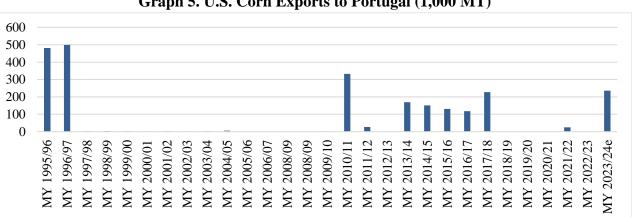
Portugal has a structural shortfall of feed grains and protein feed ingredients due to its comparatively large livestock sector, limited grain production, and highly variable grain yields and pasture availability. The Portuguese compound feed industry is the main grains and oilseeds meal buyer. The country's 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, Portugal imports a large amount of GE products. Products derived from agricultural biotechnology shipped to Portugal consist mainly of soybeans and products, and corn and corn processing by-products.

<u>Grains:</u> Grain production in Portugal averages just below 1 million metric tons (MMT) and has been declining since 2013, driven by the lower corn plantings. Corn is Portugal's most important grain crop, accounting for 75 percent of the country's total grain production. Despite the domestic grain crop, Portugal needs to import, on average, 3.9 MMT of grains per year, out of which the large majority consists of corn imports.



Graph 4. Portugal's Corn Imports by Origin (1,000 MT)<sup>2</sup>

Graph 5 shows U.S. corn exports to Portugal throughout the last 28 years. The asynchronous approval of GE events in the EU caused a drastic decline in U.S. corn exports to Portugal after the United States started planting GE corn in 1998. Since then, only occasional trade in corn took place between the United States and Portugal, except for higher level of US corn exports to Portugal in MY 2010/11 to MY 2017/18. The recovery in Portuguese 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 the EU's 25 percent retaliatory duty against U.S. steel and aluminum tariffs. In MY 2021/22, U.S. corn exports to Portugal resumed, though at a low level, in the aftermath of the retaliatory duties phase-out and the need for alternative corn suppliers other than Ukraine, following Russia's invasion. Access to Ukrainian corn and ample supplies of Brazilian corn have reverted U.S. corn exports in MY 2022/23 to negligible volumes. According to USDA's Export Sales Report, at least 135,000 MT of U.S. corn are committed to exported to Portugal in MY 2023/24 and additional sales have been reported in MY 2024/25...



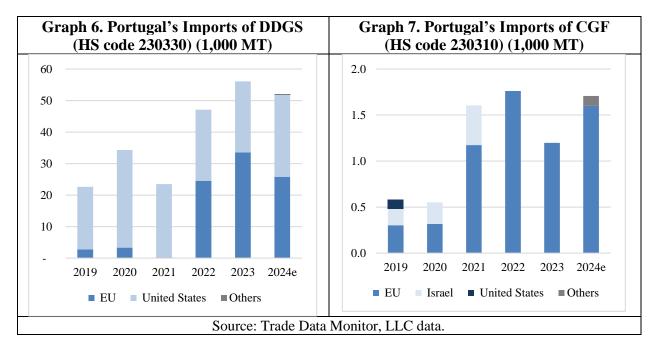
Graph 5. U.S. Corn Exports to Portugal (1,000 MT)

Source: Trade Data Monitor, LLC data and FAS Madrid Estimates based on U.S. Export Sales Report.

Source: Trade Data Monitor, LLC data.

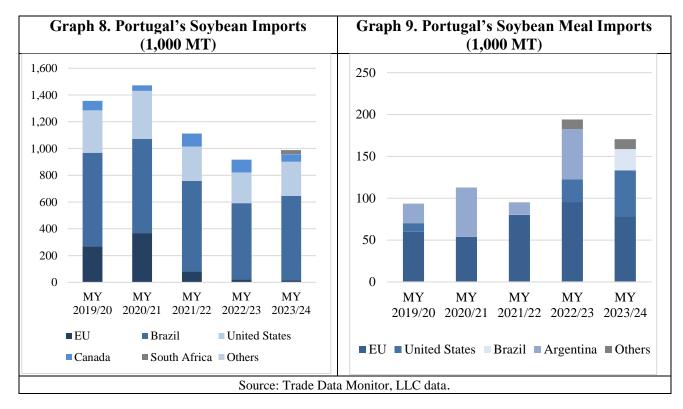
<sup>&</sup>lt;sup>2</sup> Corn Marketing Year is October to September.

Portugal has increased its imports of Distillers' Dried Grains with Solubles (DDGS) in 2022 and 2023, with a significant presence of the United States as a supplier. In the case of corn gluten feed (CGF), U.S. imports represented a lower market share as imports are largely dominated by other EU Member States.



