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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 [SP1431](#) 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.

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 is a member of the EU since 1986, and as a member of the European Union (EU), it follows all EU directives, regulations, and obligations where available. 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 and Environment (MAGRAMA) 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)¹, 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 MAGRAMA, 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 and Environment (MAGRAMA) 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 (MAGRAMA) will oversee the import. For more information on biological material import procedure, please see Spain's [FAIRS Certificate Report 2015](#).

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

Please note: The following products sourced in the United States and imported into the EU must originate from an [EU-approved U.S. establishment](#) - red meat, meat products, farmed and wild game meat, ratites, milk and milk products, seafood, bovine embryos and semen, porcine and equine semen, gelatin and animal casings. Some examples of non-fully harmonized products include collagen casings, lanolin and gelatin. :

For more information see FAS USEU section on [food safety](#) and [approved establishments](#).

Section II. Food Additives Regulations

Spain applies EU-harmonized legislation regarding food additives. 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 additives](#).

Processing aids at the EU level are regulated by [Directive 2009/32/EC](#) and are subject to Member States national legislation. In the case of Spain the Directive 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)

¹ *In February 2014, by the publication of [Royal Decree 19/2014](#) the National Institute for Consumption merged with the Spanish Food Safety and Nutrition Agency to and become AECOSAN, the Spanish Consumption, Food Safety and Nutrition Agency.*

Sub directorate General for Food Safety Promotion
C/ Alcalá, 56
28071 Madrid
Tel.: +34-91-338-0585
Fax: +34-91-227-0073
E-mail: preaesan@msssi.es

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.

For additional information, please visit the FAS USEU website section on [Food Additives](#).

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, which applies from June 14th, 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](#).

For application for pesticide registration in Spain contact:

Subdirección General de Sanidad e Higiene Vegetal y Forestal
C/Almagro, 33
28071 Madrid.
sgmpagri@magrama.es

- **Maximum Residue Levels (MRL)**

The complete list of MRLs, and commodity combinations allowed in the EU can be obtained from the [Commission’s webpage](#). Member States are responsible for risk assessment and, in the case of Spain the Autonomous Regions are responsible for surveillance and control.

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](#).

- **Import tolerance**

Tolerance for pesticide residues was harmonized in the EU in 2008. Spain strictly adheres to EU-harmonized legislation on pesticides and contaminants. If there is no EU legislation in place in the importing Member State, then the exporter can seek to obtain an "import tolerance" for active substances that have not been evaluated or used in Europe before.

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](#).

- **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](#).

Private Industry Standards

While the official standards are set by the public administration, the large 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 requirement. The most widely used schemes in Spain include AENOR, Globalgap, BRC, IFS and Q+S.

Aflatoxin Levels in Tree Nuts

[Commission Regulation \(EU\) 165/2010](#) increased the maximum aflatoxin levels for almonds and pistachios, as well as apricot kernels, hazelnuts and Brazil nuts, bringing them in line with the Codex Alimentarius levels for tree nuts adopted in July 2008. .

The new levels, effective on March 9, 2010, changes to maximum tolerance for aflatoxin to the following:

	Ready-to-Eat (RTE)	For Further Processing (FFP)
Almonds	10 ppb total /8 ppb B1	15 ppb total/12 ppb B1
Hazelnuts, Brazil Nuts	10 ppb total/5 ppb B1	15 ppb total/8 ppb B1

Pistachios	10 ppb total/8 ppb B1	15 ppb total/12 ppb B1
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For more information, see the [E50018](#) GAIN report and the latest [EU-28 Tree Nuts Report](#).

Voluntary Aflatoxin Sampling Plan for Almonds

As of September 1, 2007, the EU implemented Special Import Conditions (European Commission [Decision 2007/563/EC](#)), which called for mandatory testing of California almonds imported to EU member countries.

The California almond industry and the USDA developed a Voluntary Aflatoxin Sampling Plan (VASP) comparable to the EU sampling procedures so that almonds can be uniformly tested before they are shipped to the EU.

The EU considered the guarantees provided by the program to be sufficient to reduce the import controls on U.S. almonds shipped under the VASP program to random levels from January 2010 onwards ([Commission Regulation 1152/2009](#)).

Regulation 1152/2009 also introduced the use of a Common Entry Document (CED), similar to the Common Veterinary Entry Document (CVED) used for veterinary products. The importer has to provide prior notification to the competent authorities at the designated port of entry for the goods covered by the regulation at least 1 working day prior to the arrival of the goods, using the CED. The CED was published in Annex II of the [Regulation 669/2009](#).

