

Required Report: Required - Public Distribution

Date: January 03, 2024

Report Number: SP2023-0036

Report Name: FAIRS Annual Country Report Annual

Country: Spain

Post: Madrid

Report Category: FAIRS Country Report

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Report Highlights:

This report is an update of GAIN report SP2022-0028. It outlines the legislation applicable to 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 Food and Agricultural Import Regulations and Standards Country Report. Compared to 2022, this report contains updated links to relevant information sources and contacts, and new regulatory developments or updates from the EU report where these have specificities at the Member State level.

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Disclaimer: This report was prepared by FAS Madrid for U.S. exporters of domestic food and agricultural products. While every possible care has been 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 about 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 IMPORT APPROVAL OF ANY PRODUCTS IS SUBJECT TO THE IMPORTING COUNTRY’S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Executive Summary

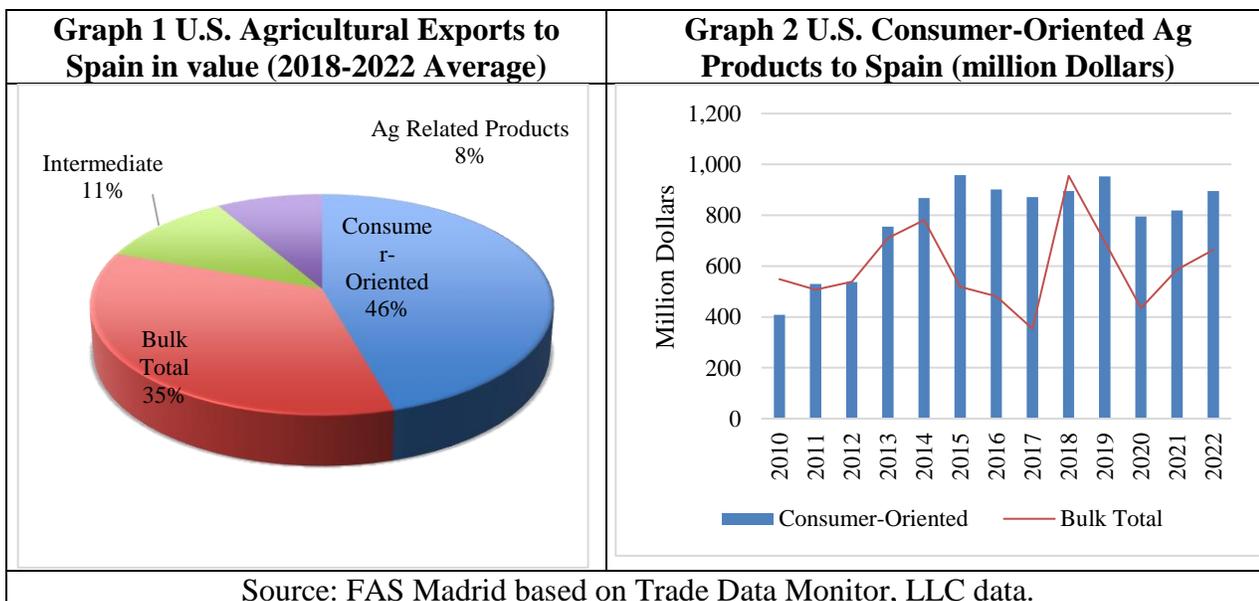
This report provides an overview of food and feed legislation currently in force in Spain, particularly on requirements that differ from EU legislation. As an EU Member State since 1986, Spain observes all EU directives, regulations, and obligations, which are either directly applicable or need to be transposed to National Law. This report should be read in conjunction with the [EU Food and Agricultural Import Regulations and Standards \(FAIRS\) Country Report](#).

Spain is a major agricultural producer and a net exporter of agricultural products. However, the country has a significant structural deficit of feedstuffs. Spain’s total agricultural and related exports (on average from 2018-2022) amounted to \$79 billion, largely exceeding imports, which totaled \$64 billion.