<u>Oilseeds:</u> Portugal's domestic oilseeds production is comprised of barely 9,000 MT of sunflower seed. Conversely the country boasts a robust domestic crushing industry that allows Portugal to be nearly selfsufficient in protein meals, except for soybean meal for which additional imports are needed to fulfill market demand. Portugal's annual combined imports of soybean and soybean meal amount to nearly 1.3 million MT. Between 2019 to 2023, Portugal imported an average of 1.2 million MT of soybean and nearly 150,000 MT of soybean meal. Most of Portugal's imported soybeans and soybean meal are GE, except for those devoted to special niche markets. The impact of the EU's slower approval pace has been less significant in the imports of protein feed ingredients than in the grain sector.

Brazil dominates Portugal's soybean seed import market, accounting for nearly half of the in-country crushed soybean seeds. Soybean imports from the United States represented approximately one third of the of Portuguese soybean imports between MY 2018/19 and MY 2022/23 (Graph 8). Argentina continues to be a major provider of Portuguese soybean meal imports, though its market dominance has fluctuated over recent years. Intra-EU soybean meal trade remains consistently high, although the U.S. soybean meal has gained some of the market share, particularly in MY 2023/24, at the expense of Argentina (Graph 9).



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

### e) FOOD AID

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

### f) TRADE BARRIERS

- For bulk commodities: The asynchronous approval of GE events cultivated in the United States 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 Portugal. For instance, in the case of corn, Ukraine has progressively increased their market share over the years at the expense of lower imports from the North America. Additionally, the limited allowance for adventitious presence<sup>3</sup> for non-approved events continues to constrain traders, who carry out a no-risk policy in their purchases.
- For consumer-oriented products: The presence of GE-labeled consumer-oriented products is very limited in the Portuguese market. To avoid labeling and marketing food products with the claim "Contains GMOs," most food manufacturers and processed food importers have either eliminated the use of GE products in food manufacturing or switched to GE-free suppliers.

<sup>&</sup>lt;sup>3</sup> Refers to the detection of unintentional presence of GE crops.

• For 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. Therefore, Portugal is forced to source its corn seeds from other EU Member States or from local breeders. In 2018 to 2023, an average of 99.9% of corn seed imported by Portugal came from other EU Member States. Additionally, to some extent seed trade is affected by the GE-free declarations. While Portugal decided not to opt out from in-country biotechnology cultivation (See GAIN Report: 19 European countries restrict the cultivation of GE crops and Section b) Approvals under Part B: Policy), Portugal was one of the first countries to create legislation that recognizes GE-Free Zones.

For additional information, please see Section n) <u>Related Issues</u> under Part B: Policy.

## PART B: POLICY

### a) REGULATORY FRAMEWORK

As an EU Member State (MS), Portugal 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 the EU Agricultural Biotechnology Regulatory Framework please see <u>EU</u> <u>Biotechnology Annual Report</u>.

Portugal transposed the European <u>Directive 2001/18</u> regarding GMOs to national regulation by <u>Decree-Law 72/2003 (in Portuguese)</u> as amended by <u>Decree-Law 164/2004 (in Portuguese)</u>. There are two Ministerial Departments that weigh-in on Portugal's biotechnology decision-making process:

• **Directorate General for Food and Veterinary Affairs (DGAV):** The Directorate General for Food and Veterinary Affairs (DGAV), within the Ministry of Agriculture and Fisheries, is responsible for the coordination and implementation of the regulation of GE crops for cultivation as well as for coexistence monitoring and reporting. This Directorate General is also responsible for the coordination and implementation of the regulation of GE crops intended for imports and human or animal consumption and the food and feed chain control. In addition, the DGAV oversees the process for registering and monitoring GE seed for planting. For a list of corn varieties approved for commercial cultivation in Portugal, consult this <u>link (in Portuguese)</u>.

• **Portuguese Agency of Environment (APA):** The Portuguese Agency of Environment, ascribed to the Ministry of Environment and Ecological Transition, is responsible for the authorization of confined use (<u>Decree Law 55/2015 (in Portuguese</u>) and deliberate environmental release of GE products for purposes different than marketing (<u>Decree-Law 72/2003 (in Portuguese</u>). Decisions are based on risk assessment consider both environmental and human health potential risks. After the Directorate General of Health (DGS) and the Directorate General for Food and Veterinary affairs (DGAV) weigh in, public consultation may be deemed appropriate.

