Spain is a member of the European Union (EU) and follows EU directives and regulations. This report is an update of SP1725 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. Updated information is also available on 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 has been a member of the European Union (EU) since 1986 and follows all EU directives, regulations, and obligations. While EU Regulations are binding and directly applicable to the Member States, EU Directives have to be transposed into National law. EU Decisions are binding and directly applicable to whom they are addressed. Detailed information on the EU procedures can be found in GAIN report “How the EU works – A guide to EU decision-making” (updated September 2017) and on our website at http://www.usda-eu.org/eu-basics-questions/.

This report outlines the applicable legislation regarding the export of U.S. food products to 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. 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 Spain specific permits and are not subject to special rules or regulations for 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.

In March 2017, the Commission launched a single web portal where citizens and stakeholders can provide feedback on all initiatives throughout the law-making process. The “REFIT” program, evaluates whether existing legislation is still fit for the purpose and makes changes where needed. Information on the Better Regulation Package and the REFIT program is available on the European Commission’s website https://ec.europa.eu/info/law/law-making-process/better-regulation-why-and-how_en.

Spanish Food law

At the EU level, Regulation (EC) 178/2002 sets out general principles and objectives for 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 equally to domestic 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 responsible for food regulation. 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, Consumption and Social Services (MSSSI) controls agricultural product imports intended for human consumption; while the Ministry of Agriculture, Fisheries and Food (MAPA) 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), under MSSSI that coordinates the food chain control. AECOSAN was established as an independent agency and it is also responsible for risk management. Within the MAPA, the Sub directorate General for Livestock Resources coordinates the National plan in feedstuffs.

Importing biological material must be approved by the Ministry of Agriculture, Fisheries and Food (MAPA), or the Ministry of Health, depending on the nature of the potential risk. In cases where the biological material could potentially pose a threat in human health, the MOH is responsible for the import approval. In cases where the potential risk would affect to animal health, the Ministry of Agriculture (MAPA) oversees the import. For more information on biological material import procedure, please see Spain’s latest FAIRS Certificate Report.

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. Annex III to Regulation 1333/2008 contains a second list of food additives approved for the use in food ingredients such as other food additives, food enzymes, food flavorings and nutrients. Specifications for food additives listed in Annexes II and III are laid down in **Commission Regulation 231/2012**.

In July 2016, EFSA completed a re-evaluation of approved food colors and amended Annex V to Regulation 1333/2008 in order to introduce mandatory labeling information for six food colors\(^1\). Foods containing these colors have to be labeled “may have an adverse effect on activity and attention in children”. **Commission Regulation 232/2012** lowered the limits for food colors Quinoline Yellow (E104), Sunset Yellow (E110) and Ponceau 4R (E124). Food color Red 2G (E 128) was removed from the EU’s permitted list.

The Commission’s **food additives database** together with its **user guide** provides detailed information on the different food additives allowed in the EU. More information on the use of food additives can be obtained from the **European Commission’s website**.

- **Regulation 1334/2008** on flavorings.

For detailed information on the EU-harmonized legislation on food additive regulations, please consult the [EU-28 FAIRS Report](https://www.fairs.eu) as well as the FAS USEU website section on Food Additives.

**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 interested party can prove that they are being marketed in other EU Member States.

**Processing aids** at the EU level are regulated by [Directive 2009/32/EC](https://eur-lex.europa.eu) which was transposed by [Royal Decree 1101/2011](https://www.boe.es). 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**.

Section III. Pesticides and Other Contaminants

\(^1\): Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Tartrazine (E102), Azorubine/Carmoisine (E122) and Allura Red AC (E129)
• **Pesticide Registration**

Regulation (EC) 1107/2009 for placing plant protection products on the market replaced Directive 91/414/EEC. This new piece of regulation, applied since June 14th, 2011, defines zonal authorizations. 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 of Agriculture, Fisheries and Food, is responsible for the product registration. For application for pesticide registration in Spain contact Subdirección General de Sanidad e Higiene Vegetal y Forestal (MAPA). 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.

• **Endocrine Disruptors (EDs)**

“Endocrine disruptors” (EDs) are substances with the potential to alter and cause unintentional adverse health effects to the endocrine systems of humans and wildlife. Both the Plant Protection Products Regulation 1107/2009 (Pesticides) and the Biocidal Products Regulation 528/2012 (Biocides) introduced “endocrine disrupting properties” as one of the categories of hazard-based cut-off criteria.

