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## Spain

### Food and Agricultural Import Regulations and Standards - Narrative

### FAIRS Country Report

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**Report Highlights:**

Spain is a member of the European Union (EU) and it follows EU directives and regulations. This report is an update of [SP1530](#) and outlines the applicable legislation regarding the export of U.S. food products to Spain, particularly those rules that differ from EU legislation. This report should be read in conjunction with the [EU-28 Food and Agricultural Import Regulations and Standards Report](#). Updates of the information provided are also available in the USEU/FAS website [www.usda-eu.org](http://www.usda-eu.org).

**DISCLAIMER:** This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Madrid, Spain 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 the full set of 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**

Spain has been a member of the European Union (EU) since 1986, and as such 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.

This report outlines the applicable legislation regarding the export of U.S. food products to Spain, 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, Spanish laws apply and imported product must meet existing Spanish requirements. To our experience, 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 ([FAIRS](#)), 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 Spanish permits and are not subject to special rules or regulations regarding retail sale in Spain. However, all products must comply with the generally applied rules and regulations required for any food and beverage product sold within the EU market. Spain's food regulations apply to both domestically produced and imported food products.

### **Spanish Food law**

At the EU level, [Regulation \(EC\) 178/2002](#) sets out general principles and objectives in food law. In Spain, the Food Safety and Nutrition Law ([Law 17/2011](#)) published in July 2011, outlines the basic Spanish food and feed regulations. This law is based in EU Regulations and Directives and includes the traditional food safety aspects of detection and removal of physical, chemical and biological hazards as well as other less conventional issues such as obesity prevention and food advertising rules. It applies to domestically produced and imported products.

The Spanish Food Safety and Nutrition Law establishes basic definitions, goals and principles for food safety. It also defines procedural rules, coordination mechanisms between the different public administrations with responsibilities in official food control. It sets out general food safety and health protection rules, regulates inspections and inspection fees, detention and seizure rules of suspect food and classifies breaches.

Spain has a decentralized system for testing and controlling the feed and food chain. While the central government has total oversight over the controls carried out in customs, the autonomous communities are responsible for enforcement and they establish their own monitoring and sampling plans throughout the food and feed chain coordinated by national authorities. Sampling plans are based on risk assessment and sampling is primarily done at the wholesale and the processing level.

### **Relevant Competent Authorities**

In Spain, the Ministry of Health, Social Services and Gender Equality (MSSSI) controls agricultural product imports intended for human consumption; while the Ministry of Agriculture, Food, Fisheries and Environment (MAPAMA) controls imports of animal feed/ingredients and live animals not intended for direct human consumption.

Food Safety is the responsibility of the Spanish Consumption, Food Safety and Nutrition Agency (AECOSAN), ascribed to the MSSSI that coordinates the food chain control. AECOSAN was established as an independent agency and it is also responsible for risk management. Within the

MAPAMA, the Sub directorate General for Livestock Resources coordinates the National plan in feedstuffs.

The import of biological material has to be approved by the Ministry of Agriculture, Food, Fisheries and Environment (MAPAMA) or the Ministry of Health depending on the nature of the potential risk. In those cases where the biological material could potentially pose a threat in human health, the MOH will be responsible for the import approval. In those cases where the potential risk would affect to animal health, the Ministry of Agriculture (MAPAMA) will oversee the import. For more information on biological material import procedure, please see Spain's [FAIRS Certificate Report 2016](#).

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**

Spain 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](#) and [Regulation 1334/2008 on flavorings](#). For detailed information on the EU-harmonized legislation on food additive regulations, please consult the [EU-28 FAIRS Report](#) as well as the FAS USEU website section on [Food Additives](#).

**Processing aids** at the EU level are regulated by [Directive 2009/32/EC](#) which was transposed by [Royal Decree 1101/2011](#). The use of processing aids is subject to authorization at the Member State level. Requests should be addressed to Agencia Española de Consumo Seguridad Alimentaria y Nutrición (AECOSAN). Contact details can be found in **Appendix I**.