#### Table of terms:

h) where term is used	
y Decree-Law 72/2003 (in	Any organism, with the exception of humans, whose genetic
	5
<u>Decree-Law 164/2004 (in</u> <u>Portuguese)</u>	through crossing and/or a natural recombination, understanding that, i) modification occurs when techniques referred to in Part 1
	of Annex I-A are used
	ii) modification does not occur when techniques referred to in Part 2 of Annex I-A are used.
d	dPortuguese) as amended bymDecree-Law 164/2004 (in

## **b)** APPROVALS/AUTHORIZATIONS

**For imports:** Approvals of events for imports are granted at the EU level. <u>Please see the EC website</u> 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 <u>Agricultural Biotechnology Annual European</u> <u>Union</u>.

**For cultivation:** Approvals of events for cultivation are managed at the EU level. However, since spring 2015, Member States are entitled to "opt out" in their territories (<u>Directive (EU) 412/2015</u>). Portugal abstained in the EU vote on renationalization of cultivation decisions. FAS/Madrid understands this as an attempt to express their partial dislike to some aspects of the proposal. <u>Directive (EU) 412/2015</u>, on the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms in their territory, has not yet been transposed to Portuguese law. Issued by the Portuguese Republic Assembly, on April 1, 2015, Portugal published <u>Resolution 32/2015 (in Portuguese)</u> in its official gazette. In this resolution, the Portugal Republic Assembly recommends to the government that the transposal of EU provisions on cultivation decisions is subject of Portugal Republic Assembly law. <u>Directive (EU) 2015/412</u> sets April 3, 2017, as the limit for transposal to National Law. Portugal decided not to opt out of GE cultivation.

More information in Section i) Coexistence within Part B: Policy

#### c) STACKED OR PYRAMIDED EVENTS APPROVALS/AUTHORIZATIONS

See section h) on <u>approvals</u> 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 <u>Section a) Product</u> <u>Development within Part A: Production and Trade</u>.)

#### e) INNOVATIVE BIOTECHNOLOGIES

The EU's Roadmap<sup>4</sup> on Innovative Biotechnologies for plants obtained by targeted mutagenesis and cisgenesis<sup>5</sup> includes:

- On April 29, 2022, the EU Commission released a Study on the Status of New Genomic Techniques in the EU. Portugal's full response to the European Commission enquiry is publicly available in the EC's website. Portugal's input to contribute to this study can be consulted in the link (Portuguese language only). Among other aspects, Portugal stated that NGT-related research could bring opportunities or benefits to science, society, and the agri-food sector. Further, Portugal stated: "NGTs are powerful tools for modulating characteristics associated with crop response to environmental factors. In the context of the countries most affected by climate change, the use of techniques that accelerate the development of varieties adaptable to new edapho-climatic conditions and more resilient to new pests or diseases is essential to reduce production losses due to the impacts of these changes. The reduction of 3 to 5 years in breeding programs, allowed using NGT, may be the difference to guarantee the sustainability of agricultural production in these countries, where Portugal fits. The development of breeding programs where these technologies would be introduced at an early stage would be the appropriate way to reduce the time needed to obtain varieties adjusted to the needs." Portugal also commented on the impossibility to test imported agri-food products from third countries that use NGTs to guarantee whether modifications came from a spontaneous mutation or from NGTs.
- Between April 29, 2022, and July 22, 2022, the Commission opened a public consultation on the legislation for plants produced by certain new genomic techniques. On July 5, 2023, the European

• **SDN-3:** introduces exogenous genetic material. When the genetic material comes from a sexually compatible donor, the process is known as cisgenesis or intragenesis, otherwise it is called transgenesis.

<sup>&</sup>lt;sup>4</sup> <u>Have your say (europa.eu)</u>

<sup>&</sup>lt;sup>5</sup> Site-directed mutagenesis is a generic term used to describe new mutagenesis techniques, which introduce a mutation or mutations at selected and targeted locations in the genome. Among the techniques that are included in this term is mutagenesis by Site-Directed nucleases. These types of techniques that introduce small mutations in a specific location of the genome have been classified into three groups:

<sup>•</sup> **SDN-1:** breaks the double strand of DNA and a cellular repair process results in small insertions and deletions in the genetic sequence.

<sup>•</sup> **SDN-2:** similar to SDN-1, but in this case a DNA molecule is introduced to guide cell repair and obtain the desired modifications.

Commission released a proposal for adoption of a regulation for plants obtained by targeted mutagenesis and cisgenesis, and their feed and food products. For additional information see GAIN Report entitled <u>European Commission Publishes Roadmap on Legislative Initiative for Plants</u> <u>Produced by Certain Genome Editing Techniques.</u> Contributions to this consultation can be consulted in the <u>link</u>.

