

**Required Report:** Required - Public Distribution

**Date:** February 12,2020

**Report Number:** SP2019-0049

## **Report Name:** Food and Agricultural Import Regulations and Standards Country Report

**Country:** Spain

**Post:** Madrid

**Report Category:** FAIRS Annual Country Report

**Prepared By:** Marta Guerrero

**Approved By:** Jennifer Clever

### **Report Highlights:**

This report is an update of SP1811 and outlines the applicable legislation regarding the export of U.S. food products to Spain, particularly focusing on 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. Compared to 2018, this report contains updated links to relevant information sources, and new regulatory developments following the updates carried out in the EU report, where these have specificities at the Member State level.

**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.**

**Table of Contents:**

**Executive Summary .....3**

**Section I. Food Laws.....3**

**Section II. Labeling Requirements.....5**

**Other Specific Labelling Requirements: .....6**

**Section III. Packaging and Container Regulations .....9**

**Section IV. Food Additives Regulations .....10**

**Section V. Pesticides and Other Contaminants .....11**

**Section VI. Other Requirements, Regulations and Registration Measures .....12**

**Section VII. Other Specific Standards.....15**

**Novel Foods .....15**

**Dietetic or Special Use Foods.....15**

**Food Supplements.....16**

**Irradiated Foodstuffs.....17**

**Medicated feed .....17**

**Halal Foods.....17**

**Section VIII. Trademark, Brand Names and Intellectual Property Rights .....17**

**Section IX. Import Procedures.....18**

**Appendix I. Government Regulatory Key Agency Contacts.....20**

**Appendix II. Other Import Specialist Technical Contacts .....25**

## Executive Summary

As an EU Member State since 1986, Spain observes all EU directives, regulations, and obligations, which are either directly applicable or need to be transposed to national law. This report outlines the major food laws, general and specific labeling requirements, pesticides and contaminants requirements as well as import procedures that apply to agricultural and food products, focusing on 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](#).

Nearly 60 percent of Spain's agricultural imports are sourced in other EU Member States. In 2018, the United States was the first extra EU supplier of agricultural products and related to Spain. U.S. total agricultural and related exports to Spain reached nearly \$1.3 billion out of a total agricultural import figure of \$32 billion. U.S. agricultural exports to Spain consist mainly of bulk commodities and consumer-oriented products, which accounted for 35 and 45 percent of the U.S. exports value in 2018. While bulk imports vary a lot between years, consumer-oriented products registered a more consistent growth.

### 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/>.

Spain is one of the most decentralized countries in Europe. Spain is comprised of 17 autonomous regions (plus the two North African enclaves of Ceuta and Melilla), each with its own elected parliament and government. Beyond cultural and geographic diversity, each community has considerable financial and legislative authority. This is particularly true in agricultural issues. Trade and international relations are among central government's responsibilities. However, in other agricultural regulatory topics, the central government plays a coordinating role, while regional governments carry out local implementation and control.

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/>.

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.

Where legislation has not been harmonized at EU-level, “mutual recognition” should guarantee the free movement of goods in the EU. Under the principle of mutual recognition, products lawfully produced and/or marketed in one Member State should, in theory, be allowed to be marketed in any other Member State. Some examples of non-harmonized products include collagen casings, lanolin, gelatin and composite products.

There is one exception to the principle of mutual recognition, as certain directives allow Member States to make exceptions e.g. in cases where a country can prove public safety, health or environmental concerns about a product intended for import. [Regulation 764/2008](#) sets out the procedural requirements for denying mutual recognition and defines the rights and obligations of national authorities on the one hand and enterprises on the other. A new Regulation on the mutual recognition of goods will apply as of April 19, 2020. [Regulation 2019/515](#) on the mutual recognition of goods lawfully marketed in another Member State replacing Regulation 764/2008. It introduces a voluntary ‘mutual recognition declaration,’ which businesses can use to demonstrate that their products are lawfully marketed in another EU country. Detailed information about the new rules can be found on the [European Commission’s website](#):

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.