In March 2012, the European Commission implemented the [Regulation 274/2012](#), amending Commission Regulation 1152/2009, imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins. Regulation 274/2012 states almonds without a VASP will no longer be authorized.

Provisions for methods of sampling and analysis for the official control of mycotoxins including aflatoxins are laid down in [Commission Regulation 401/2006](#) as amended by [Commission Regulation 178/2010](#). For additional information see Annex VII B of the EU [guidance document](#) or check the [Almond Board of California](#) website.

Based on favorable control results and favorable outcome of FVO (Food and Veterinary Office) audits, as of September 3, 2014, [Regulation \(EU\) 884/2014](#) imposing special conditions governing the import of certain feed and for from certain third countries due to contamination by aflatoxins, eliminates the special conditions for import of almonds from the United States. As a result, a VASP certificate will no longer be a pre-condition for importing almonds into the EU.

For additional information on the VASP program see:

- <http://www.almondboard.com/Handlers/FoodQualitySafety/VASP/Pages/default.aspx>
- [USDA-AMS Technical Services – Almond Aflatoxin Program](#)

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**

Plastics: Adhesives used in food packaging must comply with [Regulation \(EC\) 1935/2004](#) on materials and articles intended to come into contact with food requirement as well as with the established in [Regulation \(UE\) 10/2011](#) on plastic materials and articles intended to come into contact with food, [Regulation \(EC\) 282/2008](#) on recycled plastic materials in contact with food and [Regulation \(EC\) 2023/2006](#) on good manufacturing practices for materials and articles intended to come into contact with food.

Polymers and regenerated polymers: As additional provisions, at the national level, [Royal Decree 847/2011](#) defines the positive list of polymeric substances allowed to be in contact with foodstuffs.

Rubber: [Directive 93/11/ECC](#) on the release of N-nitrosamines and N-nitrostable substances from elastomer or rubber teats and soothers was transposed to national regulation by [Royal Decree 1184/1994](#).

Regenerated cellulose film: [Directive 2007/42/EC](#) on materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs was transposed to national regulation by [Royal Decree 1413/1994](#) as amended by [Royal Decree 691/2005](#).

Ceramics: [Directive 84/500/EC](#) on ceramic articles intended to come into contact with foodstuffs was transposed to national regulation by [Royal Decree 891/2006](#) as amended by [Royal Decree 1631/2011](#).

[Commission Implementing Regulation 321/2011](#) bans the use of Bisphenol A in plastic infant feeding bottles.

For more detailed information on the EU's harmonized legislation on packaging and container regulations, please consult the [EU-28 FAIRS Report](#) as well as the [USEU website section on packaging](#).

- **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.

As of December 13, 2014 general rules on the labeling, presentation and advertising of foodstuffs will be laid down by [Regulation \(EC\) 1169/2011](#). This regulation consolidates general labeling requirements in a single text. For detailed information on the EU-harmonized labeling legislation, please consult the [EU-28 FAIRS Report](#) well as the [USEU website section on labeling](#). Detailed information on labeling requirements that will apply from December 13, 2014 can be found in the [USEU report on New EU food labeling rules](#), supplemented by [GAIN report "How to Comply with the EU's New Food Labeling Rules."](#)

Spain applies EU-harmonized legislation to:

- General Labeling Requirements
- Nutritional Labeling
- Product-Specific Labeling
- GE products labeling ([Regulation \(EC\) 1829/2003](#)).

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.

- **General Labeling Requirements**

[Royal Decree 1334/1999](#) as amended, establishes that mandatory information required includes:

- Product name
- List of ingredients and quantity of certain ingredients or category of ingredients
- Alcoholic content when it is over 1.2% in volume
- Net weight in packaged products
- Expiration date
- Storage and use conditions
- Use instructions when essential to make a proper use the product
- Company identification: name and address of the manufacturer or packer or seller established within the European Union
- Batch information
- Country of Origin
- Information requested according to Annex V of [Royal Decree 1334/1999](#).

According to the general principles for labeling, misleading labeling attributing properties that the foodstuff does not have is not accepted. The label will not confuse the consumer in regards to the nature of the foodstuff, identity, qualities, composition, quantity shelf-life, origin or type of processing. It cannot attribute properties not offered by the product, in particular as it regards to health claims. These restrictions are applicable to labeling and to publicity.

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.

- **Country of Origin Labeling**

In the EU, country of origin labeling 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, 2014, 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](#).

- **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.

Genetically Modified Foods and Feeds

There are two relevant Authorities that weigh-in on Spain's biotechnology decision making process, which are the National Biosafety Commission (CNB) and the Inter-ministerial Council for GMOs (CIOMG). The CNB takes a scientific approach, whereas CIOMG's approach is technical. Both bodies are ascribed to the Ministry of Agriculture, Food and Environment.

