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Food and Agricultural Import Regulations and Standards – Narrative

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Food and Agricultural Import Regulations and Standards - Narrative

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Report Highlights:

Portugal is a member of the European Union (EU) and it follows EU directives and regulations. This report is an update of <u>PT1205</u> and outlines the applicable legislation regarding the export of U.S. food products to Portugal, particularly those rules that differ from EU legislation. This report should be read in conjunction with the <u>EU-28 Food and Agricultural Import Regulations and Standards Report</u>. Updates of the information provided are also available in the USEU/FAS website <u>www.usda-eu.org</u>.

DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service for Spain and Portugal for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information regarding these policies was not available. It is highly recommended that U.S. exporters verify import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped.

FINAL CUSTOMS CLEARANCE APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

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Section I. Food Laws

Portugal has been a member of the European Union (EU) since 1986, and follows all EU directives, regulations, and obligations. While EU Regulations are binding and directly applicable to the Member States, EU Directives have to be transposed into National law. EU Decisions are binding and directly applicable to whom they are addressed.

Detailed information on the EU procedures can be found in <u>GAIN report "How the EU works – A guide to EU decision-making"</u> (updated April 2016) and on our website at http://www.usda-eu.org/eu-basics-questions/.

This report outlines the applicable legislation regarding the export of U.S. food products to Portugal, particularly those rules that differ from EU legislation or regulation. Exporters should be aware that when EU-wide legislation is incomplete, absent or there is room for interpretation, Portuguese laws apply and imported product must meet existing Portuguese requirements. Some examples of non-harmonized products include collagen casings, lanolin, gelatin and composite products.

For detailed information on EU Food and Agricultural Import Regulations and Standards (<u>FAIRS</u>), see reports produced by the U.S. Mission to the EU in Brussels, Belgium which can be accessed from their website: http://www.usda-eu.org/.

Food and beverage products originating in the United States do not require any special Portuguese permits and are not subject to special rules or regulations regarding retail sale in Portugal. However, all products must comply with the generally applied rules and regulations required for any food and beverage product sold within the EU market. Portugal's food regulations apply to both domestically produced and imported food products.

At the EU level, Regulation (EC) 178/2002 sets out general principles and objectives in food law. In Portugal the Directorate General for Food and Veterinary (DGAV), within the Ministry of Agriculture, Forestry and Rural Development, is responsible for imports of feed, plants, live animals, animal products, and food products. The enforcement of Food Safety laws is the responsibility of the Portuguese Food Safety and Economic Agency (ASAE) within the Ministry of Economy. Food intended for human consumption must meet the general food safety requirements of EU law.

For more information see FAS USEU section on food safety.

Contact data for the above mentioned departments can be found in **Appendix I**.

Section II. Food Additives Regulations

Portugal applies EU-harmonized legislation regarding **food additives** and **flavorings**. The EU's "Package on Food Improvement Agents" includes four Regulations:

- Regulation 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings
- Regulation 1332/2008 on food enzymes
- Regulation 1333/2008 on food additives
- Regulation 1334/2008 on flavorings.

For detailed information on the EU-harmonized legislation on food additive regulations, please consult the <u>EU-28 FAIRS Report</u> as well as the FAS USEU website section on <u>Food Additives</u>.

Enzymes: Until the adoption of an EU positive list of authorized enzymes, at the national level enzymes are considered either as additives or processing aids. In the first case, they would need to be included in the EU additive regulations. In the latter case, they can be used if they are included in the Technical-Sanitary Sectorial Regulation or if the economic operator can prove that they are being marketed in other EU Member State.

Processing aids at the EU level are regulated by <u>Directive 2009/32/EC</u> which was transposed by <u>Decree - Law 103/2011</u>. The use of processing aids is subject to authorization at the Member State level. Requests should be addressed to the Autoridade de Segurança Alimentar e Económica (ASAE). Contact details can be found in **Appendix I**.

Section III. Pesticides and Other Contaminants

Pesticide Registration

Regulation (EC) 1107/2009 for placing plant protection products on the market replaced Directive 91/414/EEC. This new piece of regulation, applied since June 14th, 2011, defines zonal authorizations. Portugal is included in the Zone C (South) along with Bulgaria, Cyprus, France, Greece, Italy, Malta and Spain). Commission implementing Regulation 540/2011 establishes a list of approved active substances. The "Pesticide Package" also contains Directive 2009/128/EC for the sustainable use of pesticides, which was transposed to national law by Law 26/2013.

The authorization-registration of plant protection products remains the responsibility of Member States to meet and particularities of its climate-region. In Portugal:

• The Directorate General for Health (DGS) is responsible for the risk assessment for the consumer associated risk.

