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Report Highlights:

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. While the country's total corn plantings registered a marginal recovery in 2018, Bt corn area in Portugal registered a nearly 20 percent decline. Farmers have opted for more profitable crop margins and supplying product to food manufacturers, who prefer to use conventional corn in food processing to avoid labeling requirements for products intended for human consumption.

Disclaimer: Portugal, as a member of the European Union (EU), conforms to EU directives and regulations on biotechnology. It is therefore recommended that this report be read in conjunction with the latest EU-28 Agricultural Biotechnology Annual report.

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY PART A: PRODUCTION AND TRADE

PART B: POLICY

PART C: MARKETING

CHAPTER 2: ANIMAL BIOTECHNOLOGY PART D: PRODUCTION AND TRADE

PART E: POLICY

PART F: MARKETING

Acronyms used in this report:

ANPROMIS Portuguese Association of Corn and Sorghum Producers

ANSEME Portuguese Seed Breeders Association o
APA Portuguese Agency of Environment

CGF Corn Gluten Feed

CPVR Community Plant Variety Right

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

GATS Global Agricultural Trade System

GE Genetically Engineered

GMO Genetically Modified Organism

GTA Global Trade Atlas

Ha Hectares

IB Innovative Biotechnologies

MS Member State(s)
MT Metric ton (1,000 kg)

Glossary:

Agricultural biotechnology (referred to in this document as genetic engineering), is a term used for crops or animals developed through recombinant DNA technologies (transgenesis). The product of this technology is known in Europe as a genetically modified organisms (GMO).

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.

EXECUTIVE SUMMARY

Portugal allows crops product through genetically engineering and IBs in confined research and field trials subject to prior notice and approval by competent authorities. However, the limited ability for the commercialization of new genetically engineered (GE) crops discourage investment in GE crop research in Portugal.

Portugal is the European Union's (EU's) second largest grower of GE crops (after Spain); representing five percent of the total EU GE planted area. While the country's total corn plantings registered a marginal recovery in 2018, Bt corn area (a GE corn resistant to the corn borer) in Portugal registered a nearly 20 percent decline. Possibilities for further expansion for the country's GE crop area are limited given that just one insect resistance event is available. Portugal's GE area is limited to the land where the target insect, the European corn borer, has an impact in final yields.

In addition, in search for better margins, farmers are switching to conventional corn to keep their options open to supply product to the food industry rather than the feed industry. The local food processing industry prefers conventional corn for their processes in order to avoid the "Contains GMO" wording in the labeling of products intended for human consumption.

However, given the country's deficiency in feed ingredients, nearly all feed marketed in Portugal is GE. Because the domestic feed grain production in Portugal is not large enough to meet the domestic livestock industry demand, Portugal on average imports about 3.5 million metric tons (MT) of grains, about 875,000 MT of soybeans, and 170,000 MT of soybean meal. Most of the Portuguese feed and food chain links strongly support plant biotechnology as a means of achieving higher competitiveness. Additionally, feed producers and livestock breeders defend their right to compete in equal conditions and to produce using the same technology as their main competitors.

U.S. agricultural exports to Portugal consist mainly of bulk commodities, which accounted for over 50 percent of the U.S. export value during 2006-2017. Soybeans are the most important traded product, representing nearly one third of total agricultural imports from the United States.

Portugal has fully implemented all EU regulations. By allowing the cultivation of GE corn, it preserves both farmers' and consumers' choices. The Portuguese Administration has traditionally followed a science-based approach in its decision-making process. However, since 2015, Portugal has been less consistent in following EFSA's (European Food Safety Authority) advice in the EU approval process for GE events.

The European Court of Justice (ECJ) issued a ruling on July 25, 2018 to regulate genome editing as a GE product. This came as surprise to Portuguese stakeholders. For the scientific community, the ECJ decision is particularly worrisome since the concern is that small research companies and public institutions that may not have the resources to navigate the burdensome approval process in place for GE products. The ruling also ignited domestic discussions on the feasibility of its implementation at the Member State (MS) level. Agricultural stakeholders have expressed their concerns about continuing to face third countries competition without having access to the same tools as their competitors. Public awareness on this topic remains very limited.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

FAS Madrid is unaware of any GE crops under development in Portugal.