This cut off would allow the EU to ban certain products from the market based on hazard identification rather than risk assessment without taking exposure into account. On June 15, 2016, the European Commission presented two draft measures outlining scientific criteria to identify EDs under the Plant Protection Products Regulation (1107/2009) and Biocidal Products Regulation (528/2012), using the World Health Organization (WHO) definition for EDs as a basis.
On October 4, 2017, the European Parliament rejected the Commission’s proposal for scientific criteria to identify EDs under the Plant Protection Regulation which means that interim criteria continue to apply. Commission Delegated Regulation 2017/2100, adopted on September 4, 2017, sets scientific criteria for the determination of EDs in biocidal products.

- Maximum Residue Levels (MRL)

The European Commission fixes MRLs for all food and feed, based on the EFSA (European Food Safety Authority) assessment report, 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 for 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.

- Upcoming Review – REFIT

On November 13, 2017, the European Commission launched its public consultation (open until February 12, 2018) and stakeholder survey (open until December 31, 2017) on the “REFIT” evaluation of EU legislation on pesticides and pesticides residues. The public consultation aims to collect the views of citizens (EU and non-EU), stakeholders, and trading partners in order to identify the strengths and weaknesses of the legislation and the perceived level of protection of human and animal health and the environment. For more information see GAIN report “REFIT – Public Consultation on PPPs and MRLs Launched.”

- Official Control

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. Commission Implementing Regulation 2017/660 outlines the latest version of the coordinated multi annual control program of the EU for pesticides residues, which requires Member States to take and analyze samples for product and pesticide
residue combinations in food of plant and animal origin. Annex I to the Regulation sets out the pesticide and product combinations to be monitored. Annex II sets out the number of samples that need to be taken for each combination. The Member States must submit results of the sample tests to the EU by 31 August 2019, 2020 and 2021 for samples tested in 2018, 2019 and 2020 respectively. For more information see the European Commission website.

Private Industry Standards

While the official standards are set by the public administration, many retailers require their own certification of good agricultural practices. The private certification schemes often include stricter limits for MRL and also additional requirements.

- Contaminants


Please note that the EU has started to discuss the expansion of the group of products subject to a maximum level for ochratoxin A for: dried figs and dried apricots or all dried fruit, mixtures of spices, sunflower and pumpkin seeds, pistachios, hazelnuts or all tree nuts, liquorice placed on the market for the final consumer, herbs and herbal teas, and cocoa powder. More information can be found in the GAIN report “Additional EU Maximum Levels for Ochratoxin A on the Horizon”.

Official Controls of Maximum Levels in Foodstuffs

The following regulations concern the sampling methods and methods of analysis for the official controls of the levels of the different contaminants. Annex I describes the methods of sampling; Annex II concerns the sample preparation and the performance criteria for the methods of analysis:

- Dioxins: Commission Regulation 2017/644
- Heavy metals, Tin, 3-MCPD and benzo(a)pyrene: Commission Regulation 333/2007
- Erucic acid: Commission Regulation (EU) 2015/705

Official Aflatoxin Controls on U.S. Products

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

The USDA Agricultural Marketing Service began issuing PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which was no longer required after September 2014 when the EU voted to remove California Almonds from Special Measures.

Following the publication of Commission Implementing Regulation (EU) 2017/1269 on July 14, 2017, the U.S. pre-export program for peanuts is no longer recognized by the EU. There is no restriction on the export of U.S. peanuts; however, shipments are no longer benefitting from the reduced testing level for aflatoxin upon entry in the EU.

For additional information on aflatoxin PEC certification, see:

- http://www.almonds.com/newsletters/handle/gearing-pec-program
- 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. This list was updated in 2017. Now Member states have to test 10 percent of all incoming shipments. This regulation does not impose any requirements on exporters.

Residues in Animal Products


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

<table>
<thead>
<tr>
<th>Material</th>
<th>EU legal Framework</th>
<th>Spanish Legal framework</th>
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<td>Regulation (EC) 1935/2004</td>
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<td>Regulation (EC) 282/2008</td>
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<td>Regulation (EC) 2023/2006</td>
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<tr>
<td>Polymers and regenerated polymers</td>
<td>Regulation (EC) 10/2011</td>
<td>Royal Decree 847/2011 defines the positive list of polymeric substances allowed to be in contact with foodstuffs.</td>
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<tr>
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<td>Ceramics</td>
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<td>Royal Decree 1631/2011</td>
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<tr>
<td>Bisphenol A in plastic for enfant bottles</td>
<td>Commission Implementing Regulation 321/2011 (Ban)</td>
<td>Directly applicable</td>
</tr>
</tbody>
</table>

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2 On November 28, 2017, the European Commission published a “roadmap” to evaluate whether regulation 1935/2004 is still fit for purpose and delivers as expected. The evaluation is scheduled to be finalized mid-2019.
Packaging waste management:


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 applicable labeling requirements.