- The Directorate General for Food and Veterinary (DGAV), within the Ministry of Agriculture, Forestry and Rural Development, is responsible for the risk assessment for the animal associated risk and product technical evaluation. DGAV also is responsible for the product registration. For application for pesticide registration in Portugal contact DGAV.
- The Portuguese Agency for Environment (APA) is responsible for environmental risk evaluation.
- The Regional Directorates for Agriculture and Fisheries, coordinated by DGAV, are responsible for surveillance and control. Additional information can be found in the <u>link</u> (Portuguese language only).

• Maximum Residue Levels (MRL)

The European Commission fixes MRLs for all food and feed, based on the assessment report risk to consumers of EFSA (European Food Safety Authority), and after consultation with Member States through the Standing Committee on Plants, Animals, Food and Feed.

The complete list of MRLs, and commodity combinations allowed in the EU can be obtained from the Commission's webpage. The Maximum Residue Levels (MRLs) for substances not on the Commission implementing Regulation 540/2011 list of approved active substances will be set at default level of 0.01 mg/kg.

Import tolerance

The legislation allows exporters to request an "import tolerance" for active substances not yet evaluated or in use in the EU. Applications for import tolerances must be submitted to the "Rapporteur Member State" (RMS). The Commission assigns a Member State, if no RMS exists. Since 2008 all MRLs, including import tolerances, apply EU wide.

For detailed information on EU-harmonized legislation on pesticide and contaminant regulations, please consult the EU-28 FAIRS Report as well as the USEU website section on pesticides.

Private Industry Standards

While the official standards are set by the public administration, the majority of food retailers, as a marketing tool, require certification of good agricultural practices. The private certification schemes include not only stricter limits for MRL but also with other additional requirements.

• Contaminants

Portugal applies EU-harmonized legislation regarding food contaminants. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the <u>EU-28 FAIRS Report</u> as well as the USEU website section on <u>contaminants</u>. Governing regulations include: <u>Regulation (EC) 1881/2006</u>, <u>Regulation (EC) 1882/2006</u>, <u>Regulation (EC) 401/2006</u>, <u>Regulation (EC) 589/2014</u>, Regulation (EC) 333/2007 and Commission Regulation (EU) 2015/705.

Official Aflatoxin Controls on U.S. Products

In April 2015, the EU approved the pre-export checks (PEC) program for U.S. almonds. U.S. almonds were included in the Annex to Regulation (EU) 2015/949 which lists all EU approved Pre-export Check programs. The acceptance of the U.S. program reflects the EU's recognition of aflatoxin controls performed at U.S. origin in line with Article 23 of the EU Regulation on Official Food and Feed Controls (Regulation (EC) No 882/2004).

With the publication of Commission Implementing Regulation (EU) 2015/949, all EU accepted programs have been combined under the one regulation. The U.S. peanut program which was approved in 2009 is now also covered by the general provisions of <u>Commission Implementing Regulation (EU)</u> 2015/949. Under the regulation, import authorities are directed to subject consignments of U.S. almonds and peanuts with a PEC certificate to a **less than 1% control level** at the border. The PEC program is voluntary; a PEC certificate is not a requirement for import into the EU. Shipments without a PEC certificate do not benefit from the reduced inspection levels upon import into the EU.

For additional information on aflatoxin PEC certification, see:

• http://www.ams.usda.gov/services/lab-testing/aflatoxin

On April 1, 2015, U.S. pistachios were included in the list of products/origins subject to increased import controls under <u>Commission Regulation (EC) No 669/2009</u>. Member states have to test 20 percent of all incoming shipments until the list in the Annex of the regulation is amended. This regulation does not impose any requirements on exporters.

Residues in Animal Products

<u>Council Directive 96/23/EC</u> on measures to monitor certain substances and residues thereof in live animals and animal products and <u>Council Directive 96/22/EC</u> were transposed to national law by <u>Decree law 148/1999</u> and <u>Decree law 148/1999</u>.

For additional information, please visit the FAS USEU website section on <u>Pesticides</u>, <u>Contaminants</u> and <u>Residue Plans</u>.

Section IV. Packaging and Container Regulations

Portugal applies EU-harmonized legislation to packaging and containers

• Size and Content

There are two EU Directives related to the making-up by weight or by volume of certain prepackaged products (<u>Council Directive 76/211/EEC</u>) and laying down rules on nominal quantities for pre-packed products (<u>Directive 2007/45/EC</u>) that were transposed into Portugal's National Law by <u>Decree - Law 199/2008</u>.

Materials in contact with foodstuffs

Material	EU legal Framework	Portuguese Legal
		framework
Plastics	Regulation (EC) 1935/2004 Regulation (EC)	Directly applicable
	282/2008 Regulation (EC) 2023/2006	
Polymers and	Regulation (EC) 10/2011	Directly applicable
regenerated polymers		
Rubber	Directive 93/11/ECC	Portaria 863/1994.
Regenerated cellulose film	Directive 2007/42/EC	Decree Law 194/2007
Ceramics	Directive 84/500/EC	Decree Law 190/2007
Bisphenol A in plastic for	Commission Implementing Regulation 321/2011	Directly applicable
enfant bottles	(Ban)	

• Packaging waste management:

<u>Decree-Law 366-A/1997</u> as amended transposes <u>Directive 94/62/EC</u> into national Law.