Other EU countries are Spain’s main trading partners, accounting on average for more than 50 percent of the agricultural and related imports and for over 65 percent of the country’s exports. EU markets enjoy an advantage over trading with third countries since between Member States there are no tariffs in place and mutual recognition allows for free movement of goods across the EU.

In 2022, outside the EU, the most important suppliers to Spain were Brazil, followed by China, Argentina, Morocco, and the United States. The top imported products included seafood, corn, fresh fruits, vegetable oils, corn, dairy products, and biodiesel, and blends, fresh fruits forest products and soybeans.

U.S. agricultural exports to Spain consist mainly of bulk commodities and consumer-oriented products, which accounted for 35 and 46 percent of the U.S. exports value during the 2018-2022 period (**Graph 1**). Bulk commodities experience variations depending on price competitiveness against alternative origins. Annual exports of U.S. bulk commodities follow an expansion trend since 2020. After hitting a low level in 2020, since 2021, exports of U.S. consumer-oriented products continue to recover (**Graph 2**).



Section I. Food Laws

Spain has been a member of the European Union (EU) since 1986 and follows all EU directives, regulations, and obligations associated with the treaties and international agreements to which the EU is a party. While EU Regulations are binding and directly applicable to the Member States, EU Directives must be transposed into National Law. EU Decisions are binding and directly applicable to whom they are addressed. All EU Member States share a customs union, a single market in which goods can move freely, a common trade policy, and a common agricultural and fisheries policy. 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).

Most but not all food legislation is harmonized at the EU level. 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. A new Regulation on the mutual recognition of goods applies as of April 19, 2020. [Regulation 2019/515](#) on the mutual recognition of goods lawfully marketed in another Member State replaces [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](#),

Exporters should also 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.

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.

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 the 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/>.

- **Spanish Food law**

At the EU level, [Regulation \(EC\) 178/2002](#) sets out general principles and objectives for food law. Since December 2019, [Regulation 2017/625](#), repealing [Regulation 882/2004](#), sets the rules for harmonized food controls. [Regulation 2019/1381](#) is on the transparency and sustainability of the EU risk assessment in the food chain and aims at ensuring more transparency, increasing the independence of studies, strengthening the governance of EFSA, as well as developing comprehensive risk communication.

In Spain, the Food Safety and Nutrition Law ([Law 17/2011](#)) (Spanish language only) 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 and 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. The central government has total oversight over customs controls. However, the autonomous communities are responsible for enforcement, and they establish their own monitoring and sampling plans throughout the food and feed chain in coordination with 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 (MOH) controls imports of agricultural products 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), ascribed to the Ministry of Consumption, 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 MAPA or the MOH, depending on the nature of the potential risk. In cases where the biological material could potentially pose a threat to human health, the MOH is responsible for the import approval. In cases where the potential risk would affect animal health, MAPA oversees the import. For more information on biological material import procedure, please see Spain's latest [FAIRS Certificate Report](#).

Enforcement of EU food legislation is done by Member State officials. Auditing oversight of Member State performance is done by European Commission officials. For more information, see FAS USEU section on [food safety](#). Contact data for the above-mentioned Competent Authorities can be found 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 since December 13, 2016, are available 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 (Spanish Association for Distributors and Supermarkets), ACES (Association of Spanish Supermarket Chains) and ANGED (National Association of Large Distributors) have published a [guidance document](#) for [Regulation \(EC\) 1169/2011](#) compliance.

A legislative proposal was expected in the fourth quarter of 2022, but it has been delayed. For more information, please see [GAIN Report “Commission Publishes Roadmap on the Upcoming Revision of Food Labeling Requirements.”](#) In this regard, Spain advocates for an EU-harmonized system in the European Union.

- **Language Requirements and Use of 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](#) (Spanish language only).