- **Spanish Food law**

At the EU level, [Regulation \(EC\) 178/2002](#) sets out general principles and objectives for food law. In January 2018, the Commission finalized a “[fitness check](#)” of General Food Law regulation 178/2002. It found that ineffective risk communication has a negative impact on consumers’ trust and on the acceptability of risk management decisions. In June 2019, the EU Official Journal published [Regulation 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain which amended the General Food law. The main elements of the regulation aim at ensuring more transparency, increasing the independence of studies, strengthening the governance of the European Food Safety Authority (EFSA) as well as developing comprehensive risk communication. The regulation will have an influence on eight sectoral legislative acts across the agri-food industry including food additive; smoke flavoring; food contact materials; food additive, food enzymes and flavoring and novel foods. For more information, please see GAIN Report E18037 on “[Proposed New Rules on Transparency and Risk Communication](#)”.

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 on 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 assessments and sampling is primarily done at the wholesale and the processing level.

- **Relevant Competent Authorities**

In Spain, the Ministry of Health, Consumption and Social Welfare (MSCBS) controls imports of agricultural product 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.

The Spanish Consumption, Food Safety and Nutrition Agency (AESAN), under MSCBS, is responsible for Food Safety and coordinates control of the food chain. AESAN was established as an independent agency and it is also responsible for risk management. Within 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 (MOH), 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 Ministries are in **Appendix I**.

## Section II. Labeling Requirements

- **General 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.

- **Language Requirements and Stickers**

**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](#).

### **Other Specific Labelling Requirements:**

- **Country of Origin Labeling**

Before the adoption of FIC [Regulation 1169/2011](#) COOL was already mandatory for honey, fruit and vegetables, olive oil, fishery and aquaculture products, and beef. The FIC regulation extends the mandatory COOL requirement to fresh, chilled and frozen pork, sheep and goat meat and poultry.

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](#).

On May 29, 2018, the European Commission published [Implementing Regulation 2018/775](#), which introduces mandatory dual origin labeling when a country of origin is given or visually implied on the label of a food product but the origin is not the same as that of its primary ingredient. More information can be found in the GAIN report [“Commission Briefing on New Origin Labeling Rules”](#)

In 2018, Spain enacted country of origin labelling for dairy<sup>1</sup> products. It requires companies to provide details of the origin of milk used in a product and the country where it has been processed. Dairy industry operators must 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 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](#). Additional information on the origin labelling for dairy products can be found in the [GAIN Report “Spain Enacts Country of Origin Labeling for Dairy and Dairy Products”](#).

- **Product-Specific Labeling**

For some products, specific labeling requirements have been established in addition to the general requirements described above. For more details see **Section VI** and the links below:

<a href="#">Beef</a>	<a href="#">Wine</a>	<a href="#">Organic Products</a>
<a href="#">Cocoa &amp; Chocolate Products</a>	<a href="#">Fruit Juice</a>	<a href="#">Sugars</a>
<a href="#">Coffee &amp; Chicory Extracts</a>	<a href="#">Genetically Modified Food and Feed</a>	<a href="#">Fruit Jams, Jellies &amp; Marmalades</a>
<a href="#">Dietetic or Special Use Foods</a>	<a href="#">Nutrition and Health Claims</a>	<a href="#">Honey</a>
<a href="#">Fortified Foods</a>		<a href="#">Wholly Dehydrated Preserved Milk</a>

For additional information in regards to EU labeling requirements, please visit the FAS USEU website section on [labeling requirements](#).

- **Genetically Modified Foods Labeling**

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

---

<sup>1</sup> *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.*

and feed chain in coordination with national authorities. Sampling plans are based on risk assessments 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, most food manufacturers have eliminated the use of biotech products from food product manufacturing to avoid having to label products as “Contains GMOs.”

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

- **Nutrition and Health Claims**

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

[Regulation \(EC\) 432/2012](#), which establishes a list of permitted **health claims** made on foods, other than those referring to the reduction of disease risk and to children’s development and health became applicable on December 14, 2012, although mandatory nutrition declaration became applicable on December 13, 2016. For detailed information on health/nutritional labeling, please consult the latest [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](#).

- **Frozen Foodstuffs**

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



- **Vertical & 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.”](#)

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

### **Section III. 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](#).

- **Packaging Waste Management**

Member States are required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials. [Council Directive 94/62/EC](#) provides for measures aimed at limiting the production of packaging waste and promoting recycling, re-use and other forms of waste recovery. [Council Directive 94/62/EC](#) on packaging and packaging waste was transposed to Spanish Law as amended by [Law 11/1997](#). [Directive 2018/852](#) amending [Council Directive 94/62/EC](#) is yet to be transposed to national Law.