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 marketed feed contains GE soybean as a source of protein, and consequently it is default labeled as "contains GE products". On the contrary, 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](#).

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 on 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](#).

Experts belonging to AECOSAN (Spanish Consumption, Food Safety and Nutrition Agency) participate in the EU decision making process by attending the discussions in the Novel Food Working Group.

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).

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

The broad scope of what is currently considered a novel food presents challenges for U.S. exporters in determining the legal status of specific substances or ingredients. An overview of the current novel foods regulatory environment and a negative list of substances and ingredients not authorized under the current novel foods framework can be found in the report [E14034](#).

A [European Commission proposal to revise the current Novel Foods rules](#) is currently being discussed; hence, U.S. Exporters are advised to check the legal status of novel food.

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 will apply as of July 20, 2016, and repeal 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.

Foods that no longer fall within the scope of the current dietetic food rules 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](#).

As of July 20, 2016, the rules on foods for persons with gluten intolerance currently set out in [Regulation 41/2009](#) will fall within the scope of the Food Information to Consumers [Regulation 1169/2011](#).

For additional information, visit FAS USEU website section on [dietetic foods](#) . and [see GAIN report “New EU Rules on Dietetic Foods.”](#)

Specific directives on foods and beverages for athletes or on foods intended for diabetics are still subject to Member State legislation.

The introduction of foodstuffs intended for particular nutritional uses for which no specific rules are set must be notified to the Member State where the food is sold. Spain’s competent authority is AECOSAN. Notification should be addressed to:

Agencia Española de Consumo Seguridad Alimentaria y Nutrición (AECOSAN)
Dirección Ejecutiva
C/ Alcalá, 56
28071 Madrid
Tel.: +34-91-338-0389
Fax: +34-91-227-0375
E-mail: preaesan@msssi.es

Health / Nutritional Claims Labeling

[Regulation 1924/2006](#) sets out EU-wide conditions for the use of nutrition and health claims on foods. Food must fit certain nutrient profile. 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](#). Council Directive 90/496/EC will be repealed on December 13, 2014 when the EU's new labeling [Regulation 1169/2011](#) becomes applicable.

[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 will only become applicable since 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](#).

[Commission Regulation 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](#).

Organic Foods

On February 15, 2012, the European Union and the United States announced that beginning June 1st, 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](#).

[Council Regulation 834/2007](#) is the EU's general framework regulation that sets out rules for organic production and labeling. A [Commission proposal](#) to revise the current rules on organic food production and labeling is currently being discussed.

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](#).

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."](#)

More information about EU fruit juice labeling requirements can be found in the GAIN Report [E70022](#).

[Directive 2014/63/EU](#) amending Directive 2001/110/EC relating to honey remain pending of being transposed to national law (amendment to [Royal Decree 1049/2003](#) on Honey Quality Standards) when this report was prepared.

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.

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.

Quick-frozen foodstuffs sold to the final consumer should carry the following additional labeling indications: the product name with the indication “quick-frozen”; the date of minimum shelf life; the period during which the purchaser may store the product; the storage temperature and/or type of storage equipment required; batch identification; a clear indication of the type “do not re-freeze after defrosting”.

Current food labeling Directive [2000/13/EC](#) was repealed in December 13, 2014. At the EU level, as of December 13, 2014 general rules on the labeling, presentation and advertising of foodstuffs will be laid down by [Regulation \(EC\) 1169/2011](#).

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

[Council Regulation 2406/96](#) lays down common marketing standards for certain fishery products. 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](#)”.

As of December 13, 2014, all seafood sold at RETAIL must have nutritional information on the package. [Regulation 1169/2011](#) describes the minimum information to mention of labels intended for retail or mass caterers. Exporters should pay specific attention to Article 9 and following articles as well as all annexes of the Regulation.

A new requirement regarding labeling of frozen food is in place since July 1, 2012. The intention of [Regulation 16/2012](#) is to ensure that the information on the date of production and freezing is provided to the food business operator to whom the food is supplied and not to the consumers.

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](#).

Conditions for mixing veterinary medicine into feed are set out in [Directive 90/167/EEC](#), transposed to national law by Royal Decree 157/1995 amended [by Royal Decree 2098/2004](#). On September 10, 2014, the European Commission presented a proposal to replace the outdated Directive 90/167/EEC on medicated feed

Section VII. Facility and Product Registration Requirements

- **Facility Registration**

Exports of product of animal origin such as red meat, meat products, farmed and wild game meat, raptures, 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 [link](#).