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 X (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” and EU-28: EU Agriculture Ministers Divided Over National COOL Measures.

In Spring 2017, Spain presented a draft piece of regulation for public consultation in regards to country of origin labelling for dairy\(^3\) products. It requires companies to provide details of the origin of milk

\(^3\) Liquid milk, powder, yoghurts and butter. Ice cream is excluded from the requirement as well as imported dairy products (of which cheese represents a large share) or cheeses under GI labels.
used in a product and the country where it has been processed. Dairy industry operators shall have appropriate documents, systems or procedures to demonstrate to the competent authority the country of origin of milk used in the preparation of milk and milk products falling within the scope of the Royal Decree and conforming to the labelling of these products. Dairy industry operators are also allowed to expand on the obligatory country of origin labelling with more precise information on regional or territorial origin if it comes entirely from the indicated source. The requirements set out in the drafted bill, will be in place “on an experimental basis for a period of two years” similar to rules launched in other member states, such as France, Italy and Portugal.

A report released by the Spanish National Authority for Competition and Markets states that the mandatory labeling by origin might fragment the market, restrict free movement of goods and negatively affect competition.

- **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**


Under the new centralized authorization, procedure authorizations may take up to 18 months. In November 2017, the EFSA application helpdesk published an overview highlighting the main steps of the authorization procedure. On November 10, 2016, EFSA published guidance documents on novel foods and traditional food from third countries explaining in detail what kind of information applicants need to provide and how it should be presented.

On April 9, 2018, a new EU law enters into force that sets out a procedure to determine the "novel food status" of a particular food. Commission Implementing Regulation 2018/456 maps out a consultation procedure that food business operators have to follow in order to verify whether or not a food they
intend to market in the EU for the first time, falls within the scope of the EU’s Novel Food regulation 2015/2283.

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

Food from Clones

At the moment, food derived from animal clones falls under the scope of Novel Food Regulation (EC) 258/1997. The European Commission proposed two pieces of regulation (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). To date, the European Parliament and the Council of the EU have not made any progress on the cloning proposals. Until separate legislation is adopted, food from clones falls within the scope of the Novel Foods regulation. For detailed information see GAIN Report New EU Law on Novel Food Status Determination.

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.

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.

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.

Gluten-Free

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

Nutrition and Health Claims Labeling

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


Regulation (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. In May 2016, the Commission released a report on the feasibility of an EU eco-label scheme for fishery and aquaculture products.

Regulation 1379/2013 sets out labeling rules for fishery and aquaculture products listed in Annex I to the regulation. For more information, see the European Commission’s website.

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.
Commission Implementing Regulation 2016/1842 published on October 19, 2016, sets new rules for the certification of EU organic food imports. Since October 19, 2017, only certificates initiated through the EU’s Trade Control and Expert System (TRACES) are valid. For more information see GAIN report “Electronic Certificate of Inspection Required for EU Organics Trade”.

In 2014 the European Commission launched negotiations with a sweeping regulatory reform agenda for regulation of organic production and labelling of organic products, repealing the current framework dating from 2007. After Parliament approval in April 2018, Council will adopt in a future meeting without debate and then, it will be published in the European Union’s Official Journal and will enter into force January 1, 2021.

For additional information in the new organic rules, see GAIN Report “New EU Organic Regulations for Early 2018” and New EU Organic Regulation formally approved.

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 GAIN report “EU Wine Policy” and 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.

For detailed information see GAIN report “EU Alcohol Industry Labeling Proposal - Labeling Apart Together”.
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. All alcoholic beverages must comply with the allergen labeling requirements. Spain’s beer labeling requirements are set out in Royal Decree 678/2016.

Meat Labeling

Spain applies EU-harmonized legislation regarding meat labeling.


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

Frozen Foodstuffs


Vertical and Product Specific Legislation

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.”