- **Materials in contact with foodstuffs**

[European Parliament and Council Regulation 1935/2004](#) specifies the main requirements for all materials that come into contact with foodstuffs. It also sets out labeling and traceability requirements and the procedure for the authorization of substances through the European Food Safety Authority (EFSA). Annex I to regulation 1935/2004 lists the group of materials, which may be covered by specific measures.

[Commission Regulation 2023/2006](#) lays down rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food listed in annex I to Regulation 1935/2004.

Specific measures set out additional requirements and include lists of authorized substances and materials. To date, [specific directives](#) have been developed for [plastic materials \(Commission Regulation 10/2011\)](#), including a union list of authorized substances. In Spain, [Royal Decree 847/2011](#) defines the positive list of polymeric substances allowed to be in contact with foodstuffs.

[Commission Implementing Regulation 321/2011](#), amending Regulation 10/2011 on plastic materials, bans the use of Bisphenol A in plastic infant feeding bottles, while [Commission Regulation \(EU\) 2018/213](#) is limiting the use of bisphenol A in varnishes and coatings intended to come into contact with food. This is directly applicable in Spain.

[Directive \(EU\) 2019/904](#) on the reduction of the impact of certain plastic products on the environment targets the ten single use plastic products most often found on Europe's beaches and seas, as well as lost fishing gear. The ban of certain products could also affect food packaging in the future.

#### **Section IV. 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](#) established a common authorization procedure for **food additives**, **food enzymes** and **food flavorings**.
- [Regulation 1332/2008](#) on **food enzymes**, which introduced harmonized rules for their scientific evaluation and authorization in the EU. Until the Commission draws up an EU-list of authorized food enzymes, national rules will continue to apply. For detailed information, see the [European Commission's website](#) on the subject.
- [Regulation 1333/2008](#) on **food additives**. The Commission's [food additives database](#) together with its [user guide](#) provides detailed information on the different food additives allowed in the EU.
- [Regulation 1334/2008](#) on **flavorings**. An [on-line database](#) allows consumers, food businesses and food control authorities to verify which flavoring substances are authorized in food. [Regulation 1334/2008](#) lays down additional rules on the use of the term "natural". Guidance documents by FoodDrink Europe (EU Food and Drink Industry Confederation) can be found in the [link](#).

At the EU level, processing aids are regulated by [Directive 2009/32/EC](#) which was transposed by [Royal Decree 1101/2011](#). The use of processing aids is subject to authorization at the Member State level.

Requests should be addressed to Agencia Española de Seguridad Alimentaria y Nutrición (AESAN). Contact details are in **Appendix I**.

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

## Section V. Pesticides and Other Contaminants

### PESTICIDES

- **Pesticides Registration**

[Regulation \(EC\) 1107/2009](#) for placing plant protection products on the market replaced Directive 91/414/EEC. This piece of regulation, applied since June 14<sup>th</sup>, 2011, defines zonal authorizations. Spain is included in the Zone C (South) along with Bulgaria, Cyprus, France, Greece, Italy, Malta and Portugal). [Commission implementing Regulation 540/2011](#) establishes a list of approved active substances. The “Pesticide Package” also contains [Directive 2009/128/EC](#) for the sustainable use of pesticides, which was transposed to national law by [Royal Decree 1311/2012](#).

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

- AESAN is responsible for the risk assessment of 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](#).
- **Upcoming Review**

The European Commission did a regulatory fitness and performance check ([REFIT on the EU legislation on pesticides and pesticides residues](#)). The evaluation process consisted of different steps, such as a roadmap, an external study, as well as a consultation strategy with an online public

consultation, focus groups, in-depth interview, case studies etc. in order to collect data and information. The final report concluding the REFIT of the EU pesticide legislation was finalized in the first half of 2019 but as of the date of this report has yet to be released. In addition to the Commission's evaluation, the European Parliament formed a special Committee on Pesticides that investigated glyphosate and other pesticide products. Some of the recommendations from the [PEST Committee's final report](#) were also used for the final REFIT report.

- **Official Controls**

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 2019/533 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 2021, 2022 and 2023 for samples tested in 2020, 2021 and 2022 respectively. For more information see the European Commission [website](#).

## 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](#).

- **Residues in Animal Products**

[Council Directive 96/23/EC](#) on measures to monitor certain substances and residues 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.