Section V. Labeling Requirements

The U.S. standard label does not comply with EU labeling requirements. Detailed information on labeling requirements that apply from December 13, 2016 can be found in the <u>USEU report on New EU food labeling rules</u> as set out in the <u>"Food Information to Consumers (FIC)" regulation 1169/2011.</u> This information can be supplemented by <u>GAIN report "How to Comply with the EU's New Food Labeling Rules."</u>

The Government of Portugal permits multi-language labeling and stickers; however, one of the languages must be Portuguese. U.S. food manufacturers or exporters are encouraged to contact their potential importer to learn the labeling requirements applicable.

For non-packaged food, <u>Regulation (EC) 1169/2011</u> provisions have been implemented at the national level by <u>Royal Decree 111/2016</u>.

• Country of Origin Labeling

In the EU, country of origin labeling (COOL) is mandatory for beef and veal, fruit and vegetables, eggs, poultry meat, wine, honey, olive oil, aquaculture products and for organic products carrying the EU logo. The EU's new labeling Regulation 1169/2011 which became applicable on December 13, 2016, extends the mandatory country of origin labeling to meat listed in Annex XI (swine, sheep and goat, poultry) and when the country of origin of a food is not the same as its primary ingredient.

For additional information, please visit the FAS USEU website section on <u>country of origin labeling</u> as well as <u>GAIN report "The EU's Country of Origin Labeling Policy"</u> and <u>EU-28: EU Agriculture</u> Ministers Divided Over National COOL Measures.

Since Spring 2017, the new country of origin labelling for milk and dairy products is in place in Portugal. It requires companies to provide details of the origin of milk used in milk and dairy products¹. For additional details see Decree-Law 62/2017 (Portuguese language only).

• Product-Specific Labeling

For a number of products, specific labeling requirements have been established in addition to the general requirements described above. More details can be found in **Section VI**.

For additional information in regards to EU labeling requirements, please visit the FAS USEU website section on <u>labeling requirements</u>.

Section VI. Other Specific Standards

For detailed information on the EU-harmonized legislation on other specific standards, please consult the <u>EU-28 FAIRS Report</u> or the <u>USEU import rules</u> website.

Novel Foods

The Novel Food Regulation (EC) 258/1997 lays down detailed rules for the authorization of novel foods and novel food ingredients. It defines novel foods as foods and food ingredients that were not used to a significant degree in the EU before May 15, 1997. The EU catalogue of Novel Foods can be consulted in the EU Commission's website. This catalogue provides information on whether or not a product would require authorization under the Novel Food Regulation. The list of novel food applications,

¹ Milk and milk used as an ingredient in dairy products including caseins, caseinates and their mixtures for use in foodstuffs.

authorizations, rejections and withdrawals can be also found in the <u>Commission's website</u> or <u>GAIN</u> <u>report "Negative List for Novel Foods and Ingredients"</u>. Additionally a guide on how to prove "Human Consumption to a significant degree" is available in the <u>link</u>.

New authorizations can be submitted to Member State's competent authorities, in the case of Portugal, to the Autoridade de Segurança Alimentar e Económica (ASAE). Contact details can be found in **Appendix I**.

A new EU regulation on novel food was adopted (<u>Regulation (EC) 2283/2015</u>), but will not be fully implemented until January 2018.

Food from Clones

At the moment, food derived from animal clones falls under the scope of Novel Food Regulation (EC) 258/1997. The two European Commission's proposals (proposal on the placing on the market of food from animal clones and proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes) are currently being assessed by the European Parliament.

For additional information, visit FAS USEU website section on animal cloning.

Nanotechnology

Currently, EU food legislation on nanotechnology includes <u>Regulation 1169/2011</u> on the provision of food information to consumers, <u>Regulation 1333/2008</u> on food additives and <u>Regulation 450/2009</u> on active and intelligent materials and articles intended to come into contact with food. Also, the new <u>novel foods proposal</u> contains different provisions on nanotechnology.

For additional information, visit FAS USEU website section on nanotechnology.

Fortified Foods

<u>European Parliament and Council Regulation 1925/2006</u> as amended by <u>Regulation (EC) 1170/2009</u> establishes an EU-wide regulatory framework for the addition of vitamins and mineral and of certain other substances such as herbal extracts to foods. It lists the vitamins and minerals that may be added to foods and sets criteria for setting maximum and minimum levels. The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed.

For additional information, visit FAS USEU website section on fortified foods.