• The combination of the delayed release of the Commission Proposal on NGTs (published on July 5 while it was initially scheduled for June 7, 2023) and the lower than anticipated level of consensus between key EU Member States on the proposal to date has impeded the formation of a Council agreement on the NGT regulation. As of writing this report, this piece of law remains stuck at the EU Council level.

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

## f) COEXISTENCE

Portugal was the first EU Member State to regulate coexistence. By <u>Decree-Law 160/2005 (in</u> <u>Portuguese)</u>, Portugal regulated coexistence back in 2005 following the <u>Commission Recommendation</u> <u>2003/556/EC</u>. Coexistence measures include observing an isolation distance that runs from 200 to 300 meters depending on whether conventional or organic crops are grown in the adjacent plot. Other options to minimize adventitious presence of GE pollen in other plots is the use of conventional corn border rows (24 to 28 rows), physical isolation, or the use of staggered plantings or staggered flowering or temporal isolation (less commonly used). Farmers must also keep conventional corn zones, also known as insect refugee areas, of at least 20 percent of the total GE corn area.

Decree-Law 160/2005 allows farmers to create GE Production Zones. In GE Production Zones farmers are still mandated to fulfill all legal obligations related to farming GE varieties, namely completing training requirements and notifying the DGAV and adjacent farmers about their GE crop farming intentions. However, except for limit zones, farmers are exempt from applying measures to minimize the adventitious presence of GE material.

The creation of GE Production Zones, which has been increasingly used to facilitate compliance with coexistence requirements, is a good example of how small farmers can benefit from biotechnology by coming to an agreement with neighboring farms. According to 2023 data, these zones represented 29 percent of the land planted with GE corn and nearly 38 percent of GE corn farmers. Over the last 10 years, these zones have decreased from representing 48 percent of land planted with GE corn in 2014 to 29 percent in 2023.

ANSEME, the Portuguese Seed Breeders Association, has an informatory leaflet published on their website. Latest version of the recommendations is available in the <u>link</u> (in Portuguese).

On a yearly basis, the Directorate General for Food and Veterinary (DGAV) publishes information related to coexistence measures implementation. Full reports (Available in Portuguese language only) can be found in the <u>DGAV website</u>.

### g) LABELING AND TRACEABILITY

There is no national level biotech labeling regulation developed in Portugal. Portugal, as an EU member, follows the rules set out in <u>Regulation (EC) 1829/2003</u> on Genetically Modified Food and Feed, and <u>Regulation (EC) 1830/2003</u> on the Traceability and Labeling of Genetically Modified Organisms. There is no "non-GMO" labeling regulation developed at the national level.

Food and feed products with GE content above 0.9 percent per ingredient must be labeled. Most feed products are labeled as "contains GE products" as opposed to food products, for which food companies have opted for reformulating to avoid GE products.

Detailed information on the EU-harmonized labeling legislation is available in the <u>EU Food and</u> <u>Agricultural Import Regulations and Standards Report</u> well as the <u>USEU website section on labeling</u>.

### h) MONITORING AND TESTING

Portugal has a decentralized system for testing and controlling unauthorized presence of GMO in the feed and food chain. DGAV is responsible for the coordination of the food and feed chain control.

The Portuguese regulations for sampling and testing are based on EU legislation, for more information please see the <u>EU Agricultural Biotechnology Annual report</u>. Portuguese imports are subject to random testing upon border entry, unless the <u>EU Rapid Alert System for Food and Feed (RASFF) database</u> flags a particular product and origin for additional measures.

### i) LOW LEVEL PRESENCE (LLP) POLICY

As an EU member, Portugal conforms to EU directives and follows EU regulations on agricultural biotechnology. Since July 2011, EU legislation sets a 0.1 percent<sup>6</sup> 'technical zero' level for shipments devoted to the feed market. However, for products that will enter the food chain the tolerance is an absolute zero level. Consequently, adventitious presence continues to be a concern for traders, who carry out a no-risk policy in their purchases, regardless of final use.

<sup>&</sup>lt;sup>6</sup> 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.

The absence of a threshold limit for GE material in seeds results in trade disruptions. Because the EU only allows cultivation of MON810, it serves as a trade barrier for U.S. seed exports containing or with adventitious presence of other GE events. Most seed companies operating in Portugal acquire corn seed locally or import it from other from other EU MS. Seed imports from non-EU countries represent less than one percent of the corn seed trade.

For additional information, see f) Trade Barriers within Part A: Production and Trade.