[Council Directive 96/23/EC](#) on measures to monitor certain substances and residues 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](#) as amended by [Royal Decree 2178/2004](#).

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

## Section VI. Other Requirements, Regulations and Registration Measures

- **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](#). Detailed information on approved U.S. establishments is available on our website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>. 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. Detailed information is provided in **Section VI “Other Specific Standards.”**

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](#). In Spain, the Agencia Española de Seguridad Alimentaria y Nutrición (AESAN) is responsible for these procedures. Contact details are in **Appendix I**.

- **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](#).

An overview of all U.S. authorities that issue the legally required certificates for export to the EU is available on our website at <https://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/u-s-agencies-providing-eu-certificates/>.

[Council Directive 2000/29/EC](#), harmonizes the importation requirements of plants and plant products into the EU. Some examples of non-fully harmonized products include collagen casings, lanolin and gelatin and composite products<sup>2</sup>. Notification of imports of non-fully harmonized food products should

---

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

be addressed to Subdirección General de Sanidad Exterior. Notification of imports of non-fully harmonized non intended for human consumption should be addressed to Subdirección de Acuerdos Sanitarios y Control en Frontera. Contact details can be found in **Appendix I**.

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

- **Product inspection**

[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. Specific detailed inspection requirements exist for animal products ([Directive 97/78/EC](#)), transposed to Spanish law by [Royal Decree 1977/1999](#).

[European Parliament and Council Regulation 854/2004](#) lays down specific rules for the organization of official controls on products of animal origin. [European Parliament and Council Regulation 882/2004](#) lays down general rules for the performance of official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

On December 14, 2019, the [European Parliament and Council Regulation 2017/625](#) will repeal Regulations 854/2004 and 882/2004. 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 (MSCBS) is responsible for products intended for human consumption, the Ministry of Agriculture, Fisheries and Food (MAPA) is responsible for agricultural products for purposes other than human consumption.

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. Check the above for contact details.

U.S. exporters interested in introducing a product into the Spanish market should obtain local representation and/or a local importer/distributor to gain knowledge of the market, up-to-date information and guidance on trade laws and business practices, sales contacts, and market development

expertise. As local importers have primary responsibility to the Spanish Government for imported food products entering Spanish territory, they are in the best position to provide guidance to U.S. exporters through the market-entry process.

Additionally, Member State authorities are responsible for carrying out inspections in the food and feed chain. Products can be checked at import or at all further stages of marketing. Spain is comprised by 17 Autonomous Regions and it has a decentralized system for the feed and food chain control, however, the central government has oversight over customs control operations. The Autonomous Regions establish their own monitoring and sampling plans throughout the food and feed chain in coordination with 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 eligible 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](mailto:agmadrid@fas.usda.gov) ).

## **Section VII. Other Specific Standards**

### **Novel Foods**

A new [EU framework regulation 2015/2283 on Novel Foods](#) was adopted in November 2015 and became applicable on January 1, 2018. It defines novel food as food that has not been consumed to a significant degree in the EU before May 15, 1997 and falling within at least one of the categories listed in Article 3 of the regulation. A [guidance document](#) on “human consumption to a significant degree” is available on the European Commission’s website. Novel foods require a pre-market authorization. Applications for authorization must be submitted to the European Commission via an [e-submission system](#). [Commission Implementing Regulation 2018/456](#) lists the procedural steps that food business operators must follow to consult with the competent authority of the Member State where they first intend to market their product. In Spain, requests should be addressed to Agencia Española de Seguridad Alimentaria y Nutrición (AESAN). Contact details can be found in **Appendix I**.

For detailed information see [GAIN report “New EU Law on Novel Food Status Determination.”](#)

### **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.

Additionally, [Commission Delegated Regulation 2016/128](#) sets out specific requirements for food for special medical purposes (FSMPs). [Commission Delegated Regulation 2016/217](#) sets out specific compositional and information requirements for infant-formula and follow-on formula. [Commission Delegated Regulation 2017/1798](#) sets out new rules for “total diet replacements for weight control”. The new rules will become applicable on October 27, 2022. For detailed information see [GAIN report “The Skinny on New EU Rules for Weight Loss Products.”](#)

[Commission Regulation 2018/97](#) bans the use of artificial sweeteners in fine bakery products. For more information, see [GAIN report “EU bans use of artificial sweeteners in dietetic bakery products.”](#)

New rules on the reduction of acrylamide levels in food, set out in [Commission Regulation 2017/2158](#), became applicable on April 11, 2018. The new rules also apply to baby food and processed cereal-based food intended for infants and young children.