**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.

## **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 14<sup>th</sup>, 2011, defines zonal authorizations. Spain is included in the Zone C (South) along with Bulgaria, Cyprus, France, Greece, Italy, Malta and

Portugal). [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 [Royal Decree 1311/2012](#).

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

- AECOSAN is responsible for the risk assessment for the consumer associated risk. [Royal Decree 971/2014](#) establishes the risk evaluation procedure in Spain.
- The Ministry for Agriculture, Food, Fisheries and Environment, is responsible for the product registration. For application for pesticide registration in Spain contact Subdirección General de Sanidad e Higiene Vegetal y Forestal (MAPAMA). Contact details can be found in **Appendix I**. Form available in the [link](#).
- The Autonomous Regions are responsible for surveillance and control of MRLs. Harmonized sampling methods are established for the official control of residues in and on products of plant and animal origin by [Commission Directive 2002/63/EC](#), which was transposed to national law by [Royal Decree 290/2003](#).
- **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 require certification of good agricultural practices. The private certification schemes include not only stricter limits for MRL but also with other additional requirements.

- **Contaminants**

Spain applies EU-harmonized legislation regarding food contaminants. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the [EU-28 FAIRS Report](#) as well as the USEU website section on [contaminants](#). Governing regulations include: [Regulation \(EC\) 1881/2006](#), [Regulation \(EC\) 1882/2006](#), [Regulation \(EC\) 401/2006](#), [Regulation \(EC\) 589/2014](#) and [Regulation \(EC\) 333/2007](#).

## 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](#)). The USDA Agricultural marketing Service started to issue PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which stopped being required in September 2014 when the EU voted to remove California Almonds from Special Measures.

With the publication of Commission Implementing Regulation (EU) 2015/949, all EU accepted programs have been combined in the one regulation. The U.S. peanut program which was approved in 2009 is now also covered by the general provisions of [Commission Implementing Regulation \(EU\) 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 in the EU.

For additional information on aflatoxin PEC certification, see:

- <http://www.almonds.com/newsletters/handle/almond-industry-flexes-its-pecs>
- <http://www.peanutsusa.org.uk/eu-food-aflatoxin-legislation>
- <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 [Commission Regulation \(EC\) No 669/2009](#). 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

[Council Directive 96/23/EC](#) on measures to monitor certain substances and residues thereof in live animals and animal products and [Council Directive 96/22/EC](#) were transposed to national law by [Royal Decree 1749/1998](#) and [Royal Decree 1373/1997](#), respectively.

For additional information, please visit the FAS USEU website section on [Pesticides](#), [Contaminants](#) and [Residue Plans](#).

## **Section IV. Packaging and Container Regulations**

Spain 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 ([Council Directive 76/211/EEC](#)) and laying down rules on nominal quantities for pre-packed products ([Directive 2007/45/EC](#)) that were transposed into Spain's National Law by [Royal Decree 1801/2008](#).

- **Materials in contact with foodstuffs**

<b>Material</b>	<b>EU legal Framework</b>	<b>Spanish Legal framework</b>
<b>Plastics</b>	<a href="#">Regulation (EC) 1935/2004</a> <a href="#">Regulation (UE) 10/2011</a> <a href="#">Regulation (EC) 282/2008</a> <a href="#">Regulation (EC) 2023/2006</a>	Directly applicable
<b>Polymers and regenerated polymers</b>	<a href="#">Regulation (EC) 10/2011</a>	<a href="#">Royal Decree 847/2011</a> defines the positive list of polymeric substances allowed to be in contact with foodstuffs.
<b>Rubber</b>	<a href="#">Directive 93/11/ECC</a>	<a href="#">Royal Decree 1184/1994</a> .
<b>Regenerated cellulose film</b>	<a href="#">Directive 2007/42/EC</a>	<a href="#">Royal Decree 1413/1994</a> <a href="#">Royal Decree 691/2005</a> .
<b>Ceramics</b>	<a href="#">Directive 84/500/EC</a>	<a href="#">Royal Decree 891/2006</a> <a href="#">Royal Decree 1631/2011</a>
<b>Bisphenol A in plastic for infant bottles</b>	<a href="#">Commission Implementing Regulation 321/2011</a> (Ban)	Directly applicable