Confined research with GE organisms is regulated by <u>Decree Law 55/2015 (in Portuguese)</u>, which establishes prior notice and approval by competent authorities (such authorities are listed in Part B, Policy).

As in other European Member States, the limited ability for GE crops to be commercially available for planting, discourages investment in GE crop research in Portugal.

To date, according to the <u>Joint Research Center</u>, in 2018, no notifications for deliberate environmental release of GE plants for any other purposes than market-placing were submitted in Portugal.

b) COMMERCIAL PRODUCTION

MON810 corn has been commercially grown in Portugal since 2005 and the country is the EU's second largest producer of Bt corn, after Spain. Total area planted to corn varies every year depending on water availability, price, and competition from alternative crops.

Since MY2014/15, total planted area for corn has been declining due to lower margins compared to alternative crops, and to a lesser extent to crop diversification established by EU's-greening measures¹. However, in 2018, for the first time in years, 2018 total corn area in Portugal showed a marginal recovery (**Table 1**). Despite initial fears, storage water levels did not call for irrigating restrictions this season. However, farmers made planting decisions on corn crop alternatives prior to the spring rains, when the water supply was not entirely guaranteed. For example, tomatoes for processing is a water-intensive crop and subject to contracts with industry. Alternatively, farmers shifted towards less water-intensive spring crops such as corn.

The Portuguese Ministry of Agriculture, in conjunction with major stakeholders, presented a five-year strategy to increase Portugal's self-sufficiency rates to 50 percent in the case of corn and 20 percent in the case of winter grains. The priority measures identified to achieve these targets pursue different goals. For the full list of the priority measures check this <u>link</u> (Portuguese language only). When fully implemented, this strategy could contribute to additional growth for total domestic corn area. Despite the potential growth in total corn area, any increases in Bt corn planting will ultimately depend on its competitiveness compared to conventional corn.

Table 1. Portugal's Total Corn Area*

Marketing Year	MY2014/15	MY2015/16	MY2016/17	MY2017/18	MY2018/19
Total Corn (1,000 Ha)	137	126	118	116	118

Source: ANPROMIS.

*Continental area of grain corn and silage corn is considered.

¹ A large part of the support to farmers (30%) is linked to greening measures. To comply with greening measures, crop diversification has to 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.

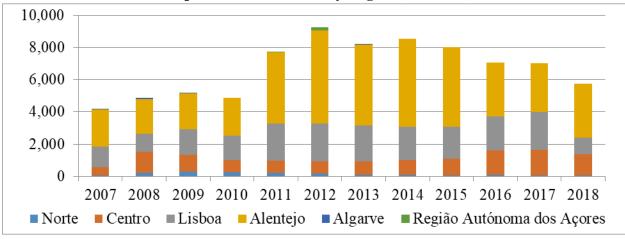
Area planted for Bt corn in Portugal increased steadily until 2012 when it reached its highest level (see **Table 2, Graph 1,** and <u>GAIN Report SP1234</u>). Between 2013 and 2015, Bt corn area only suffered slight variations staying around 8,250 Ha. In 2016 and 2017, Bt corn area stabilized around 7,000 Ha. As a dry milling plant began operations in the area, demand for GE-free corn increased and discouraged Bt corn plantings. While the country's total corn plantings registered a marginal increase in 2018, Bt corn area in Portugal registered a nearly 20 percent decline. The increased Bt corn area in the Alentejo Region did not offset the sharp reduction in the Lisbon and Centro Regions.

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

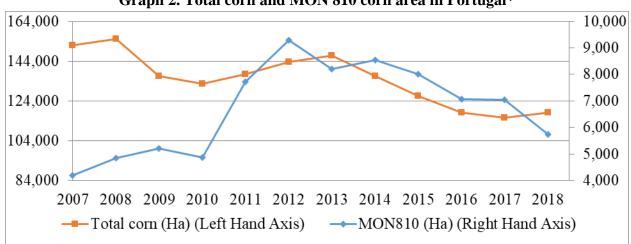
Region	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Norte	298	248	209	165	85	78	60	100	45	61
Centro	1,013	765	758	774	853	933	1,013	1,485	1,609	1,311
Lisboa	1,603	1,511	2,294	2,322	2,215	2,074	2,002	2,138	2,337	1,023
Alentejo	2,246	2,344	4,460	5,796	5,041	5,457	4,942	3,346	3,045	3,338
Algarve	42	-	-	13	8	0	0	0	0	0
Açores	-	-	3	208	0	0	0	0	0	0
Total	5,202	4,869	7,724	9,278	8,202	8,542	8,017	7,069	7,036	5,733

Source: DGAV.