### j) ADDITIONAL REGULATORY REQUIREMENTS

- **Mandatory Training:** Farmers who want to cultivate GE crops in Portugal must participate in mandatory training sessions provided by the seed companies. The content of the training sessions is established by the DGAV and includes information about national and EU regulations for GE crops. In 2023, 23 farmers participated in these training sessions. GE corn seed lots are marketed accompanied by leaflets containing information regarding coexistence, traceability, and labeling.
- **GE Crops Field Register:** Farmers who want to grow GE crops must submit a completed notification form to DGAV 20 days before planting. In 2023, there were 56 notifications, a decrease from the 69 notifications registered in 2022, and a significant decline from the 171 notifications registered in 2018. Most of the notifications corresponded to the Centro and Alentejo Regions (**Table 1**).

Notifications	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Norte	14	9	14	9	10	9	6	8	3	5
Centro	51	49	94	82	74	65	59	45	35	26
Lisboa	44	44	53	48	21	17	9	17	4	8
Alentejo	129	114	81	63	66	49	49	52	27	17
Algarve	0	0	0	0	0	0	0	0	0	0
R. A. dos Açores	0	0	0	0	0	0	0	0	0	0
R. A. da Madeira	0	0	0	0	0	0	0	0	0	0
Portugal	238	216	242	202	171	137	123	122	69	56

Table 1. Number of Farmers Growing GE crops in Portugal

Source: DGAV

Farmers must communicate to neighboring farmers their intention to plant GE corn, and the plots within distances established in <u>Decree-Law 160/2005 (in Portuguese)</u>.

• **GE Crops Coexistence measures:** Farmers must put in place measures to avoid adventitious presence in neighboring fields (See Coexistence Section above) and comply with traceability and labeling requirements as well as facilitate official control by competent authorities in their farms.

## 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 (EPC) 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.

Plant Varieties Protection Rights in Portugal are regulated by <u>Decree-Law 213/90</u> and <u>Portaria 940/1990</u> (in Portuguese). The registration in the Protected Plant Varieties Catalog is voluntary and managed by CENARVE (National Center for Protected Varieties Register). Registration provides seed breeders with a 15-20 years protection period for annual or permanent crops respectively.

MON810 is the only GE event commercially grown in Portugal. As with most of the corn cultivated in Portugal, MON810 is also a hybrid. As a result, IPR is not an issue for Portugal's GE crops since hybrid seeds are not replanted.

## I) CARTAGENA PROTOCOL RATIFICATION

The EU is a signatory to the Cartagena Biosafety Protocol, as is Portugal. Portugal became a party to the Protocol in 2004, in <u>Decree 7/2004 (in Portuguese)</u>. At the national level, <u>APA</u>, the Portuguese Environmental Agency, is the competent authority of the Protocol. Additional information on the Cartagena's Biosafety Protocol can be found in its <u>official website</u>.

### m) INTERNATIONAL TREATIES AND FORUMS

Portugal is a member of various international treaties and conventions, including the International Plant Protection Convention (<u>IPPC</u>) and the Codex Alimentarius (<u>CODEX</u>). Portugal's Points of Contact for each of the organizations are available in the links. However, being an EU member, Portugal votes along EU lines, unless it is a non-EU harmonized decision, wherein each MS has the right to vote. For more information, see the <u>EU Agricultural Biotechnology Annual report</u>.

#### n) RELATED ISSUES

**GE Production Zones and GE-Free Zones:** Portugal was one of the first countries to create legislation that recognizes the right of farmers to voluntarily associate and establish both GE Production Zones and GE-Free Zones. The initiative to create a GE-Free Zone as defined in <u>Portaria 904/2006 (in Portuguese)</u>, and amended by <u>Portaria 1611/2007(in Portuguese)</u>, initiates with the farmers or from the Municipal Administration. In the latter case, farmers are still required to express their opinion, and the process will only advance if farmers give their public consent. The right for an individual farm to be excluded from the free zone is safeguarded.

Autonomous Region of Madeira: By the publication of <u>Regional Legislative Decree 15/2010M (in</u> <u>Portuguese) in 2010</u>, the Autonomous Region of Madeira became the first Region of the EU to declare itself a zone free of the cultivation of genetically modified organisms. More detailed information available in the GAIN Report: <u>Portugal Agricultural Biotechnology Annual 2011</u>. Although EFSA concluded that no new scientific evidence would justify a prohibition of the cultivation of GE plants in Madeira, as the Commission's deadline expired, the Portuguese Decree was tacitly accepted.

**Autonomous Region of the Azores:** <u>Regional Legislative Decree 28/2012/A (in Portuguese)</u> published in June 2012 prohibits the cultivation of GE crops for commercial purposes in the Azores, as allegedly the Region's environmental quality and biodiversity wealth would be endangered by the cultivation of GE crops.

#### PART C: MARKETING

#### a) PUBLIC/PRIVATE OPINIONS

**Competent Authorities:** The Portuguese Administration has traditionally followed a science-based approach in the biotech decision-making process and has fully implemented all EU regulations in its territory, including strict coexistence rules.