- **Packaging waste management:**

[Law 11/1997](#) as amended transposes [Directive 94/62/EC](#) 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 [USEU report on New EU food labeling rules](#) as set out in the [“Food Information to Consumers \(FIC\)” regulation 1169/2011](#). This information can be supplemented by [GAIN report “How to Comply with the EU’s New Food Labeling Rules.”](#)

The Spanish Federation of Food and Beverage Industries (**FIAB**) along with Spanish retailers associations (ASEDAS, ACES and ANGED) have published a [guidance document](#) for [Regulation \(EC\) 1169/2011](#) compliance.

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

For non-packaged food, [Regulation \(EC\) 1169/2011](#) provisions have been implemented at the national level by [Royal Decree 126/2015](#).

- **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 [country of origin labeling](#) as well as [GAIN report “The EU’s Country of Origin Labeling Policy”](#).

At the moment, the Spanish administration is drafting a piece of regulation to request country of origin label for milk and dairy products. Final details on this piece of regulation are yet to be released.

- **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 [labeling requirements](#).

## **Section VI. Other Specific Standards**

For detailed information on the EU-harmonized legislation on other specific standards, please consult the [EU-28 FAIRS Report](#) or the [USEU import rules](#) 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, authorizations, rejections and withdrawals can be also found in the [Commission's website](#). Additionally a guide on how to prove “Human Consumption to a significant degree” is available in the [link](#).

New authorizations can be submitted to Member State's competent authorities. A summary on the authorization process when submitted to the Spanish competent authorities can be found in the [link](#) (Spanish language only).

A new EU regulation on novel food was adopted ([Regulation \(EC\) 2283/2015](#)), 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 [Regulation 1169/2011](#) on the provision of food information to consumers, [Regulation 1333/2008](#) on food additives and [Regulation 450/2009](#) on

active and intelligent materials and articles intended to come into contact with food. Also, the new [novel foods proposal](#) contains different provisions on nanotechnology.

For additional information, visit FAS USEU website section on [nanotechnology](#).

### Fortified Foods

[European Parliament and Council Regulation 1925/2006](#) as amended by [Regulation \(EC\) 1170/2009](#) 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](#).

### Dietetic or Special Use Foods

In June 2013, the EU adopted European Parliament and Council [Regulation 609/2013](#) 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. As of July 20, 2016, the rules on foods for persons with gluten intolerance set out in [Regulation 41/2009](#) will fall within the scope of the Food Information to Consumers [Regulation 1169/2011](#). Hence, foods that no longer fall within the scope of the current dietetic food rules<sup>1</sup> will be regarded as “normal foods” and regulated under the Food Information of Consumers [Regulation 1169/2011](#) unless they make a nutrition or health claim in which case they will have to comply with the EU’s Nutrition and Health Claims [Regulation 1924/2006](#). Additionally, [Commission Delegated Regulation 2016/128](#) sets out specific requirements for food for special medical purposes (FSMPs). [Commission Delegated Regulation 2016/217](#) 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 [Royal Decree 1430/1997](#). For additional information, visit FAS USEU website section on [dietetic foods](#), and [see GAIN report “New EU Rules on Dietetic Foods.”](#), complemented by [GAIN report “New EU Rules on Dietetic Foods – Update”](#).

### Nutrition and Health Claims Labeling

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<sup>1</sup> For instance: Food for diabetics, Food for young children, Food intended for Gluten intolerants, Food for lactose intolerant, Food intended for sportspeople.

[Regulation 1924/2006](#) sets out EU-wide conditions for the use of **nutrition** and **health claims** on foods. Food products carrying health claims must also comply with the provisions of nutritional labeling [Directives 90/496/EC](#) as amended by Directives [2003/120/EC](#) and [2008/100/EC](#). [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 [EU-28 FAIRS Report](#) or visit the FAS USEU website section on [nutritional claims](#).