Graph 1. GE Corn Area by Region (Hectares)



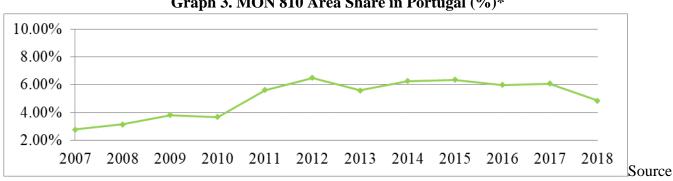
Source: FAS Madrid based on DGAV data.



Graph 2. Total corn and MON 810 corn area in Portugal*

Source: FAS Madrid based on DGAV and ANPROMIS data.

^{*}Continental area of grain corn and silage corn is considered.



Graph 3. MON 810 Area Share in Portugal (%)*

: FAS Madrid based on DGAV, ANPROMIS and INE data.

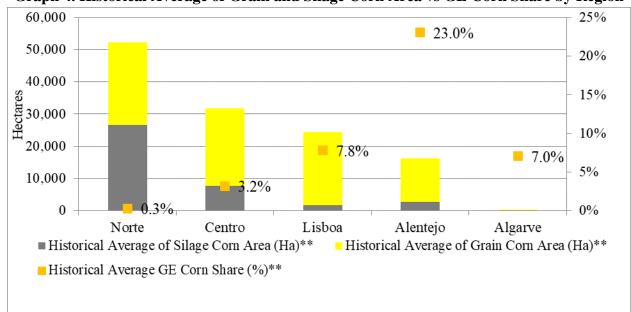
Further expansion of GE corn area in Portugal is limited by a number of factors:

With the exception of 2018 plantings, total corn area in Portugal has registered a long-term **decline:** Poor crop margins, competition by other crops, crop diversification established by greening², and limited amounts of water for irrigation purposes in certain areas continues to reduce total corn area.

^{*}Continental area of grain corn and silage corn is considered.

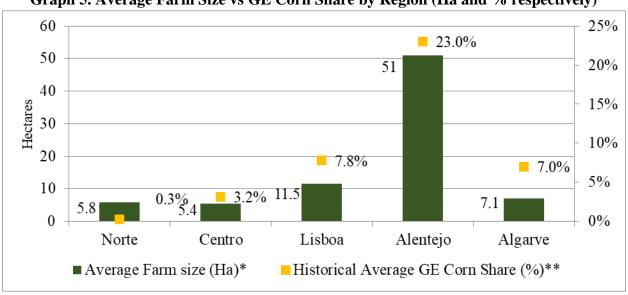
 $^{^{2}}$ A large part of the support to farmers (30%) is linked to greening measures. To comply with greening measures, crop diversification has to be observed. Farms between 10 and 30 ha must grow at least two different crops, and farms over 30 ha must grow at least three different crops in their arable land, which ultimately introduces slight variations in areas where monoculture is carried out.

- 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. In a small crop margins scenario, 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 grower's interest in GE crops.
- GE corn is only consumed by feed compounders: The large majority of 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 consequently it is by default labeled as "contains GE products." Portuguese farmers generally accept the technology. However, they are switching back to conventional corn, as crop margins have proved to be more profitable when supplying product to food manufacturers. Food manufacturers prefer to use non-GE corn in processing in order to avoid the "Contains GMO" wording in the labeling of products intended for human consumption.
- An important share of the Portuguese continental corn area (30 percent) 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 (Graph 4).
- Coexistence rules limit GE corn crop expansion: Given the small average farm size that prevails throughout the country, in order to fulfill coexistence rules, smaller farmers need to come to agreements with their neighbor farms to create GE areas. Bigger farmers can implement coexistence within their farm. Graph 5 shows how in Alentejo Region, where farm size is bigger, the share of GE corn is higher. (See Coexistence Section for additional information)



Graph 4. Historical Average of Grain and Silage Corn Area vs GE Corn Share by Region

Source: FAS Madrid based on INE, DGAV and ANPROMIS data. **2007-2018 average



Graph 5. Average Farm Size vs GE Corn Share by Region (Ha and % respectively)