Other Specific Labelling Requirements:

- **Country of Origin Labeling**

Before the adoption of FIC (Food Information to Consumers) [Regulation 1169/2011](#), origin labeling was already mandatory for honey, fruit and vegetables, olive oil, fishery and aquaculture products, and beef. The FIC regulation extends the mandatory origin requirement to fresh, chilled, and frozen pork, sheep and goat meat and poultry. For additional information, please visit the FAS USEU website section on [EU labeling requirements](#) as well as the GAIN reports [“The EU’s Country of Origin Labeling Policy”](#) and [“EU Agriculture Ministers Divided Over National COOL Measures.”](#) Other products that could become subject to origin labeling at the national level include pulses, rice, or tree nuts.

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, by [Royal Decree 1181/2008](#) (Spanish language only), Spain enacted country of origin labeling for dairy¹ 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 the 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.”](#) [Royal Decree 24/2021](#) extended dairy country of origin labeling until January 22, 2023.

- **Nutrition Declaration**

Spain has not implemented yet any additional front-of-pack nutritional labeling schemes. However, large manufacturers marketing food products in Spain have already adopted the Nutri-Score labeling scheme on a voluntary basis.

- **Genetically Modified Foods Labeling**

Spain follows EU-harmonized legislation on labeling of Genetically Modified Food and Feed ([Regulation \(EC\) 1829/2003](#), and [Regulation \(EC\) 1830/2003](#) on the Traceability and Labeling of Genetically Modified Organisms). Spain does not have a “non-GMO” labeling regulation 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 total control over customs controls, the 17 autonomous communities establish their own monitoring and sampling plans throughout the food 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 by default labeled as “contains GE products.” Meanwhile, in the 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.” National legislation defining “non-GM,” “GM-free” or similar labeling terms does not exist.

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

- **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](#) (Spanish language only) as amended.

¹ 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.

- **Honey:** [Directive 2014/63/EU](#) amending [Directive 2001/110/EC](#) relating to honey was transposed to National Law by [Royal Decree 473/2015](#) (Spanish language only) amending [Royal Decree 1049/2003](#) on Honey Quality Standards.
- **Fruit Juices and Similar Products:** Directive 2001/112/EC amended by [Directive 2012/12/EU](#) regulates fruit juices and certain similar products intended for human consumption. Key amendments which affect 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](#) (Spanish language only). Detailed information on key changes introduced by the new directive can be found in [GAIN report “New EU Fruit Juice Labeling Rules.”](#)
- **Vertical & Product-Specific Legislation:** Vertical legislation on the manufacture and marketing of specific products has been developed. These Directives are often referred to as the “breakfast directives”:
 - **Sugars:** [Directive 2001/111](#) was transposed to Spanish law by [Royal Decree 1052/2003](#).
 - **Preserved milk:** [Directive 2001/114](#) was transposed to Spanish law by [Royal Decree 1054/2003](#).
 - **Coffee extracts and chicory extracts:** [Directive 1999/4](#) was transposed to Spanish law by [Royal Decree 243/2003](#).
 - **Fruit jams and similar products** [Directive 2001/113](#) was transposed to Spanish law by [Royal Decree 863/2003](#).
 - **Cocoa and chocolate products:** [Directive 2000/36](#) was transposed to Spanish law by [Royal Decree 1055/2003](#).

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](#)). These were transposed into Spain’s National Law by [Royal Decree 1801/2008](#) (Spanish language only).

- **Packaging Waste Management**

The European Union (EU) has longstanding rules on food packaging that date back to 1994 with [Council Directive 94/62/EC](#) that require EU Member States to introduce systems for reuse, recovery, and recycling of packaging materials. [Council Directive 94/62/EC](#) provides measures aimed at limiting the production of packaging waste and promoting recycling, reuse, and other forms of waste recovery. This Directive on packaging and packaging waste was transposed to Spanish Law by [Law 11/1997](#) (Spanish language only). [Directive 2018/851](#) on waste, the so-called Single Use Plastic (SUP)² Directive ([Directive \(EU\) 2019/904](#)) and [Directive 2018/852](#) on packaging and packaging waste are the EU regulatory basis for Member State level legislation.