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

In Spain, [Royal Decree 903/1992](#) as amended by [Royal Decree 2180/2004](#) and [Royal Decree 1669/2009](#) transpose the current EU governing directives into national law. More information can be found in [AECOSAN'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 [link](#). At the national level these EU Directives were transposed by [Royal Decree 348/2001](#), 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](#).

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

### Genetically Modified Foods and Feeds

Spain follows EU-harmonized legislation on labeling ([Regulation \(EC\) 1829/2003](#) on Genetically Modified Food and Feed, and [Regulation \(EC\) 1830/2003](#) on the Traceability and Labeling of Genetically Modified Organisms) and there is no “non-GMO” labeling regulation developed at the national level. No Non-GMO labeling scheme has been developed at the national level.

Spain has a decentralized system for testing and controlling unauthorized presence of GMO in the feed and food chain. While the government has a total control over the controls carried out in customs, the 17 autonomous communities establish their own monitoring and sampling plans throughout the food and feed chain coordinated by national authorities. Sampling plans are based on risk assessment and primarily carried out at the wholesale and the processing level.

In Spain, practically all animal feed contains GE products, and consequently it is default labeled as “contains GE products”. Meanwhile, in the human food chain, the large majority of food manufacturers have eliminated biotech products from food product composition to avoid labeling as “Contains GMOs”.

For more information, please see [Spain’s Biotech Annual Report](#). or visit FAS USEU website section on [Biotechnology](#).

### Organic Foods

[Council Regulation 834/2007](#) is the EU’s general framework regulation that sets out rules for organic production and labeling. [Commission Implementing Regulation 2016/1842](#) 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 [GAIN Report E48106](#) or in the FAS USEU website section on [organic production](#) and [organic labeling requirements](#).

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 [USDA Organics Home Page for International Agreements](#). Information on the EU-28 Organic Market can be found in the [Report EU-U.S. Organic Trade Update](#).

A [Commission proposal](#) 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 [Directive 2007/45/EC](#), which was transposed to National law by [Royal Decree 1801/2008](#).

**Beer:** There is no specific EU-harmonized legislation for beer. Spain's beer labeling requirements are set out in [Royal Decree 53/1995](#).

### Meat Labeling

Spain applies EU-harmonized legislation regarding **meat labeling**. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the [EU-28 FAIRS Report](#) as well as the FAS USEU website section on [meat labeling](#).

### Frozen Foodstuffs

[Council Directive 89/108/EEC](#) sets rules for quick-frozen foodstuffs and for their packaging and labeling. This Directive is transposed into National Law by [Royal Decree 1109/1991](#) as amended.

### Vertical Legislation (Breakfast Directives)

[Directive 2001/112/EC](#) amended by [Directive 2012/12/EU](#) 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 [Royal Decree 781/2013](#). Detailed information on key changes introduced by the new directive can be found in [GAIN report “New EU Fruit Juice Labeling Rules.”](#)

[Directive 2014/63/EU](#) amending Directive 2001/110/EC relating to honey was transposed to national law by [Royal Decree 473/2015](#) amending [Royal Decree 1049/2003](#) on Honey Quality Standards).

### Halal Foods

In Spain, 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. [Law 26/1992](#) established the framework for Cooperation with the Islamic Commission in Spain. An Islamic Committee has to issue an authorization certificate in the country of origin. Since 2003, the Halal Institute is authorized by the Spanish Office for Patents and Trademarks to use and manage 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](#).

- **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. In Spain, requests should be addressed to Agencia Española de Consumo Seguridad Alimentaria y Nutrición (AECOSAN). Contact details can be found in **Appendix I**.

Also, when introducing foodstuffs with **particular nutritional uses**, vitamin enriched foods or **nutritional supplements** exporters need to notify the Member States competent authorities. A summary on the notification process requirements can be found in the [link](#) (Spanish language only).

## **Section VIII. Other Regulations and Testing Requirements**

- **Product inspection:**

Agricultural products are examined when they enter Spain by the Spanish Border Inspection Posts. There are a number of border inspections points in Spain that carry out [plant health inspection](#) and 42 veterinary inspection points for animal products [intended](#) for human consumption, 38 out of which are authorized to inspect animal products not intended for human consumption. Contact data for each of them can be found in the links.