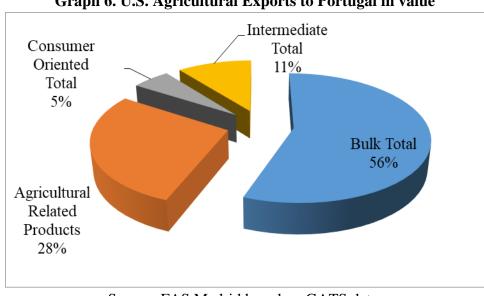
Source: FAS Madrid * based on Survey 2009 data and ** 2007-2018 average.

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 production internally.

d) IMPORTS

Portugal's imports of U.S. agricultural exports consist mainly of bulk commodities, which accounted for over 55 percent of the U.S. exports during 2013-2017 (by value). Soybeans are the most important traded product, accounting for nearly 28 percent of total the U.S. agricultural exports to Portugal (Graph 6).

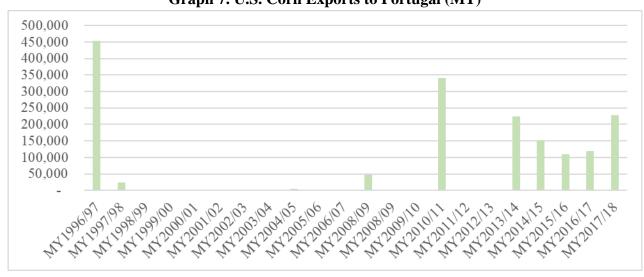


Graph 6. U.S. Agricultural Exports to Portugal in value

Source: FAS Madrid based on GATS data.

Portugal has a structural shortfall of feed grains and protein meals due to its comparatively large livestock sector, limited grain production, highly variable grain yields, and pasture availability. Regardless of the domestic grain crop, on average Portugal needs to import 3.5 million MT of grains per year, of which 1.7 million MT correspond to corn imports.

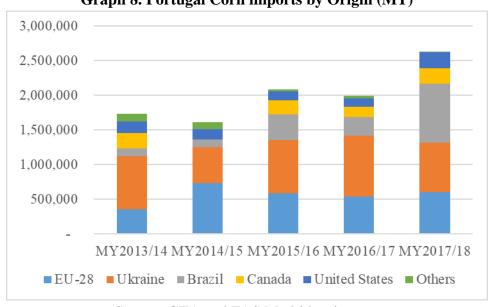
Graph 7 shows U.S. corn exports to Portugal throughout the last 20 years. It shows how the lack of approvals of GE events in the EU caused a drastic decline in U.S. corn exports to Portugal. This occurred after the United States started planting GE corn in 1998 (asynchronous approvals is the effect of a product is approved in the country of production, but not yet approved in the country of import). Since then, only occasional trade in corn took place between the United States and Portugal. This situation persisted until the last five marketing years were U.S. corn export to Portugal averaged over 160,000 MT per year.



Graph 7. U.S. Corn Exports to Portugal (MT)

Source: GTA and FAS Madrid Estimates.

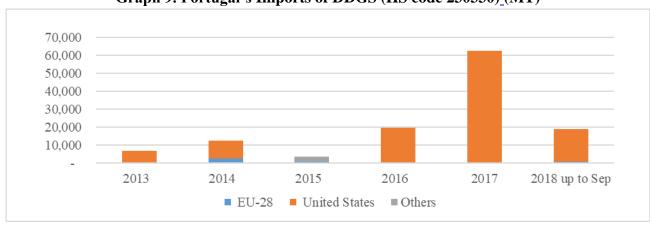
The origin of Portugal's corn imports has evolved throughout the years. In order to avoid border rejections due to asynchronous approvals, there has been a shift away from suppliers that whose rate of biotechnology adoption outpaces EU's of approvals. In years where the gap in approvals narrows, trade from these suppliers can increase. In MY2017/18, Ukraine and Brazil supplied half of the Portuguese corn market (**Graph 8**).