<u>Dietetic or Special Use Foods</u>

In June 2013, the EU adopted European Parliament and Council <u>Regulation 609/2013</u> on dietetic foods. This new regulation applies as of July 20, 2016, and repeals the current rules on Foodstuffs for Particular Nutritional Uses. The scope of this regulation is limited to infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control.

Additionally, <u>Commission Delegated Regulation 2016/128</u> sets out specific requirements for food for special medical purposes (FSMPs). <u>Commission Delegated Regulation 2016/217</u> sets out specific compositional and information requirements for infant-formula and follow-on formula.

At the national level, food for weight reduction is regulated by <u>Royal Decree 1430/1997</u>. For additional information, visit FAS USEU website section on <u>dietetic foods</u> and <u>see GAIN report "New EU Rules on Dietetic Foods."</u>, complemented by <u>GAIN report "New EU Rules on Dietetic Foods – Update"</u>.

Gluten-Free

Harmonized compositional and labeling rules for foods for persons with gluten intolerance were previously set out in the EU's directive on foods for particular nutritional uses (<u>Regulation 41/2009</u>). With the adoption of the <u>new dietetic foods regulation 609/2013</u>, it was decided that gluten-free foods would be regulated under <u>Regulation 1169/2011</u>. Commission Implementing Regulation 828/2014, applicable since July 20, 2016, sets out conditions for using "gluten-free" and "very low gluten" statements on food labels.

Nutrition and Health Claims Labeling

<u>Regulation 1924/2006</u> sets out EU-wide conditions for the use of **nutrition** and **health claims** on foods. The use of **nutrition claims** not included in the annex is not allowed.

Regulation 353/2008 sets out implementing rules for applications for the authorization of **health claims** as provided for in Article 15 of Regulation 1924/2006. GAIN Report E48055 describes how application dossiers for authorization of health claims should be prepared and presented. A guidance document on how companies can apply for health claim authorizations can be downloaded from EFSA's website at http://www.efsa.europa.eu/en/nda/ndaclaims.htm.

Regulation (EC) 432/2012, which establishes a list of permitted **health claims** made on foods, other than those referring to the reduction of disease risk and to children's development and health became applicable on December 14, 2012, although mandatory nutrition declaration became applicable on December 13, 2016.

For detailed information on health/nutritional labeling, please consult the latest <u>EU-28 FAIRS Report</u> or visit the FAS USEU website section on <u>nutritional claims</u>.

<u>Regulation (EC) 907/2013</u> establishes rules for the use of "generic descriptors" which could be interpreted by consumers as health claims. For more information see <u>GAIN report "Health Claims – New EU Regulation on Generic Descriptors."</u> Non-compliant trademarks and brand names must be entirely removed from the EU market by January 19, 2022.

In Portugal, <u>Decree-Law 54/2010</u> transposes the current EU governing directives into national law. More information can be found in ASAE's website.

Food Irradiation

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU- wide approval. Framework Directive 1999/2/EC outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Irradiated foods must be labeled "irradiated" or "treated with ionizing radiation". Implementing Directive 1999/3/EC establishes a Community list of foods and food ingredients authorized for irradiation treatment. The list contains only one food category: "dried aromatic herbs, spices and vegetable seasonings".

Until the EU positive list is expanded, national authorizations continue to apply. The list of Member States' authorizations of food and food ingredients which may be treated with ionizing radiation can be consulted in the <u>link</u>. At the national level these EU Directives were transposed by <u>Decree-Law 377/2001</u>, according to which, only dried aromatic herbs, spices and vegetal seasonings can be treated with ionizing irradiation.

Seafood

NOAA (National Marine Fisheries Service) of the U.S. Department of Commerce is the unique competent authority for the certification of fishery and aquaculture products intended for the EU. More detailed information can be found in the Guide: "How to export Seafood to the European Union". Information on labeling can also be found in the European Commission's "Pocket Guide to the EU's new fish and aquaculture consumer labels", published in December 2014.

Pet Food

Information on requirements to export pet food to the EU can be found in the FAS USEU website section on Pet food as well as in the GAIN Report Exporting Pet Food to the EU.

<u>European Parliament and Council Regulation 767/2009</u> sets out new rules for the labeling and marketing of feed and pet food. Additional information can be found in the <u>GAIN Report EU Feed and Pet food labeling requirements</u>.

Genetically Modified Foods and Feeds

Portugal follows EU-harmonized legislation on labeling (<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) and there is no "non-GMO" labeling regulation developed at the national level. No Non-GMO labeling scheme has been developed at the national level.

Portugal has a decentralized system for testing and controlling unauthorized presence of GMO in the feed and food chain. The Directorate General for Food and Veterinary (DGAV) is responsible for the coordination of the food and feed chain control and Regional Directorates are responsible for its implementation.

In Portugal, as in other European countries, GE products are primarily used for feed purposes. The presence of GE labeled consumer oriented products is inexistent, as the large majority of food manufacturers eliminated GE products from the composition to avoid labeling as "Contains GMOs."