**Agricultural Stakeholders:** Portugal is the second largest producer of GE crops in the EU after Spain, which demonstrates that the farmers are generally supportive of the technology. Portugal is an importer of corn feed products and protein feed ingredients like soybeans. Given the needs of the domestic animal production sector and the limited domestic grain availability, most of the Portuguese feed and food chain operators strongly support plant biotechnology as a means of achieving higher competitiveness. Feed producers and livestock breeders defend their right to compete in equal conditions and be able to farm using the same technology as their main competitors. 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 adverse climatic events or 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 or climate resilience.

The <u>Biotechnology Information Center</u> (CIB) is a non-profit organization supported by different public and private institutions. Created in 2002, CIB's main goal is to promote communication on biotechnology in Portugal as well as in other Portuguese speaking countries. CIB shares information, engages in public debates, and consults in biotechnology-related regulation development. It also organizes seminars targeting different audiences.

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

### b) MARKET ACCEPTANCE/STUDIES

In Portugal, as in other European countries, GE products are primarily used as feed ingredients. The presence of GE labeled consumer-oriented products in the marketplace is limited, as most food manufacturers eliminated GE products from the food composition to avoid labeling as "Contains GMOs." However, feed producers and livestock breeders defend their right to compete in equal conditions and be able to produce using the same technology as their main competitors.

In June 2024, Portugal's Cabinet for Policy and Planning (GPP) issued a monographic on <u>New</u> <u>Breeding Techniques</u>. This publication assembles views of different stakeholders ranging from regulators to scientists, seed industry and agricultural producers. The publication intends to promote access to technical knowledge so that industry actors can have informed opinion on this topic, stimulate debate, confront existing interests, and thus contribute to the definition of public policies related to the use and development of best practices available in the area of improvement and genomic techniques.

In December 2023, Portugal's Biotechnology Industry Organization (P-BIO) and the Confederation of Farmers of Portugal (CAP), through a partnership titled AgroBioTech, presented a <u>report</u> on the use of biotechnology in Portugal's agricultural sector. The goal of the partnership is to increase the development and adoption of biotechnological innovation in the agricultural sector in Portugal. More specifically, the report's goal was to map and compile biotechnology initiatives and businesses currently operating in Portugal.

Portuguese public opinion on biotechnology and gene editing is generally positive, is comparatively more positive than the EU average, and has become more positive over time. A <u>2021 special</u> <u>Eurobarometer study</u> on EU citizen's attitudes towards science and technology showed that 93 percent of Portuguese citizens surveyed believed that biotechnology and genetic engineering would have a positive effect on our way of life in the next 20 years. This was the highest in the EU, as the EU average of this figure was 70 percent. Further, in Portugal, public perception that biotechnology and genetic engineering will bring about positive change has grown more than any EU member state, increasing 31 percentage points since 2005.

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY<sup>7</sup>**

### PART D: PRODUCTION AND TRADE

#### a) PRODUCT DEVELOPMENT

In Portugal, research conducted using animal biotechnology is permitted although subject to prior notice, public information, and authorization by APA according to Decree-Law 9/2003, in Portuguese. According to the public log managed by <u>APA</u>, notifications of confined research on GE animals between 2015 and 2024 included rodents, flies, frogs, and zebra fish. Most of the notifications in this area consist of basic science research for pharmaceutical purposes carried out by public institutions. In 2022, the Facultade de Ciencias da Universidade de Lisboa (FCUL) reported confined research activity with sea urchins (*Paracentrotus lividus*). The full list of confined activities authorized in Portugal can be found in <u>APA's website</u>.

#### **b)** COMMERCIAL PRODUCTION

There are no GE animals nor cloned animals commercially used in Portugal. There is no production of GE animals or clones intended for the Portuguese food market.

#### c) EXPORTS

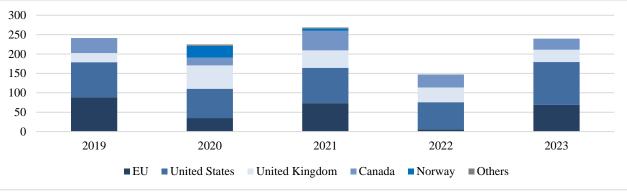
Portugal does not produce commercial GE animals, clones, or products; hence there are no known exports within these categories.

#### d) IMPORTS

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. The Portuguese livestock industry may have imported semen and embryos from cloned animals.