Graph 8. Portugal Corn imports by Origin (MT)

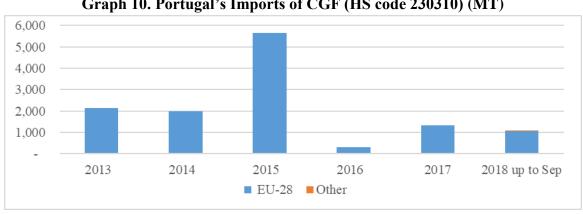
Source: GTA and FAS Madrid estimates.

Lower bioethanol production in neighboring Spain along with competitive prices, provided new opportunities for the import of distiller's dried grains and solubles (DDGS) in 2017 (Graph 9), the United States being a major supplier. Intra-EU trade of corn gluten feed (CGF) was particularly high in 2015 (**Graph 10**).



Graph 9. Portugal's Imports of DDGS (HS code 230330) (MT)

Source: GTA.

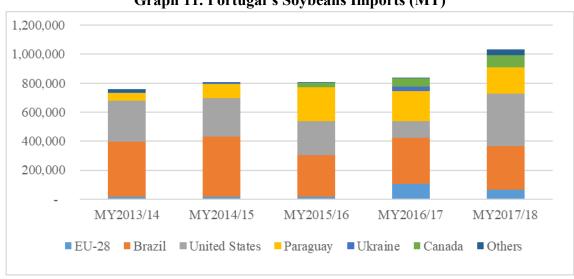


Graph 10. Portugal's Imports of CGF (HS code 230310) (MT)

Source: Global Trade Atlas (GTA)

Portugal's annual combined imports of soybean and soybean meal amount to over one million MT. Most of Portugal's imported soybeans and soybean meal are GE, with the exception of those devoted to special market niches. 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.

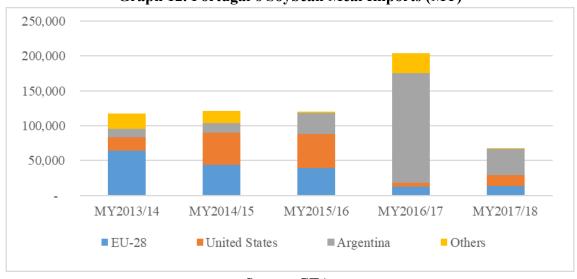
Brazil dominates Portugal soybean seed import market, accounting for nearly half of the in-country crushed soybean seeds. Soybean imports from the United States represent nearly one third of Portuguese soybean imports (**Graph 11**). In MY2017/18, the United States increased its participation in the Portuguese soybeans import market.



Graph 11. Portugal's Soybeans Imports (MT)

Source: GTA.

Between MY2013/14 and MY2015/16, more competitive U.S. soybean meal prices increased U.S. share of the Portuguese market. Argentina supplied the majority of the soybean meal imports in 2016/17 and 2017/18 (**Graph 12**).



Graph 12. Portugal's Soybean Meal Imports (MT)

Source: GTA.

e) FOOD AID

Portugal is not a recipient of food aid. It provides food aid in accordance with the best practices of the United Nations but does not provide GE commodities for food aid. Having said that, while in the case of emergencies, when the local markets have collapsed, in-kind food aid may be given. Normally, local purchases in recipient countries are preferred to avoid pushing down local prices and discouraging domestic production in recipient countries.

Portugal is founding member of International Fund for Agricultural Development (IFAD) List A since 1978, a United Nations Agency created to enable poor rural population to overcome poverty and hunger. It is also a member of the United Nations Food and Agriculture Organization (FAO) and a strong supporter of the World Food Program (WFP) working closely with the Community of Portuguese Speaking Countries (CPLP) and its member governments.

FAO works closely with Portugal and CPLP to promote the dissemination and exchange of information and knowledge with the aim of strengthening technical cooperation and familiarizing the public with the work of FAO, particularly on the issue of hunger.

The Portuguese Ministry of Foreign Affairs created the Camões Institute in 2012. It is responsible for the supervision, management, and coordination of the cooperation for development of programs and projects primarily for the CPLP countries. It works either directly through its own resources or in the collaboration with other national or international organizations and Non-Government Organizations (NGOs).

f) TRADE BARRIERS

- **For bulk commodities:** The asynchronous approval of GE events cultivated in the United States yet not authorized for imports to the EU-28 remains the main trade barrier. Additionally, the limited allowance for adventitious presence³ for non-approved events continues to constraint traders, who carry out a no-risk policy in their purchases. 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 consistently gained market share at the expenses of lower imports from the United States, Argentina, and Brazil (See **Graph 8**).
- **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," the large majority of food manufacturers and processed food importers have either eliminated the use of GE products in food manufacturing or switched to GE-free suppliers.
- For Seed: Seed trade is affected by the zero tolerance of adventitious presence. The fact that the EU only allows cultivation of MON 810, serves as a trade barrier for U.S. seed exports containing or with adventitious presence of other GE events. The EU has not yet set a threshold level for the adventitious presence of GE material. Portugal sources most of its corn seeds from other EU Member States or from local breeders. 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 the country was one of the first countries to create legislation that recognizes GE-Free Zones.