For more information, please see <u>Portugal's Biotech Annual Report</u>. or visit FAS USEU website section on <u>Biotechnology</u>.

Organic Foods

<u>Council Regulation 834/2007</u> is the EU's general framework regulation that sets out rules for organic production and labeling. <u>Commission Implementing Regulation 2016/1842</u> published on October 19, 2016, sets new rules for the certification of EU organic food imports. Starting October 19, 2017, the EU will require electronic certification through the EU's Trade Control and Expert System (TRACES). Information on labeling can be found in the <u>GAIN Report E48106</u> or in the FAS USEU website section on <u>organic production</u> and <u>organic labeling requirements</u>.

On February 15, 2012, the European Union and the United States announced that beginning June 1, 2012 their respective countries' certified organic products will be recognized. All products traded under the agreement must be accompanied by an organic export certificate. More information about this partnership can be found on the <u>USDA Organics Home Page for International Agreements</u>. Information on the EU-28 Organic Market can be found in the <u>Report EU-U.S. Organic Trade Update</u>.

A <u>Commission proposal</u> to revise the current rules on organic food production and labeling is currently being discussed.

Wine, Beer and Other Alcoholic Beverages

Wine: The EU's Single Common Market Organization Regulation 1308/2013 establishes framework rules for wine. Regulation (EC) 607/2009, as amended by Commission Implementing 1185/2012, lays down detailed rules on protected designations of origin and geographical indications, traditional terms and labeling. For detailed information on the EU's wine legislation see the European Commission's website. Commission Implementing Regulation 579/2012 sets out the modalities for the labeling of allergens on wine. Information on the authorized languages to label allergens in the different EU Member States is available on the European Commission's website in the link. In March 2006, the U.S. and the EU and the U.S. signed the "Agreement between the United States and the European Community on Trade in Wine", which covers wine with an actual alcohol content of not less than 7% and not more than 22%.

Spirit Drinks: European Parliament and Council Regulation 110/2008 lays down general rules on the definition, description and presentation of spirit drinks. Commission Implementing Regulation 716/2013 lays down rules for the application of Regulation 110/2008 as regards the use of compound terms and geographical indications of the spirit drinks. This regulation prohibits the use of the term "spirit drink" as part of a compound term. Regulation (EC) 936/2009 applies the agreements between the EU and third countries on the mutual recognition of certain spirit drinks. Under this regulation, "Tennessee Whisky" and "Bourbon Whisky" are protected product designations.

Nominal Quantity: Mandatory nominal quantities for wines and spirits are set out in the Annex to <u>Directive 2007/45/EC</u>, which was transposed to National law by <u>Decree Law 195/2008</u>.

Beer: There is no specific EU-harmonized legislation for beer. All alcoholic beverages must comply with the allergen labeling requirements. Portugal's beer labeling requirements are set out in Decree-Law 93/1994.

Meat Labeling

Portugal applies EU-harmonized legislation regarding **meat labeling**.

<u>Regulation 1760/2000</u> sets out rules for compulsory and voluntary beef labeling. Detailed rules for the implementation of Regulation 1760/2000 are set out in <u>Regulation 1825/2000</u>.

<u>Commission Implementing Regulation 1337/2013</u> sets out new rules for the indication of the country or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the <u>EU-28</u> <u>FAIRS Report</u> as well as the FAS USEU website section on <u>meat labeling</u>.

Frozen Foodstuffs

<u>Council Directive 89/108/EEC</u> sets rules for quick-frozen foodstuffs and for their packaging and labeling. This Directive is transposed into National Law by <u>Decree-Law 230/1990</u> and later amended by <u>Decree-Law 288/98</u>.

Vertical Legislation (Breakfast Directives)

<u>Directive 2001/112/EC</u> amended by <u>Directive 2012/12/EU</u> regulates to fruit juices and certain similar products intended for human consumption. Key amendments which affect to the fruit juice labeling rules include orange juice, nutrition claims, mixed juices and sugars and sweeteners. Directive 2012/12/EC was transposed to national law by <u>Royal Decree 145/2013</u>. Detailed information on key changes introduced by the new directive can be found in <u>GAIN report "New EU Fruit Juice Labeling Rules</u>."

<u>Directive 2014/63/EU</u> amending Directive 2001/110/EC relating to honey was transposed to national law by <u>Decree Law 126/2015</u> amending <u>Decree Law 214/2003</u> on Honey Quality Standards.

Halal Foods

In Portugal, there are no government-established halal standards, as halal is seen as a religious attestation and not a sanitary requirement and the government does not play a role in Halal labeling. The Portuguese Halal Institute is managed the Halal trademark.