² For further background on Single Use Plastics, please see GAIN Report: [European Union Single Use Plastics Directive Enters into Force](#).

- **Spain's Special Tax on Non-Reusable Plastic Packaging**

[Law 7/2022](#) on waste and contaminated soils transposed [Directive 2018/851](#) on waste, and partially transposed [EU Directive 2019/204](#) on single use plastic. [Law 7/2022](#) also updates the current regulations on waste and contaminated soils contained in [Law 22/2011](#). Among other measures, such as Extended Producers Responsibility (EPR), [Law 7/2022](#) introduces a special tax on non-reusable plastic packaging.

Additional information regarding this tax implementation is available in the GAIN Report [Special Tax on Non-Reusable Plastic Packaging Entered into Force in January 2023](#), as well as in [Law 7/2022](#) and [Ministerial Order HFP/1314/2022](#). Forms and practical implementation details are available in the [Spanish Treasury Website](#) (Spanish language only).

- **Reducing Packaging Related Waste**

Some provisions of [Directive \(EU\) 2019/904](#) to reduce the impact of certain plastic products on the environment, such as the ban on single-use plastics, went into effect on July 3, 2021. Other provisions in the Directive, such as extended producer responsibility, will take effect by the end of 2024.

[Royal Decree 1055/2022](#) sets targets and measures for the prevention, reuse and incorporation of recycled plastic, separate collection, recycling. It regulates EPR (Extended Producer Responsibility) for domestic, commercial, and industrial packaging, indicating the scope of costs to be assumed.

For more information about the upcoming legislative changes, please see GAIN Report [European Union Single Use Plastics Directive Enters into Force](#) and [European Commission Proposes New Rules on Packaging and Packaging Waste](#).

- **Materials in contact with foodstuffs**

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 1413/1994](#) (Spanish language only) regulates regenerated cellulose in contact with foodstuffs.
- [Royal Decree 891/2006](#) (Spanish language only) regulates ceramics in contact with foodstuffs and establishes migration limits for lead and cadmium.
- [Royal Decree 846/2011](#), (Spanish language only) regulates requirements for recycled polymers in contact with foodstuffs.
- [Royal Decree 847/2011](#) (Spanish language only) defines the positive list of polymeric substances allowed to be in contact with foodstuffs.

Member States can provisionally authorize the use of certain substances not listed in one of the specific directives. They may also restrict or temporarily prohibit the use of certain materials authorized by the specific directives for reasons of public health. When there is no specific EU legislation, Member States may establish national measures. Additional information regarding applications for authorization can be downloaded in the [link](#) (Spanish language only).

Section IV. Food Additives Regulations

Spain applies EU-harmonized legislation regarding **food additives, flavorings, and enzymes**. However, at the EU level, processing aids are regulated by [Directive 2009/32/EC](#) which was transposed by [Royal Decree 1101/2011](#) (Spanish language only). 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 (AESAN). Contact details are in **Appendix I**.

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

Section V. Pesticides and Other Contaminants

PESTICIDES

- **Authorization of Pesticides to be used in the EU**

[European Parliament and Council Regulation 1107/2009](#) sets out rules for the authorization of plant protection products (PPPs). PPPs (also referred to as 'pesticides') contain at least one approved active substance. Only PPPs containing active substances included in the list of approved active substances as established in [Commission Implementing Regulation 540/2011](#) may be authorized for use in the EU.

Before any PPP can be placed on the market or used, it must be authorized in the relevant Member State(s). According to Annex I of Regulation 1107/2009, the EU is divided in three different zones. Spain belongs to the EU zone “C.”

Once a Member State approves the PPP, it can be mutually recognized and thus authorized within the EU. Exporters can look up specific details on PPPs approved for use in a certain Member State in the [EU pesticide database](#). In Spain, information regarding PPPs authorized for use is available in the [Ministry of Agriculture database](#).

- **Maximum Residue Levels (applicable for EU and non-EU products)**

[European Parliament and Council Regulation 396/2005](#) harmonizes all MRLs in the EU on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients. A general default MRL of 0.01 mg/kg applies where a pesticide is not specifically mentioned. A list of authorized active substances or pesticide-MRL combinations is available in the European Commission’s [online database](#).