For additional information on the EU's opt-out for cultivation see Part B; Section b) Approvals. For additional information on the GE-Free zones, see Part B; Section n) Related Issues.

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³ Refers to the detection of unintentional presence of GE crops.

PART B: POLICY

a) REGULATORY FRAMEWORK

The EU Regulations directly apply in all EU member States. However, EU Directives must be transposed into national laws, and the EU provides the opportunity for MS governments to exercise some discretion without altering the basic scope of the EU directive. For EU Agricultural Biotechnology Regulatory Framework please see <u>EU-28 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 weight-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, Forestry and Rural Development, 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, please consult this link..
- **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 considering 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.

b) APPROVALS

- **For imports:** Approvals of events for imports are managed at the EU level. Member States have the chance to weigh in during 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, and the list of approved GE events, please see <u>EU-28 Agricultural Biotechnology Annual report</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 (Directive (EU) 412/2015). Portugal abstained in the EU vote on this renationalization of authority for the cultivation decisions. FAS/Madrid understands this as an attempt to express their partial dislike to some aspects of the proposal. Directive (EU) 412/2015, 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 Resolution 32/2015 (in Portuguese) 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. Directive (EU) 2015/412 sets April 3, 2017 as limit for transposal to National Law. Portugal, as with four other Member States countries that grow GE corn, decided not to opt out of GE cultivation. For additional information See GAIN Report FR9180.

More information see Part B; Section f) Coexistence.

c) STACKED OR PYRAMIDED EVENTS APPROVALS:

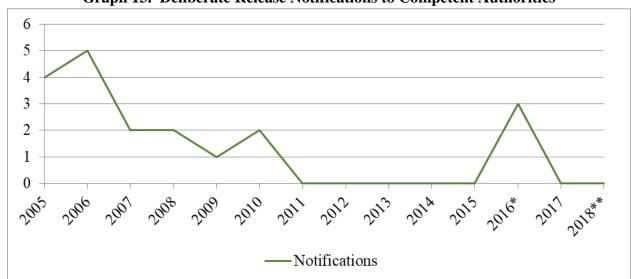
Stacked events are subject to risk assessment on an EU-level. The approval process is the same as for single events. Risk assessment of stacked events follows the principles provided in EFSA's Guidance Document, which stipulates that where all single events have been assessed, the risk assessment of stacked events should focus mainly on issues related to a) stability, b) expression of the events, and c) potential interactions between the events.

d) FIELD TESTING:

<u>Decree-Law 72/2003 (in Portuguese)</u>, as ameded by <u>Decree-Law 164/2004 (in Portuguese)</u>, regulates the deliberate release in the environment of a "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 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 DGS and the DGAV.

No field trial notifications have been recorded since 2010. 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. European seed breeding companies have concentrated their efforts to non-European markets, and most of their research in plant biotechnology is conducted outside Europe. No deliberate releases were notified in 2018.



Graph 13. Deliberate Release Notifications to Competent Authorities

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

* In 2016, three deliberate releases in the field of medical research have been notified to competent authorities. Additional information about deliberate releases is available in the <u>Portuguese Agency of Environment website</u>.

**2018 data are based on data available up to December 15, 2018.

e) INNOVATIVE BIOTECHNOLOGIES

As of the date of this report, the Government of Portugal has not yet issued an official position on IBs.

The ECJ Ruling on July 25, 2018, determining that organisms produced with IBs must abide by EU <u>Directive 2001/18</u>, has ignited domestic discussions on the feasibility of its implementation at the MS level.