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](#).

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.

## **Food Supplements**

[EU Directive 2002/46/EC](#) only sets out EU-harmonized rules on labeling and vitamins and minerals that may be used in food supplements. Key aspects in the marketing of food supplements such as minimum and maximum levels of vitamins and minerals or the use of other substances such as botanical extracts remain the competence of the Member States. [Royal Decree 1487/2009](#) as amended by [Royal Decree 130/2018](#) transposes the Directive to Spanish Law.

For more information see [GAIN report “Certification and Labeling of EU Whey Protein Supplements.”](#) Marketing food supplements in the EU is a very complex issue. [GAIN report “Exporting Food Supplements to the EU”](#) provides detailed information on marketing food supplements in the EU.

## **Irradiated Foodstuffs**



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.

### **Medicated feed**

Conditions for mixing veterinary medicine into feed are set out in [Directive 90/167/EEC](#). In January 2019, the European Union published [Regulation 2019/4](#) in the EU's Official Journal which will replace Directive 90/167/EEC as of January 28, 2022. The new Regulation explicitly includes the manufacturing of medicated feed for pets in the scope of the legislation. More information is available on the Commission's [website](#).

### **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.

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.

## **Section VIII. Trademark, Brand Names and Intellectual Property Rights**

### **• Trademarks**

In the EU, trademarks can be registered at the EU or national level. The EU-harmonized trademark regulation did not replace the existing laws at the Member State level. Both systems coexist.

EU level: Rules on the protection of trademarks in the EU are set in EU [Directive 2015/2436](#), [Commission Implementing Regulation 2018/626](#) which sets out detailed rules on application procedures. [Commission Delegated Regulation 2018/625](#) sets out procedural rules on opposition and revocation of EU trademarks. Applications for the protection of a trademark in all EU Member States must be submitted to the European Union Intellectual Property Office (EUIPO). An online application costs 850 EUR. Full details on the registration process are available on the [EUIPO website](#). For detailed information on EU-harmonized legislation, please consult the [EU-28 FAIRS Report](#).

National level: Trademarks registered at the national level are protected in one EU Member State. 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](#). 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. See **Appendix I for contact details**.

- **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 For more information see [GAIN report “EU Prepares to Join Lisbon Agreement on Geographical Indications.”](#) and [GAIN report “The EU’s Traditional Specialties Guaranteed Scheme Explained.”](#)

[Commission Regulation 2019/33](#) and [Commission Regulation 2019/34](#) lay down detailed rules on protected designations of origin and geographical indications, traditional terms and labeling, and set out rules on the use of traditional terms. The new EU database for wines and spirits “[eAmbrosia](#)” lists the traditional terms that are protected in the EU.

Specific information about Spain’s registered products under this schemes can be found in the [link](#).

## **Section IX. Import Procedures**

- **Union Customs Code and Customs Clearance**

The “Union Customs Code” (UCC) established in [European Parliament and Council Regulation 952/2013](#) is the framework regulation on rules and procedures for customs throughout the EU. 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. The Code lists all the customs procedures applicable to the trade in goods with third countries. A [guidance document on “Customs formalities on entry and import into the European Union”](#) is available on DG Taxud’s website.

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.

The European Commission’s “Trade Helpdesk” provides a complete overview of documents needed for customs clearance: <http://trade.ec.europa.eu/tradehelp/>.

- **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 of Treasury, is the responsible entity. For contact details see **Appendix I**.

Goods are only released after payment of the import duty and other taxes that may be due. EU harmonized duties payable on goods imported into the EU include when applicable: import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces), additional duties on flour and sugar (processed products), entry price (fruit and vegetables). Non -harmonized taxes applicable to agricultural products include, when applicable: inspection fees, [Value Added Tax](#) (VAT) – and excise duties ([alcohol](#) and [tobacco](#)).

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).

- **Import Documentation and Process**

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

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

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

The import process requires:

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

- **Temporary Entry**

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

- **Samples and Advertising Material**

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 must 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](#).