- **Import Tolerance**

If there is no EU legislation in place in the importing Member State, then the exporter can seek to obtain an "import tolerance" for active substances that have not been previously evaluated or used in Europe. Applications for import tolerances must be submitted to the “Rapporteur Member State” (RMS). The Commission assigns a Member State if no RMS exists. The RMS reviewed dossiers are evaluated by the EFSA before being forwarded to the Commission. Information on import tolerances is available in the [“Pesticide Use and Food Safety” guide](#) published by CropLife Europe. All MRLs, including import tolerances, apply EU wide since September 2008.

For application of an import tolerance for a not yet regulated substance in Spain, please contact the AESAN. Contact details can be found in **Appendix I**. Form available in the [link](#).

- **Sustainable Use of Pesticides**

As part of the “Pesticide Package,” [Directive 2009/128/EC](#) for the sustainable use of pesticides as amended by [Directive 2019/782](#) regarding the establishment of harmonized risk indicators was transposed to National Law by [Royal Decree 1311/2012](#) (Spanish language only) and amended by [Royal Decree 1050/2022](#). The authorization-registration of plant protection products remains the responsibility of Member States and depends on particularities of its climate-region. In Spain, [Royal Decree 971/2014](#) (Spanish language only) establishes the risk evaluation procedure in Spain.

As part of the Farm to Fork (F2F) strategy, the EU intends to reduce the use and risk of pesticides by 50 percent by 2030. The pesticide initiatives outlined in the F2F together with the reevaluation of the functioning and effectiveness of the EU legislation on plant protection products and pesticide residues (REFIT) lead to a revision of the Sustainable Use of Pesticides Regulation (SUR). Additional information is on the European Commission website on [Sustainable use of pesticides](#).

- **Competent Authorities in Spain**

- The Directorate General of Health of Agricultural Production (Ministry of Agriculture, Food and Environment) is responsible for the authorization and renewal of marketing of phytosanitary products. To apply 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 Directorate General of Quality, Environmental Assessment and Natural Environment (Ministry for the Ecological Transition and Demographic Challenge) focuses on environmental aspects.
- The Directorate General of Public Health (Ministry of Health) focuses on human health implications.
- AESAN (Spanish Agency for Consumption, Food Safety and Nutrition) ascribed to the Ministry of Health focuses on consumers’ associated risks.
- The Autonomous Regions are responsible for surveillance and control of maximum residue limits (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](#) (Spanish language only).

- **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 2022/741](#) outlines the latest version of the coordinated multi annual control program of the EU for pesticides residues. The control program 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 August 31, 2021, 2022, and 2023 for samples tested in 2020, 2021, and 2022 respectively. For more information see the European Commission [website](#). The Directive was transposed to National Law by [Royal Decree 290/2003](#) (Spanish language only) regarding sampling methods for pesticides residue control in food of plant and animal origin.

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 FAIRS Country 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](#) prohibiting the use of hormones in meat production were transposed to National Law by [Royal Decree 1749/1998](#) and [Royal Decree 1373/1997](#) (Spanish language only) as amended by [Royal Decree 2178/2004](#).

Since December 16, 2022, [Regulation \(EU\) 2017/625](#) provisions on residues of veterinary medicinal products apply.

For additional information on how to export food of animal origin to the EU, please see the EU's [Guidance on EU requirements for imports of products of animal origin – Monitoring for residues of veterinary medicines, pesticides and contaminants](#)

Section VI. Other Requirements, Regulations and Registration Measures

- **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 the [USEU site for U.S. agencies providing EU Certificate](#).

Since December 14, 2019, [Regulation \(EU\) 2016/2031](#) established protective measures against plant pests for the entire EU.