For additional on ECJ Ruling on New Plant Breeding Techniques, please see GAIN Report: "EU

f) COEXISTENCE

Portuguese) Portugal regulated coexistence in 2005 following the Commission Recommendation 2003/556/EC. Coexistence measures include observing an isolation distance that runs from 200 to 300 meters depending if the adjacent plot is growing a conventional crop or an organic crop. 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, and 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 **2017** data, these zones represented 46 percent of the land planted to GE corn and nearly 50 percent of GE corn farmers. The use of GE production Zones (**Table 3**) has contributed to the use of agricultural biotechnology.

Table 3. GE Zones Share of GE Area by Region (%)

Region	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Norte	17.5	16.6	12.3	12.1	15.5	7	4	0	0	0
Centro	52.6	54	66.4	51.2	61.9	57	57	55	55	60
Lisboa	32.8	54.7	28.3	42	49.2	48	41	36	51	60
Alentejo	65.2	39.4	54.8	54.9	71.6	65	50	25	31	29
Algarve	0	0	0	0	0	0	0	0	0	0
Acores	0	0	0	0	11.7	0	0	0	0	0
Portugal	51.9	45.1	46.2	49.5	62.7	59	48	42	42	46

Source: DGAV reports.

Farmers must put in place measures to avoid adventitious presence in neighboring fields and comply with traceability and labeling requirements as well as facilitate official control by competent authorities in their farms. They must also communicate to neighboring farmers their intention to plant GE corn, and the plots within distances established in Decree-Law 160/2005.

The Portuguese Seed Breeders Association (ANSEME), has an informational leaflet is published on their website. The latest version of the recommendations is available at this <u>link</u> (in Portuguese). On a yearly basis, the Directorate General for Food and Veterinary (DGAV) publishes information related to the implementation of coexistence measures. Full reports (Available in Portuguese language only) can be found in the <u>DGAV website</u>.

g) LABELING

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. The large majority of feed products are labeled as "contains GE products" as opposed to food products, for which food companies have opted for reformulating in order to avoid GE ingredients.

Detailed information on the EU-harmonized labeling legislation is available in the <u>EU-28 Food and 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. The DGAV is responsible for the coordination of the food and feed chain control and regional authorities are responsible for its implementation.

The Portuguese regulations for sampling and testing are based on EU legislation, for more information please see the <u>EU-28 Agricultural Biotechnology Annual report</u>. Portuguese imports are subject to random testing upon border entry, unless <u>the EU Rapid Alert System for Food and Feed (RASFF)</u> database 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 percent⁴ 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 the final use.

The absence of a threshold limit for GE material in **seeds** results in trade disruptions. Because the EU-28 only allows cultivation of MON 810, it serves as a trade barrier for U.S. seed exports containing or with adventitious presence of other GE events. The large majority of seed companies operating in Portugal acquire corn seed locally or import it from other from another EU MS. Seed imports from non-EU countries represent less than 1 percent of the corn seed trade.

For additional information, see Part A; f) Trade Barriers.

j) ADDITIONAL 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
 2017, 44 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 2018, there were 171 notifications, a significant decrease from the 202 notifications registered in 2017. The large majority of the notifications (over 40 percent) corresponded to the Centro and Alentejo Regions. Producers must also communicate any alteration of the planting plan to the regional authorities for agriculture. With only 171 farmers notifying GE corn plantings, 2018 is the year with the lowest number of notifications since 2007 (**Table 4**).

Table 4. Number of Farmers Growing GE crops in Portugal

Number of	200	201	201	201	201	201	201	201	201	201
Notifications	9	0	1	2	3	4	5	6	7	8
Norte	69	44	36	29	19	14	9	14	9	10

⁴ This level corresponds to the lowest level of GE material taken into account 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.

Centro	66	51	48	55	48	51	49	94	82	74
Lisboa	36	31	55	54	51	44	44	53	48	21
Alentejo	62	65	107	120	113	129	114	81	63	66
Algarve	1	0	0	1	1	0	0	0	0	0
R. A. dos Açores	0	0	2	19	0	0	0	0	0	0
R. A. da Madeira	0	0	0	0	0	0	0	0	0	0
Portugal	234	191	248	278	232	238	216	242	202	171

Source: DGAV

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

The Community Plant Variety Right (CPVR), issued by the Community Plant Variety Office in Angers, (France), provides intellectual property rights for protection of plant varieties. However, the European Patent Convention of October 1973 excludes patents for plant varieties. The CPVR grants to breeders 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 National Center for Protected Varieties Register. Registration provides seed breeders with 15 or 20 years of protection 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.