Competent authorities on certificates vary depending on the type of products. While the Ministry of Social Services and Gender Equality (MSSSI) is responsible for products intended for human consumption, the Ministry of Agriculture, Food, Fisheries and Environment (MAPAMA) is responsible for agricultural products for purposes other than human consumption.

U.S. exporters interested in introducing a product into the Spanish 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 responsibility to the Spanish Government for imported food products entering Spanish territory, they are in the best position to provide guidance to U.S. exporters through the market-entry process.

Additionally, Member State authorities are responsible for carrying out inspections in the food and feed chain. Products can be checked at import or at all further stages of marketing. Spain is comprised by 17 Autonomous Regions and it has a decentralized system for the feed and food chain control, however, the central government has control over the controls carried out in customs. The Autonomous Regions establish their own monitoring and sampling plans throughout the food and feed chain coordinated by national authorities. Sampling plans are based on risk assessment and it is primarily done at the wholesale and the processing level. Member States have the responsibility to designate laboratories that are allowed to perform food control analyses.

For additional information on the Spanish Market, please consult the latest [Spain's Exporters Guide](#) or contact FAS Madrid (Phone: +34 587 2555 or email: [agmadrid@fas.usda.gov](mailto:agmadrid@fas.usda.gov) )

- **Certification**

The Spanish 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](#).

[Council Directive 2000/29/EC](#), 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 products<sup>2</sup>. Notification of imports of non-fully harmonized food products should be addressed to Subdirección General de Sanidad Exterior. Contact details can be found in Appendix I.

For detailed information on specific certificates to export to Spain please consult the latest version of Spain's [FAIRS Certificate report 2016](#).

## **Section IX. Import Procedures**

As a member of the European Union (EU), Spain 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 [on-line customs data base](#). At the Member State level, it is possible to obtain Binding Tariff Information (BTI) from a Member State Customs Authority. In the case of Spain, Agencia Tributaria, ascribed to the Ministry for the Treasury and Public Administration, is the responsible entity. Contact data for Agencia Tributaria can be found in **Appendix I**.

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<sup>2</sup> *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 [Value Added Tax](#) (VAT<sup>3</sup>) and inspection fees which are not harmonized throughout the EU and excise duties applicable on [alcoholic beverages](#) and [tobacco](#) 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 Spain:

- 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 Spanish 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 [link](#) (only available in Spanish language).

## **Samples and Advertising Material**

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<sup>3</sup> Spain standard VAT rate is 21% percent, since September 1, 2012. The reduced rate applicable to passenger transport, hotel and restaurant services is set at 10 percent. The super-reduced tax for certain food products that include basic food items such as bread and grains, milk, cheese, eggs, fruits and vegetables, pulses and tubers is 4 percent.

Spain 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 Spain please consult the Spain’s latest [FAIRS Certificate report 2016](#).

## **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 [EU-28 FAIRS Report](#).

In Spain the legal basis for trademarks is laid down by National [Law 17/2001](#). The trademark protection is granted for 10 years after which it can be renewed. Requests should be addressed to the Spanish Office for Patents and Trademarks (See contact data in **Appendix I**).

In December 2012, the EU Parliament approved the regulations that would establish the single **patent** for the EU. However, Spain (and Italy) decided to opt out due to discrepancies with the patent’s linguistic regime. As a consequence, companies or individuals who want to protect their innovations throughout the whole EU will have to request a patent in three places – in Munich, the headquarters of the European patent, in Spain, and in Italy. More information on the unitary patent can be found in the [link](#).

At the Member State level, a new Law on patents ([Law 24/2015](#)) was recently issued. It will not be enforced until 2017. The Spanish Office for Patents and Trademarks, ascribed to the Ministry of Industry, Energy and Tourism, is the public body responsible for the registration and granting the different types of Industrial Property ranking from industrial property titles, including brands and commercial names (or distinctive signs), inventions, and industrial designs.

In addition, Spain 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 Spain's registered products under this scheme can be found in the [link](#).