Notification of imports of non-fully harmonized food products should be addressed to Subdirección General de Sanidad Exterior. Notification of imports of non-fully harmonized products not 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 [FAIRS Certificate Report](#). Some examples of non-fully harmonized products include collagen casings, lanolin and gelatin and composite products.³

³ Composite products are defined as foodstuffs intended for human consumption that contain processed products of animal origin and ingredients of plant origin.

- **Product inspection**

At the national level, competent authorities on certificates vary depending on the type of products. While the Ministry of Health (MOH) is responsible for products intended for human consumption, the Ministry of Agriculture, Fisheries and Food (MAPA) is responsible for live animals and agricultural products for purposes other than human consumption.

Agricultural products are examined when they enter Spain by the Spanish Border Inspection Posts (BIP). There are a number of BIPs in Spain that carry out [plant health inspection](#) (MAPA) and veterinary inspection for [animal products not intended for human consumption](#) (MAPA), and for products [intended](#) for human consumption (MOH).⁴ Check the links 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. Although Spain has a decentralized system for the feed and food chain control, 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), which 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).

Section VII. Other Specific Standards

Novel Foods

[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 Consumo, 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.”](#)

⁴ A list of products intended for human consumption subject to sanitary control can be found in the [link](#) (Spanish language only).

Food Supplements

[EU Directive 2002/46/EC](#) 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](#) (Spanish language only) 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 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 that 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](#) (Spanish language only), according to which, only dried aromatic herbs, spices and vegetal seasonings can be treated with ionizing irradiation.

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](#) (Spanish language only) established the framework for Cooperation with the Islamic Commission in Spain. An Islamic Committee must 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.

Food Formulation

The Plan for the Improvement of the Composition of Food, Beverages and Other Measures presented by AESAN for the period 2017–2020, is intended to reduce added sugar, salt, and trans fatty acids content in food.

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. Trademarks registered at the national level are protected in one EU Member State. Applications must be submitted directly to the relevant national intellectual property (IP) office ([full list of national offices](#)). In Spain the legal basis for trademarks is laid down by National [Law 17/2001](#) (Spanish language only). 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 of 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**

Several food product names considered as generic in the U.S. are protected under EU law. Lists of protected names by country, product type, registered name and name applied for are available through the Commission's [eAmbrosia database](#). Specific information about Spain's registered products under this scheme can be found in the [link](#). For more information, please see GAIN Report: [European Commission Proposes Revision of Geographical Indications Legislation](#). The legislative proposal is still going through the legislative process but is expected to be finalized by the end of 2023.

Section IX. Import Procedures

The European Commission's webpage "[Access2Markets](#)" database provides information on tariffs, rules of origin, taxes, and additional duties, import procedures and formalities, product requirements, trade barriers, trade flow statistics.

- **Imports Control**

Since December 2019, [Regulation 2017/625](#), repealing [Regulation 882/2004](#), sets the rules for harmonized food controls. On March 17, 2023, Spain notified through Technical Regulations Information System (TRIS) ([Notification Detail | TRIS - European Commission](#)) a proposal of a Royal Decree to complement [Regulation \(EU\) 2017/625](#) on official controls. The deadline for comments finalized on June 19, 2023.

- **Import Duties**

The customs duties that must be paid upon import of a product depend on the tariff classification applicable to the product. EU's applicable duties information can be found in the [on-line customs data base](#). The [EU's 2023 Tariff Schedule](#) is applicable since January 1, 2023. In the case of Spain, Agencia Tributaria, ascribed to the Ministry of Treasury, is the customs authority 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), or entry price (fruit and vegetables).

Non-harmonized Inspection fees applicable to agricultural products under [MOH](#) and [MAPA](#) oversight can be consulted respectively through the links.

Other non-harmonized taxes include:

- [Value Added Tax](#) (VAT)
- Excise duties ([alcohol](#)⁵ and [tobacco](#)).