- **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. Requests should be addressed to:

Agencia Española de Consumo Seguridad Alimentaria y Nutrición (AECOSAN)
Sub directorate General for Food Safety Promotion
C/ Alcalá, 56
28071 Madrid
Tel.: +34-91-338-0585
Fax: +34-91-227-0073
E-mail: aesande@msssi.es

Also, when introducing foodstuffs with particular nutritional uses, the Member States competent authorities where the food is sold need to be notified. Exporters of milk infant formula or nutritional supplements are mandated to notify competent authorities. A summary on the notification process requirements can be found in the [link](#) (Spanish language only).

Section VIII. Other Regulations and Requirements

- **Product inspection:**

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.

- **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](#). [A detailed Product Decision Tree to clarify the scope of the legislation was published in 2013](#). This guidance greatly expanded the number and types of products affected by the legislation.

Please note: [Council Directive 2000/29/EC](#), harmonizes the importation requirements of plants and plant products into the EU. Phytosanitary certificates, issued by an APHIS inspector, are required to accompany all plant and plant products entering the EU. Your nearest APHIS Export Certification Specialist can be found in this [link](#).

For detailed information on specific certificates to export to Spain please consult the latest version of [Spain's FAIRS Certificate report 2015](#).

Some examples of non-fully harmonized products include collagen casings, lanolin and gelatin and composite products.

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. Additional information can be found in the [link](#).

Notification of imports of non-fully harmonized food products should be addressed to:

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

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**

[Council Regulation \(EEC\) 2913/92](#) establishes the Community Customs Code. As of June 1, 2016 this will be repealed by [Council Regulation \(EU\) 952/2013](#). Commission Regulation 2454/93 as amended by [Regulation \(EU\) 1099/2013](#) lays down provisions for the implementation of the Code.

EU's applicable duties information can be found in the [on-line customs data base](#).

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**.

Other taxes applicable to agricultural products include the Value Added Tax (VAT) and inspection fees which are not harmonized throughout the EU.

- **VAT:** A list of VAT rates applicable in the different Member States can be found in the [link](#). 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.
 - **INSPECTION FEES:** Inspection fees for non-animal origin products differ from one Member State to another.
 - **EXCISE DUTIES:** Duties payable on alcohol and tobacco are not harmonized throughout the EU. A list of excise duties applicable on [alcoholic beverages](#) and [tobacco](#) can be found in the links.
- **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

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 veterinary inspection points for animal products [intended](#) for human consumption and 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 and Environment (MAGRAMA) is responsible for agricultural products for purposes other than human consumption.

Goods are only released for free circulation within the EU once the documentary and analytical requirements are checked and the import duty and other taxes that may be due are paid. Information on import duties can be consulted in the [EU on-line customs data base](#).

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. For additional information on the Spanish Market, please consult the latest [Spain's Exporters Guide](#).

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

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 2015](#).

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](#). Also please refer to [Council Regulation 207/2009](#), which created a single, unitary **trademark** registration system for the entire European Community. Applications for registering under the Community Trademark Register must be submitted to the Spanish based Office for Harmonization in the Internal Market (See contact data in **Appendix I**).

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**).

The Community Trademark did not replace the existing trademark laws of the member states but co-exists alongside national trademarks. [Directive 2008/95/EC](#) approximates the laws of the Member States relating to trade marks.

For detailed information on the EU-harmonized legislation on copyright and/or trademark laws, please consult the [EU-28 FAIRS Report](#) as well as the [USEU website](#).

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**

In November 2012, [Regulation 1151/2012](#) on quality schemes for agricultural products and foodstuffs repealing [Council Regulation 510/2006](#), was published and came into force on January 3, 2013.

Regulation 1151/2012 sets out the mechanisms to protect PDOs and PGIs in third countries. In any case, some regulations additional regulations need to be adopted for it to be fully functional.

Note: Wines and spirit drinks are covered by separate legislation.

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."](#)

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

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

Ministry of Agriculture, Food and Environment

Plant Health Unit - Inspection and Certification

Ministerio de Agricultura, 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@magrama.es

Ministry of Agriculture, Food and Environment

Animal Health Unit - Inspection and Certification

Ministerio de Agricultura, 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@magrama.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, 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@magrama.es

Ministry of Agriculture, Food and Environment

Pesticides Registration

Ministerio de Agricultura, 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@magrama.es

Ministry of Agriculture, Food and Environment

Organic Farming
Ministerio de Agricultura, 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@magrama.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

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 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

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
[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.sccc@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

[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

[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
www.usda-eu.gov

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

[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

[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

[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

[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

[Website link](#)