1) CARTAGENA PROTOCOL RATIFICATION

The EU is a signatory to the Cartagena's Biosafety Protocol, as is Portugal. Portugal became a party to the Protocol in 2004 (Decree 7/2004 (in Portuguese).

At the national level, <u>APA</u> 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's participation in international treaties and forums is not different from that of the EU. For more information on this regard it is recommended to read the EU-28 Agricultural Biotechnology Annual report.

n) RELATED ISSUES

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 nº 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 Regional Legislative Decree 15/2010M (in Portuguese) in 2010, 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 GAIN Report Portugal Biotechnology Annual 2011. 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: Regional Legislative Decree 28/2012/A (in Portuguese) published in June 2012 prohibits the cultivation of GE crops for commercial purposes in the Azores. The region alleges that the Region's environmental quality and biodiversity wealth would be endangered by the cultivation of GE crops.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

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. The Portuguese Administration has traditionally followed a science-based approach; however, since 2015, Portugal has been less consistent in following EFSA's advice in the EU approval process for GE events and has moved towards a case-by-case approach.

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 crops like soybeans. Given the needs of the domestic animal production sector and the limited

domestic grain availability, the majority of 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. Meat retailers nor consumers appear to have a strong opinion on this issue.

At the government level, in the July 17-18, 2017 Council of Ministers, Portugal was one of the 13 European Member States that did not sign the <u>European Soya Declaration</u> put forward by the German and Hungarian delegations.

b) MARKET ACCEPTANCE/STUDIES

In Portugal, as in other European countries, GE products are primarily used for livestock feed. The presence of GE labeled consumer oriented products in the marketplace is nonexistent, as the large majority of 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.

<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 consults in biotechnology related regulation development. It also organizes seminars targeting different audiences.

There are not many recent country-specific studies on marketing or acceptance of biotechnology in Portugal.

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

CHAPTER 2: ANIMAL BIOTECHNOLOGY

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.

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

FAS Madrid is not aware of any genetic engineering or cloning of farm livestock carried out in Portugal.

b) APPROVALS

N/A

c) 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.

d) EXPORTS

Not applicable.

e) IMPORTS

Portugal does not have a system to monitor the imports of GE animals and cloned offspring or genetics from clones.

f) 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-28 Biotechnology Annual Report.</u>

Part E: Policy

a) REGULATORY FRAMEWORK

For GE and cloned animals, Portugal abides by the EU law. For more information about the European framework, please see the latest <u>EU-28 Biotechnology Annual Report</u>.

b) INNOVATIVE BIOTECHNOLOGIES

Portugal has not regulated the use of innovative biotechnologies in animals.

c) LABELING AND TRACEABILITY

Portugal has implemented EU legislation on labeling and traceability. For more information on this topic, see the latest <u>EU-28 Biotechnology Annual Report</u>.

d) INTELLECTUAL PROPERTY RIGHTS (IPR):

Portugal has implemented EU legislation. For more information on this topic, see the latest <u>EU-28</u> <u>Biotechnology Annual Report</u>.

e) INTERNATIONAL TREATIES and FORUMS

Portugal's participation in international treaties and forums is no different from that of the EU. For more information on this topic, see the <u>EU-28 Biotechnology Annual Report</u>.

f) **RELATED ISSUES**

Not available.

Part F: Marketing

a) PUBLIC/PRIVATE OPINIONS

Not available

b) MARKET ACCEPTANCE/STUDIES

Not available

Related Reports

Report Title	Date Released
Netherlands: The Netherlands Calls for an Amendment of the GMO Directive	12/13/2018
EU Court Extends GMO Directive to New Plant Breeding Techniques	07/27/2018
European Court Examines Whether Some NBTs Are Exempted from GMO Law	01/30/2018
Advisory Legal Opinion Expected for New Plant Breeding Techniques	01/16/2018
Agriculture Biotechnology Annual 2017– EU-28	11/22/2017
Agriculture Biotechnology Annual 2017 – Portugal	11/22/2017
Dutch Proposal to Legislate NBTs	10/04/2017
EC Proposes Changes in Comitology Rules	03/01/2017
Change in voting behavior may lead to GE crops not being approved	09/11/2017