Since 2019, Portugal's total imports of bovine semen have averaged 224,000 units, with a sharp drop in 2022, but recovered in 2023 (**Graph 10**). The United States is the largest supplier of bovine semen to Portugal. In the 2019-2023 period, the average U.S. market share represented 39 percent of imports in quantity and 52 percent in value. In 2023, Portugal's imports of bovine genetics from the United States accounted for \$1.3 million.

<sup>&</sup>lt;sup>7</sup> 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.



Graph 10. Portugal's Imports of Bovine Semen (HS Code 051110) (1,000 Units)

### e) TRADE BARRIERS

GE or cloned trade barriers in Portugal are the same as those established at the EU level. For more information about the European framework, please see the latest <u>EU Biotechnology Annual</u> <u>Report.</u>

### PART E: POLICY

### a) REGULATORY FRAMEWORK

For GE and cloned animals, Portugal abides by EU law. For more information about the European framework, please see the latest <u>EU Biotechnology Annual Report</u>. 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). Domestic regulation applicable to GE plants also applies to GE animals. Portugal has not specifically regulated GE animals or clones.

#### Table of terms:

Legal term (in	Legal Term	Laws and Regulations	Legal Definition (in English)
official language)	(in English)	where term is used	
Organismos Geneticamente Modificados (OGM)	Genetically Modified Organism (GMO)	Decree-Law 72/2003 (in <u>Portuguese</u> ) as amended by <u>Decree-Law 164/2004 (in</u> <u>Portuguese</u> )	Any organism, with the exception of humans, whose genetic material was modified in a way that does not occur naturally, through crossing and/or a natural recombination, understanding that, i) modification occurs when techniques referred to in Part 1 of Annex I-A are used ii) modification does not occur when techniques referred to in Part 2 of Annex I-A are used.

## b) APPROVALS/AUTHORIZATIONS

No GE animals are approved for feed and food uses in Portugal. Food from clones falls under the scope of the <u>Novel Food Regulation</u> and is subject to pre-market authorization. No applications have been submitted or approved for food from clones.

Source: Trade Data Monitor, LLC data.

### c) INNOVATIVE BIOTECHNOLOGIES

Portugal has not regulated the use of IBs in animals and follows EU legislation.

#### d) LABELING AND TRACEABILITY

Portugal has implemented EU legislation on labeling and traceability. For more information on this topic, see the latest <u>EU Biotechnology Annual Report.</u>

### e) ADDITIONAL REGULATORY REQUIREMENTS

None.

#### f) INTELLECTUAL PROPERTY RIGHTS (IPR):

Portugal has implemented EU legislation. For more information on this topic, see the latest <u>EU</u> <u>Biotechnology Annual Report</u>.

#### g) INTERNATIONAL TREATIES and FORUMS

Portugal's participation in international treaties and forums is no different from that of the EU. As a member of the EU, Portugal is a member of Codex and of the World Organization for Animal Health (OIE). For more information on this topic, see the <u>EU Biotechnology Annual Report</u>.

#### h) RELATED ISSUES

Not available.

#### PART F: MARKETING

#### a) PUBLIC/PRIVATE OPINIONS

Not available.

#### 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 "<u>Europeans' attitudes towards animal cloning</u>." There are not many country-specific studies on marketing or acceptance of cloning in Portugal.

## **CHAPTER 3: MICROBIAL BIOTECHNOLOGY**

### PART G: PRODUCTION AND TRADE

### a) **PRODUCT DEVLOPMENT**

In Portugal, research conducted using GE microbes is permitted although subject to prior notice, public information, and authorization by APA according to <u>Decree Law 55/2015</u>, in Portuguese. The full list of confined activities authorized in Portugal can be found in <u>APA's website</u>. In 2022, the Faculty of Sciences of the University of Lisbon (FCUL) received authorization to conduct confined research on Genetically Modified Microorganisms (GMM) on *Escherichia coli, Agrobacterium tumefaciens, Tetrahymena thermophila* and *Saccharomyces cerevisiae*. Also in 2022, Algafuel reported research on *Phaeodactylum tricornutum* and *Chlamydomonas reinhardtii*. In 2021, University of Minho - Center for Biological Engineering (CEB) reported GMM research with *Escherichia coli, Saccharomyces cerevisae, Zymomonas mobilis, Staphylococcus epidermis, Kluyveromyces marxianus, Pichia pastoris, Yarrowia lipolytica* and *Ashbya gossypii*.

## **b) COMMERCIAL PRODUCTION**

In Portugal, 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 and veterinary drugs.

<u>P-BIO</u>, the association that represents the interests of the biotechnology and life sciences sector in Portugal, including but not limited to agricultural biotech, published a <u>study</u> in 2021 about trends, opportunities, and challenges in the Biotechnology sector in Portugal. This study shows that about 20 percent of Portuguese biotechnology firms worked primarily on agricultural and food applications.