European Parliament and Council Regulation 1308/2013 establishes a single common market organization (CMO) for all agricultural products. The single CMO provides definitions and marketing rules for rice, sugar, beef and veal, milk and milk products, eggs and poultry meat, olive oil, fruit and vegetables, spreadable fats and wine.
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. Third country lists per sector and per country are published on the European Commission’s website.

- **Product Registration**

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods. The person/company introducing a novel food has to submit a request to the authorities in the Member States where the product. 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 certain foodstuffs such as total diet replacements for weight control, falling within the scope of the EU’s Foods for Specific Groups Regulation 609/2013, 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).

Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements. A list of the competent Member State authorities is available on the European Commission’s website.

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.

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


Regulations 854/2004 and 882/2004 will be repealed by **European Parliament and Council Regulation 2017/625** on December 14, 2019. An overview of the main elements and changes introduced by the new regulation on official controls is available on the Commission’s website.

Competent authorities on certificates vary depending on the type of products. While the Health, Consumption and Social Services (MSSSI) is responsible for of products intended for human consumption, the Ministry of Agriculture, Fisheries and Food (MAPA) 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 responsible 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.

Infringements of EU food and feed legislation are reported through the Rapid Alert System on Food and Feeds (RASFF). The rapid alert system is a network of Member State authorities managed by the European Commission. The database with RASFF notifications is accessible via the [RASFF portal](#).

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)

- **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 products⁴. 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 [FAIRS Certificate report](#).

**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.

On October 2, 2017, the European Commission launched the “[Customs Decisions System](#)”, a new pan-EU electronic system that will make it easier for traders to get permission to import goods into the EU. Importers in all the Member States will be able to use the same portal and exchange applications between all the relevant customs authorities.

⁴ *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.*
• 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, 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 and 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

• 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.

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5 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.
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.

- **Inspection Fees**

  Inspection fees for non-animal origin products differ from one Member State to another. Penalties for non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

  - Inspection fees for animal products intended for human consumption can be consulted in the link (Spanish language only).
  - Inspection fees for non-animal feed ingredients can be consulted in the link (Spanish language only).
  - Inspection fees for live animals can be consulted in the link (Spanish language only).
  - Inspection fees for animal products not intended for human consumption can be consulted in the link (Spanish language only).
  - Inspection fees for plant products can be consulted in the link (Spanish language only).

**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. Rules on the protection of trademarks in the EU are set in EU Directive 2015/2436. Commission Implementing Regulation 2017/1413 sets out detailed
rules on application procedures. 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, Trade 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, Consumption and Social Services
Imported Foodstuffs, Contaminations and Compound Residues, Health Certification, Port Inspection and EU Alerts
Ministerio de Sanidad, Consumo y Servicios Sociales
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, Consumption and Social Services
Spanish Food Safety and Nutrition Agency
Ministerio de Sanidad, Consumo y Servicios Sociales
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, Fisheries and Food
Plant Health Unit - Inspection and Certification
Ministerio de Agricultura, Pesca y Alimentación
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@MAPA.es

Ministry of Agriculture, Fisheries and Food
Animal Health Unit - Inspection and Certification
Ministerio de Agricultura, Pesca y Alimentación
Subdirección General de Acuerdos Sanitarios y Control en Frontera
C/ Almagro, 33
28071 Madrid
Ministry of Agriculture, Fisheries and Food
Planting Seeds and Nursery Products
(import requirements, seed registration and certification, and commercial seed catalogs)
Ministerio de Agricultura, Pesca y Alimentación
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

Ministry of Agriculture, Fisheries and Food
Pesticides Registration
Ministerio de Agricultura, Pesca y Alimentación
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

Ministry of Agriculture, Fisheries and Food
Organic Farming
Ministerio de Agricultura, Pesca y Alimentación
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

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  
Ministerio de Hacienda  
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 – Binding Tariff Information  
Ministerio de Hacienda  
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  
Ministerio de Hacienda  
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 Industry, Trade and Tourism
Ministerio de Industria, Comercio y Turismo
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.sscc@comercio.mineco.es
Website link

Ministry of Industry, Trade and Tourism
Ministerio de Industria, Comercio y Turismo
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.sscc@comercio.mineco.es
Website link

b. For standards:

Spanish Association for Standardization and Certification
Asociación Española de Normalización y Certificación (AENOR)
Calle Génova nº 6
28004 Madrid
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

**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

**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](http://www.fiab.es)

**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@asociacionesupermercadoss.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