### **Appendix I. Government Regulatory Agency Contacts:**

#### **Ministry of Health and Social Services and Gender Equality**

Imported Foodstuffs, Contaminations and Compound Residues, Health Certification, Port Inspection and EU Alerts

Ministerio de Sanidad y Servicios Sociales e Igualdad

Subdirección General de Sanidad Exterior

Paseo del Prado, 18 y 20

28014 Madrid

Tel.: +34-91-596-1000

Fax: +34-91-596-4480

[Website link](#)

E-mail: [saniext@msssi.es](mailto:saniext@msssi.es)

#### **Ministry of Health and Social Services and Gender Equality**

Spanish Food Safety and Nutrition Agency

Ministerio de Sanidad y Servicios Sociales e Igualdad

Agencia Española de Consumo, Seguridad Alimentaria y Nutrición (AECOSAN)

C/ Alcalá, 56

28071 Madrid

Tel.: +34-91-338-0392

Fax: +34-91-338-0378

[Website link](#)

E-mail: [informacionaesan@msssi.es](mailto:informacionaesan@msssi.es)

#### **Ministry of Agriculture, Food and Environment**

Plant Health Unit - Inspection and Certification

Ministerio de Agricultura, Pesca, Alimentación y Medio Ambiente

Subdirección General de Acuerdos Sanitarios y Control en Frontera

C/ Almagro, 33

28071 Madrid

Tel.: +34-91-347-8241

Fax: +34-91-347-8248

[Website link](#)

E-mail: [sgsveget@mapama.es](mailto:sgsveget@mapama.es)

**Ministry of Agriculture, Food and Environment**

Animal Health Unit - Inspection and Certification

Ministerio de Agricultura, Pesca, Alimentación y Medio Ambiente

Subdirección General de Acuerdos Sanitarios y Control en Frontera

C/ Almagro, 33

28071 Madrid

Tel.: +34-91-347-8241

Fax: +34-91-347-8248

[Website link](#)

E-mail: [sgsveget@mapama.es](mailto:sgsveget@mapama.es)

**Ministry of Agriculture, Food and Environment**

Planting Seeds and Nursery Products

(import requirements, seed registration and certification, and commercial seed catalogs)

Ministerio de Agricultura, Pesca, Alimentación y Medio Ambiente

Subdirección General de Medios de Producción Agrícolas y Oficina Española de Variedades Vegetales

C/ Almagro, 33

28071 Madrid

Tel.: +34-91-347-6659

Fax: +34-91-347-6703

[Website link](#)

E-mail: [oevv@mapama.es](mailto:oevv@mapama.es)

**Ministry of Agriculture, Food and Environment**

Pesticides Registration

Ministerio de Agricultura, Pesca, Alimentación y Medio Ambiente

Subdirección General de Sanidad e Higiene Vegetal y Forestal

C/ Almagro, 33

28071 Madrid

Tel.: +34-91-347-4058

Fax: +34-91-347-8316

[Website link](#)

E-mail: [sgmpagri@mapama.es](mailto:sgmpagri@mapama.es)

**Ministry of Agriculture, Food and Environment**

Organic Farming

Ministerio de Agricultura, Pesca, Alimentación y Medio Ambiente

Subdirección General de Calidad Diferenciada y Agricultura Ecológica

C/ Almagro, 33

28071 Madrid

Tel.: +34-91-347-5397

Fax: +34-91-347-5410

[Website link](#)

E-mail: [sgcdae@mapama.es](mailto:sgcdae@mapama.es)

**Spanish Patent and Trademark Office**

Oficina Española de Patentes y Marcas

Paseo de la Castellana, 75

28046 Madrid

Tel.: +34-902 157 530

[Website link](#)

E-mail: [informacion@oepm.es](mailto:informacion@oepm.es)

**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](mailto:information@oami.europa.eu)

**Ministry for the Treasury and Public Administration**

Ministerio de Hacienda y Administraciones Públicas

Agencia Tributaria - Departamento de Aduanas e Impuestos Especiales

C/ Guzmán El Bueno, 132

28003 Madrid

Tel.: +34 91 582 6805

[Website link](#)