On a commercial scale, Portuguese companies such as <u>Biotrend</u> offer bioprocesses using both geneedited and not gene-edited microorganisms with marine biotechnology, pest management, and beverage manufacturing applications, such as for fermented fruit juice beverages and production of novel yeasts for viticulture.

### c) EXPORTS

There are no official statistics available regarding exports of microbial biotechnology products. However, Portugal 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, Portugal 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 Portugal are the same as those established at the EU level. For more information about the European framework, see the latest <u>Agricultural Biotechnology Annual European Union</u>.

## PART H: POLICY

## a) REGULATORY FRAMEWORK

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

- Contained use is regulated by Directive (<u>Directive 2009/41/EC</u>).<sup>8</sup> To qualify for confined use, both the GE microbe or production organism and the recombinant DNA (rDNA) used to genetically alter the organism must be absent from the final product.
- If criteria for contained use are not met, the product would fall under the scope of deliberate release to the environment, regulated by EU <u>Directive 2001/18/EC</u>.<sup>9</sup>

Portugal transposed the European <u>Directive 2001/18</u> regarding "GMOs" to national regulation by <u>Decree-Law 72/2003 (in Portuguese)</u> as amended by <u>Decree-Law 164/2004 (in Portuguese)</u>.

In practice, the Portuguese 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.

For information about Portugal's competent authorities see Section a) <u>Regulatory Framework</u> within the Plant Biotechnology Chapter, Part B: Policy.

<sup>&</sup>lt;sup>8</sup> 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."

<sup>&</sup>lt;sup>9</sup> 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	Legal Term	Laws and Regulations	Legal Definition (in English)
official language)	(in English)	where term is used	
Organismos	Genetically	Decree-Law 72/2003 (in	Any organism, with the exception of humans, whose genetic
Geneticamente	Modified	Portuguese) as amended by	material was modified in a way that does not occur naturally,
Modificados (OGM)	Organism	Decree-Law 164/2004 (in	through crossing and/or a natural recombination, understanding
	(GMO)	Portuguese)	that, i) modification occurs when techniques referred to in Part 1
		-	of Annex I-A are used
			ii) modification does not occur when techniques referred to in Part
			2 of Annex I-A are used.

### b) APPROVALS/AUTHORIZATIONS

Confined used is permitted in Portugal and subject to prior notice and approval by competent authorities as established in <u>Decree Law 55/2015 (in Portuguese)</u>.

## c) LABELING AND TRACEABILITY

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

### d) MONITORING AND TESTING

As is the case with plant biotechnology, the Directorate General for Food and Veterinary Affairs (DGAV) coordinates the food chain control. For more information see Section h) <u>Monitoring and</u> <u>Testing</u> within Plant Biotechnology Chapter. Part B: Policy.

### e) ADDITIONAL REGULATORY REQUIREMENTS

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

## f) INTELLECTUAL PROPERTY RIGHTS (IPR)

The biotechnology sector can opt for protecting its innovations internationally through the <u>European</u> <u>Patent Office</u> or the <u>Patent Cooperation Treaty</u>, or at the national level. The <u>Portuguese Institute of</u> <u>Industrial Property (INPI)</u> is the government agency that protects and promotes industrial property and accepts applications for patent registration. Information for applying for patents in Portugal can be accessed in English at the <u>link</u>.

### g) RELATED ISSUES

N/A

## PART I: MARKETING

## a) PUBLIC/PRIVATE OPINIONS

Food ingredients derived from microbial biotechnology are not widely discussed in Portugal, 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 Portugal. FAS/Madrid is not aware of any study on microbial biotechnology acceptance.

#### Definitions and Acronyms used in this report:

ANPROMIS	Portuguese Association of Corn and Sorghum Producers
ANSEME	National Association of Seed Breeders
APA	Portuguese Agency of Environment
CGF	Corn Gluten Feed
CPVR	Community Plant Variety Right
DDGS	Distiller's Dried Grains with Solubles
DGAV	Directorate General for Food and Veterinary Affairs
DGS	Directorate General for Health Issues
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAS	Foreign Agricultural Service
GE	Genetically Engineered
GMM	Genetically Modified Microorganisms
GMO	Genetically Modified Organism
GOP	Government of Portugal
На	Hectares
IB	Innovative Biotechnologies
INE	Portuguese National Statistics Institute
LLP	Low Level Presence
MS	Member State(s)
MT	Metric ton (1,000 kg)
MY	Marketing Year
N/A	Not available
TDM	Trade Data Monitor

"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).

#### Attachments:

No Attachments.