Section VII. Facility and Product Requirements

Facility Registration

Exports of product of animal origin such as red meat, meat products, farmed and wild game meat, ratites, milk and milk products, seafood, bovine embryos and semen, porcine and equine semen, gelatin, animal casings and animal by-products to the EU from the U.S. may originate only from EU approved U.S. establishments. A comprehensive list of U.S. approved establishments can be found in the FAS USEU section on approved establishments. Third country lists per sector and per country are published on the European Commission's website.

Product Registration

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods. The person/company introducing a **novel food** has to submit a request to the authorities in the

Member States where the product. Also, when introducing foodstuffs with **particular nutritional uses**, vitamin enriched foods or **nutritional supplements** exporters need to notify the <u>Member States</u> <u>competent authorities</u>. In Portugal, requests should be addressed to the Cabinet for Planning and Policy (GPP). Contact details can be found in **Appendix I**.

A list of food supplements notified to Portuguese competent authorities can be found in the <u>link</u> (Portuguese language only).

Section VIII. Other Regulations and Testing Requirements

• Product inspection:

Agricultural products are examined when they enter Portugal by the Portuguese Border Inspection Posts. There are a number of border inspections points in Portugal that carry out <u>plant</u> and <u>products</u> <u>intended for human consumption and live animals</u> inspection. Contact data for each of them can be found in the links. DGAV is the competent authorities to issue certificates. Contact details are available in **Annex I**.

Commission Decision 2009/821/EC establishes a list of EU border inspection posts approved to carry out veterinary checks on animals and animal products from third countries. Commission Decision 2007/275/EC establishes a list of animals and products that are subject to controls at border inspection posts, including certain composite products as well as a list of composite products that are not subject to veterinary checks.

<u>Commission Implementing Decision (EU) 2016/1196</u> amends Commission Decision 2007/275/EC by updating the list of products that are subject to veterinary checks as well as the list of exempted products from January 1, 2017 onwards.

U.S. exporters interested in introducing a product into the Portuguese market should obtain local representation and/or a local importer/distributor to gain knowledge of the market, up-to-date information and guidance on trade laws and business practices, sales contacts, and market development expertise. As local importers have primary responsible to the Portuguese Government for imported food products entering Portuguese territory, they are in the best position to provide guidance to U.S. exporters through the market-entry process.

Member State authorities are responsible for carrying out inspections in the food and feed chain and designate laboratories allowed to perform food control analysis. Products can be checked at import or at all further stages of marketing.

Portugal has a decentralized system for testing and controlling the feed and food chain. The Directorate General for Food and Veterinary (DGAV) is responsible for the coordination of the food and feed chain control and Regional Directorates are responsible for its implementation. For additional information on the Portuguese Market, please consult the latest Portugal's Exporters Guide or contact FAS Madrid (Phone: +34 587 2555 or email: aglisbon@fas.usda.gov)

• Certification

The Portuguese Government applies EU-harmonized legislation for other related regulations and requirements including product inspection, registration and certification. For detailed information on certification, please see the USEU certification site.

<u>Council Directive 2000/29/EC</u>, harmonizes the importation requirements of plants and plant products into the EU. Some examples of non-fully harmonized products include collagen casings, lanolin and gelatin and composite products². Notification of imports of non-fully harmonized food products should be addressed to Direção-Geral de Alimentação e Veterinária

. Contact details can be found in Appendix I.

For detailed information on specific certificates to export to Portugal please consult the latest version of Portugal's <u>FAIRS Certificate report 2017</u>.

Section IX. Import Procedures

As a member of the European Union (EU), Portugal follows all EU directives, regulations, and obligations where available. Since the EU is a customs union, all Member States apply the same import duties on goods imported from outside the EU based on tariff classification of goods and the customs value. Once import goods are cleared in one Member State, they can be moved freely throughout the EU territory.

• Import duties

EU's applicable duties information can be found in the <u>on-line customs data base</u>. At the Member State level, it is possible to obtain Binding Tariff Information (BTI) from a Member State Customs Authority. In the case of Portugal, Autoridade Tributária e Aduaneira , ascribed to the Ministry for Finance, is the responsible entity. Contact data for Autoridade Tributária e Aduaneira can be found in **Appendix I**.

² Composite products are defined as foodstuffs intended for human consumption that contain processed products of animal origin and ingredients of plant origin. All composite products containing a processed meat product are subject to a veterinary check. Generally speaking, composite products that have more than 50 of animal origin products also require a certificate, and there are certification requirements concerning the heat treatment for all dairy products.

Other taxes applicable to agricultural products include the <u>Value Added Tax</u> (VAT) and inspection fees which are not harmonized throughout the EU and excise duties applicable on <u>alcoholic beverages</u> and <u>tobacco</u> can be found in the links. Tax increases are currently being discussed at the national level. Changes may include an increase in levies on alcohol and tobacco products, and a new sugar tax on soft drinks.