**Ministry for the Treasury and Public Administration – Binding Tariff Information**

Ministerio de Hacienda y Administraciones Públicas

Agencia Tributaria - Departamento de Aduanas e Impuestos Especiales

Subdirección de Gestión Aduanera - Servicio de Arancel

Avda. Llano Castellano, 17  
28071 Madrid  
E-mail: [gesadu@aeat.es](mailto:gesadu@aeat.es)

**Ministry for the Treasury and Public Administration**

Ministerio de Hacienda y Administraciones Públicas  
Laboratorio Central de Aduanas - Customs Central Laboratory  
Calle Navaluenga, 2 A  
28035 Madrid  
Tel.: +34 91 376 80 00

**National Food Center (CNA)**

Centro Nacional de Alimentación  
Ctra. Pozuelo-Majadahonda, Km 5,100  
28220 Majadahonda (Madrid)  
Tel: +34 91 338 05 84  
Fax: +34 91 338 09 80  
Email: [cna@msssi.es](mailto:cna@msssi.es)  
[Website link](#)

**WTO Inquiry Post**

- a. For technical regulations:

**Ministry of Economy and Competitiveness**

Ministerio de Economía y Competitividad  
Secretaría de Estado de Comercio Exterior  
Subdirección General de Certificación y Asistencia Técnica de Comercio Exterior  
Paseo de la Castellana, 162, 6a planta  
28046 Madrid  
Tel: +34 91 349 37 59  
Fax: +34 91 349 37 77  
E-mail: [sgsoivre.ssc@comercio.mineco.es](mailto:sgsoivre.ssc@comercio.mineco.es)  
[Website link](#)

**Ministry of Economy and Competitiveness**

Ministerio de Economía y Competitividad  
Secretaría de Estado de Comercio Exterior  
Subdirección General de Comercio Exterior de Productos Agroalimentarios  
Paseo de la Castellana, 162, 6a planta  
28046 Madrid

Tel: +34 91 349 37 80  
Fax: +34 91 349 38 06  
E-mail: [sgagro.sccc@comercio.mineco.es](mailto:sgagro.sccc@comercio.mineco.es)  
[Website link](#)

b. For standards:

**Spanish Association for Standardization and Certification**  
Asociación Española de Normalización y Certificación (AENOR)  
Calle Génova n° 6  
28004 Madrid  
Tel: (+34 91) 432 5965  
Fax: (+34 91) 310 45 96  
E-mail: [info@aenor.es](mailto:info@aenor.es)  
[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](mailto:AgUSEUBrussels@fas.usda.gov)  
<https://www.fas.usda.gov/offices/us-mission-european-union>

**Spanish Federation of Food and Beverage Industries (FIAB)**  
Federación de Industrias de Alimentación y Bebidas  
Calle Velázquez, 64 3 planta  
28001 Madrid  
Tel.: +34 91 411 72 11

Fax: +34 91 411 73 44

Email: [fiab@fiab.es](mailto:fiab@fiab.es)

[Website link](#)

**ACES (Association of Spanish Supermarket Chains)**

Asociación de Cadenas Españolas de Supermercados

C/ Núñez de Balboa, 90 2º

28006 Madrid

Tel: +34 91 185 68 58

Fax: +34 91 185 68 59

Email: [aces@asociacionsupermercados.com](mailto:aces@asociacionsupermercados.com)

[Website link](#)

**Spanish Association for Distributors and Supermarkets (ASEDAS)**

Asociación Española de Distribuidores, Autoservicios y Supermercados

Calle Cedaceros 11, 2 planta. Despacho G

28014 Madrid

Tel.: +34 91 429 89 56

Fax: +34 91 429 4581

Email: [info@asedas.org](mailto:info@asedas.org)

[Website link](#)

**National Association of Large Distributors (ANGED)**

Asociación Nacional de Grandes Empresas de Distribución

Calle Velázquez, 24 5º Dcha.

28001 Madrid

Tel.: +34 91 522 30 04

Email: [anged@anged.es](mailto:anged@anged.es)

[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: [AgMadrid@fas.usda.gov](mailto:AgMadrid@fas.usda.gov) [Website link](#)