## **Appendix I. Government Regulatory Key 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 Bienestar Social

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@mscbs.es](mailto:saniext@mscbs.es)

### **Ministry of Health, Consumption and Social Services**

Spanish Food Safety and Nutrition Agency

Ministerio de Sanidad, Consumo y Bienestar Social

Agencia Española de Seguridad Alimentaria y Nutrición (AESAN)

C/ Alcalá, 56

28071 Madrid

Tel.: +34 91 338 0392

Fax: +34 91 338 0378

[Website link](#)

E-mail: [informacionaesan@mscbs.es](mailto:informacionaesan@mscbs.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](mailto: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  
Tel.: +34 91 347 8241  
Fax: +34 91 347 8248  
[Website link](#)  
E-mail: [sgsveget@mapa.es](mailto:sgsveget@mapa.es)

**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@mapa.es](mailto:oevv@mapa.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@mapa.es](mailto:sgmpagri@mapa.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@mapa.es](mailto:sgcdae@mapa.es)

### **Spanish Patent and Trademark Office**

Oficina Española de Patentes y Marcas

Paseo de la Castellana, 75

28046 Madrid

Tel.: +34 902 157 530

[Website link](#)

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

### **EU Trademark Register**

Office for Harmonization in the Internal Market

Avenida de Europa, 4

03008 Alicante

Tel.: +34 96 513 9100

Fax: +34 96 513 1344

[Website link](#)

E-mail: [information@oami.europa.eu](mailto:information@oami.europa.eu)

### **Ministry for the Treasury**

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](mailto: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@mscbs.es](mailto:cna@mscbs.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.sccc@comercio.mineco.es](mailto:sgsoivre.sccc@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.sccc@comercio.mineco.es](mailto:sgagro.sccc@comercio.mineco.es)

[Website link](#)

- b. For standards:

### **Spanish Association for Standardization and Certification**



Asociación Española de Normalización y Certificación (AENOR)

Calle Génova, 6

28004 Madrid

Tel: (+34 91) 432 5965

Fax: (+34 91) 310 45 96

E-mail: [info@aenor.es](mailto:info@aenor.es)

[Website link](#)

## **Appendix II. Other Import Specialist Technical Contacts**

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

2300 M Street

NW, Washington, DC 20037

Tel.: (202) 862 9500

Fax: (202) 429 1766

<http://www.euintheus.org/>

### **United States Mission to the European Union**

Office of Agricultural Affairs

27 Boulevard du Regent

1000 Brussels

Belgium

Tel.: +32 2 508 2760

Fax: +32 2 511 0918

E-mail: [AgUSEUBrussels@fas.usda.gov](mailto:AgUSEUBrussels@fas.usda.gov)

<http://www.usda-eu.org/>

### **Spanish Federation of Food and Beverage Industries (FIAB)**

Federación de Industrias de Alimentación y Bebidas

Calle Velázquez, 64 3 planta

28001 Madrid

Tel.: +34 91 411 72 11

Fax: +34 91 411 73 44

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

[Website link](#)

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

Asociación de Cadenas Españolas de Supermercados

C/ Núñez de Balboa, 90 2º  
28006 Madrid  
Tel: +34 91 185 68 58  
Fax: +34 91 185 68 59  
Email: [aces@asociacionsupermercados.com](mailto:aces@asociacionsupermercados.com)  
[Website link](#)

**Spanish Association for Distributors and Supermarkets (ASEDAS)**  
Asociación Española de Distribuidores, Autoservicios y Supermercados  
Calle Cedaceros 11, 2 planta. Despacho G  
28014 Madrid  
Tel.: +34 91 429 89 56  
Fax: +34 91 429 4581  
Email: [info@asedas.org](mailto:info@asedas.org)  
[Website link](#)

**National Association of Large Distributors (ANGED)**  
Asociación Nacional de Grandes Empresas de Distribución  
Calle Velázquez, 24 5º Dcha.  
28001 Madrid  
Tel.: +34 91 522 30 04  
Email: [anged@anged.es](mailto:anged@anged.es)  
[Website link](#)

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

**Foreign Agricultural Service**  
Office of Agricultural Affairs  
American Embassy Madrid  
C/ Serrano, 75 – Box 20  
28006 Madrid  
Spain  
Tel.: +34 91 587 2555  
Fax: +34 91 587 2556  
Email: [AgMadrid@fas.usda.gov](mailto:AgMadrid@fas.usda.gov)  
[Website link](#)

**Attachments:**

No Attachments