Import Documentation and Process

The following documents are required for ocean or air cargo shipments of food products into Portugal:

- Bill of Lading and/or Airway Bill
- Commercial Invoice
- Phytosanitary Certificate and/or Health Certificate when applicable
- Import Certificate

Most food products require an Import Certificate issued by the competent Portuguese authorities. This certificate must be obtained by a registered importer as it is intended for tariff classification purposes.

The import process requires:

- Pre-announcement by Common (veterinary) Entry Document (CVED or CED)
- Documentary Check
- Identity Check
- Physical check

Temporary Entry

Temporary entry may be permitted for goods in transit (up to 24 months), manufacturing for re-export, and/or for temporary storage. Generally, the exporter must pay normally applied import duties and VAT, which are then reimbursed upon re-export of the merchandise to a destination outside of the EU. Additional information on the temporary entry procedure can be found in the <u>link</u> (only available in Portuguese language).

Samples and Advertising Material

Portugal grants duty free entry to giveaway samples if properly labeled. Samples are, however, subject to the same import documentation requirements that apply to normal commercial imports. They also require a nominal value for customs declaration purposes on the commercial invoice which must carry the statement "Samples without Commercial Value."

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described on the FAS USEU website section on certification.

For detailed information on the procedure to import samples without commercial value to Portugal please consult the Portugal's latest <u>FAIRS Certificate report 2017</u> or see <u>link</u> (only Portuguese language)

Section X. Copyright and/or Trademark Laws

Trademarks

The regulations and standards covered under this section have been harmonized with the European Union requirements. However, the EU-harmonized trademark regulation did not replace the existing laws at the Member State level. Both systems coexist. For detailed information on EU-harmonized legislation, please consult the <u>EU-28 FAIRS Report</u>.

In Portugal the legal basis for trademarks is laid down by <u>Decree-Law 36/2003</u>. The trademark protection is granted for 20 years after which it can be renewed. Requests should be addressed to the Instituto Nacional da Propriedade Industrial (See contact data in **Appendix I**).

In December 2012, the EU Parliament approved the regulations that would establish the single **patent** for the EU. More information on the unitary patent can be found in the <u>link</u>.

In addition, Portugal is a member of the World Intellectual Property international Organization (WIPO), a signatory to the Paris Convention for the Protection of Industrial Property, and a party to the Madrid Agreement on International Registration of Trademarks and Prevention of the Use of False Origins. Both the Trademark and the Intellectual Property Laws address protection of brand names and trademarks.

Designation of Origin and Geographical Indications

European Parliament and Council Regulation 1151/2012 is the EU governing regulation on optional quality schemes for agricultural products and foodstuffs. Lists of protected names by country, product type, registered name and name applied for are available through the Commission's online "DOOR" (Database of Origin and Registration) database. Additional information is available in the FAS USEU website section on geographical indications and in the GAIN report E80061 "The EU's Traditional Specialties Guaranteed Scheme Explained." Specific information about Portugal's registered products under this scheme can be found in the link.

Appendix I. Government Regulatory Agency Contacts:

Autoridade de Segurança Alimentar e Económica

Rua Rodrigo da Fonseca, nº 73

1269-274 Lisboa

Tel. +351 217 983 600 Fax: +351 217 983 654

Email: correio.asae@asae.pt

Agência Portuguesa do Ambiente (APA)

Rua da Murgueira, 9/9A - Zambujal

Ap. 7585

2610-124 Amadora

Tel: + 351 21 472 82 00 Fax: 351 21 471 90 74

Email: geral@apambiente.pt

Website

Departamento de Riscos Alimentares e Laboratoriais (DRAL)

Edifício F - Estrada do Paço do Lumiar

1649-038 Lisboa

Tel. 217 108 400

Fax 217 108 448 / 217 983 676

Ministry of Agriculture, Forestry and Rural Development

Planting Seeds and Nursery Products

Ministerio de Agricultura, Florestas e Desenvolvimiento Rural

Direção-Geral de Alimentação e Veterinária

Campo Grande, 50

1700-093 Lisboa

Tel. +351-21 3239500 Fax: +351-21 3463518

Email: dirgeral@dgav.pt

Website

Ministry of Agriculture, Forestry and Rural Development

Cabinet for Planing and Policy (GPP)

Praça do Comércio 1149010 Lisboa

Tel.: +351 213 234 600 Fax: +351 213 234 601

E-mail: dsnsa@gpp.pt; geral@gpp.pt

Website

Ministry of Agriculture, Forestry and Rural Development

Pesticides Registration

Ministerio de Agricultura, Florestas e Desenvolvimiento Rural

Direção-Geral de Alimentação e Veterinária

Campo Grande, 50

1700-093 Lisboa

Tel. +351-21 3239500 Fax: +351-21 3463518 Email: dirgeral@dgav.pt

Website

Ministry of Agriculture, Forestry and Rural Development

Import Inspection

Ministerio de Agricultura, Florestas e Desenvolvimiento Rural

Direção-Geral de Alimentação e Veterinária

Campo Grande, 50

1700-093 Lisboa

Tel. +351-21 3239500 Fax: +351-21 3463518

Email:

- Imports of live animals or products of animal origin: secretariadoDIM@dgav.pt
- Imports of products of vegetal origin: dsna@dgav.pt
- Phytosanitary inspection: secDSSV@dgav.pt

Website

Ministry of Agriculture, Forest and Rural Development (DGADR)

Organic Farming

Ministério de Agricultura, Florestas e Desenvolvimento Rural

Direcção-Geral de Agricultura e Desenvolvimento Rural

Av. Afonso Costa, 3 1949-002 Lisboa

Tel.: +351 218 442 200 Fax: +351 218 442 202 Email: dgadr@dgadr.pt

Website link

National Institute for Industrial Property

Instituto Nacional da Propriedade Industrial (INPI)

Campo das Cebolas 1149-035 Lisboa

Phone: +0351 21 881 81 00

Email: sgq@inpi.pt or servico.publico@inpi.pt

Website

EU Trademark Register

Office for Harmonization in the Internal Market

Avenida de Europa, 4

03008 Alicante

Tel.: +34-96-513-9100 Fax: +34-96-513-1344

Website link

E-mail: information@oami.europa.eu

Ministry for Finance

Ministério das Finanças

Direcção-Geral das Alfândegas e dos Impostos Especiais sobre o Consumo (DGAIEC)

Rua Terreiro do Trigo, Edifício da Alfândega de Lisboa

1140-060 Lisboa

Tel: +351 21 881 3700 Fax: +351 21 881 42 61

Website

Ministry for Finance

Ministério das Finanças Authority for Taxation and Customs—Binding Tariff Information

Autoridade Tributária e Aduaneira

Rua do Comércio, 49

1149-021 Lisboa

Tel.: +351 21 881 26 00 Fax: +351 21 881 29 38

Website

Ministry for Finance

Ministério das Finanças

Authority for Taxation and Customs–Binding Tariff Information

Autoridade Tributária e Aduaneira

Direção de Serviços Técnicos, Análises e Laboratório (DSTAL)

Rua Terreiro do Trigo, Edifício da Alfândega de Lisboa

1140-060 Lisboa

Tel.: +351 21 881 4395 Fax: +351 21 881 3182

Website

LSA - Laboratório de Segurança Alimentar

Estrada do Paço do Lumiar. Campus do Lumiar 22

Edifício, F - 1ºandar

1649-038 Lisboa

Tel.: + 351 21 710 8400 Fax.: +351 21 710 8448

WTO Inquiry Post

a. For technical regulations:

Ministry of Agriculture, Forestry and Rural Development

Ministerio de Agricultura, Florestas e Desenvolvimiento Rural Direção-Geral de Alimentação e Veterinária Campo Grande, 50

1700-093 Lisboa

Tel. +351-21 3239500

Fax: +351-21 3463518 Email: dirgeral@dgav.pt

Website

b. For standards:

Portuguese Institute for Quality (IPQ)

Instituto Português de Qualidade Rua António Gião, 2 2829-513 Caparica

Tel. + 351 21 294 81 00 Fax. + 351 21 294 81 01

Email: ipq@ipq.pt

Website link

Appendix II. Other Import Specialist Contacts:

European Union – Delegation of the European Union to the United States

2300 M Street

NW, Washington, DC 20037

Tel.: (202) 862-9500 Fax: (202) 429-1766

http://www.euintheus.org/

United States Mission to the European Union

Office of Agricultural Affairs 27 Boulevard du Regent 1000 Brussels Belgium

Tel.: +32-2-508 2760 Fax: +32-2-511 0918

E-mail: AgUSEUBrussels@fas.usda.gov

https://www.fas.usda.gov/offices/us-mission-european-union

Portuguese Agro-food Industries Federation (FIPA)

Federação das Indústrias Portuguesas Agro-Alimentares Edifício Rosa 1 Rua Da Junqueira 39 1300-307 Lisboa,

Phone: +351 21 793 8679 Fax: +351 21 793 85 37 Email: <u>info@fipa.pt</u>

Website link

Portuguese Association of Distribution Companies (APED)

Associação Portuguesa de Empresas de Distribuição Rua Alexandre Herculano nº 23, 3º andar 1250-008 Lisboa

Tel: 351-21-751-0920 Fax: 351-21-757-1952 Email: geral@aped.pt

Website link

The USDA's Foreign Agricultural Service Office for Spain and Portugal, located in Madrid, can also assist U.S. exporters in obtaining specific national legislation on all food product directives. You may contact us at the following address:

Foreign Agricultural Service

Office of Agricultural Affairs American Embassy Madrid C/ Serrano, 75 – Box 20 28006 Madrid Spain

Tel.: +34-91-587-2555 Fax: +34-91-587-2556

Email: AgLisbon@fas.usda.gov

Website link