- **Special Tax on Non-Reusable Plastic Packaging**

[Law 7/2022](#) law aims at reducing the impact of certain plastic products on the environment. Among the fiscal measures to promote a circular economy, this law introduced a special tax on non-reusable plastic packaging that entered into force on January 1, 2023. This law also applies to imported food products. For imports, payment of the tax is the responsibility of the importer, although third country manufacturers must provide their Spanish buyers with information regarding the amount of non-recyclable plastic packaging used in their products' packaging.

For additional details, please, see GAIN Report [Special Tax on Non-Reusable Plastic Packaging Entered into Force in January 2023](#).

- **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.

⁵ Since February 2023, [Council Directive 92/84/EEC](#) as amended by [Directive 2020/1151](#) sets out common definitions of alcoholic products that are subject to excise duty and ensure that all Member States treat the same products in the same way. The excise legislation also establishes the minimum rates of tax that must be applied for each category, but Member States can decide to set rates at a higher level.

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](#).

Section X. Trade Facilitation

- **Advance Rulings**

The Binding Tariff Information (BTI) system was introduced to ensure legal certainty for business operators when calculating import duties. All BTI decisions issued by the Member States’ customs authorities are entered into an [BTI-database](#). In the case of Spain, Agencia Tributaria, ascribed to the Ministry of Treasury, is the responsible entity. For contact details see Appendix I.

- **Duplicative Inspections**

Inspections on imported foods are concentrated at the external borders of the European Union. Once goods have passed inspection and customs duties are paid, they can move freely throughout the EU. However, official controls remain possible at any stage of distribution in the EU.

The Spanish Consumption, Food Safety and Nutrition Agency (AESAN), ascribed to the Ministry of Consumption, coordinates the food chain control. Due to Spain's decentralized governmental structure, testing and controlling are carried out at the regional level, while the central government maintains authority over 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 assessments, and it is primarily conducted at the wholesale and the processing level. Spain uses the [Rapid Alert System for Food and Feed \(RASFF\) database](#) to report food safety issues to consumers, the trade, and other Member States.

Appendix I. Government Regulatory Key Agency Contacts

Ministry of Health

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

Ministerio de Sanidad

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

Ministry of Consumption

Spanish Consumption, Food Safety and Nutrition Agency

Agencia Española de Consumo, 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

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 6969

[Website link](#)

E-mail: sgacuerdos@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 6969

[Website link](#)

E-mail: sgacuerdos@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: mpayoevv@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 4058/8274

Fax: +34 91 347 4087

[Website link](#)

E-mail: sgmpagri@mapa.es

Ministry of Agriculture, Fisheries and Food

Organic Farming

Ministerio de Agricultura, Pesca y Alimentación

Subdirección General de Calidad y Sostenibilidad Alimentaria

C/ Almagro, 33

28071 Madrid

Tel.: +34 91 347 5346

[Website link](#)

E-mail: sgcsa@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

EU Trademark Register

Office for Harmonization in the Internal Market

Avenida de Europa, 4

03008 Alicante

Tel.: +34 96 513 9100

Fax: +34 965 131 344

[Website link](#)

E-mail: information@euipo.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

[Website link](#)

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

[Website link](#)

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
[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 Inspección, Certificación y Asistencia Técnica del Comercio Exterior
Paseo de la Castellana, 162, 6a planta
28046 Madrid
Tel: +34 91 349 37 54
E-mail: sgsoivre.sccc@mincotur.es
[Website link](#)

Ministry of Industry, Trade and Tourism

Ministerio de Industria, Comercio y Turismo
Secretaría de Estado de Comercio
Subdirección General de Comercio Internacional de Mercancías
Paseo de la Castellana, 162, 6a planta
28046 Madrid
Tel: +34 91 349 37 80
Fax: +34 91 349 38 06
[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
[Website link](#)

Appendix II. Other Import Specialist Technical Contacts

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

2175 K 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
[Website link](#)

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](#)

Association of Spanish Supermarket Chains (ACES)

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

Spanish Association for Distributors and Supermarkets (ASEDAS)

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

National Association of Large Distributors (ANGED)

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

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

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

Appendix III. Instructions for Exporters of FDA Regulated Products Certified by Other Agencies

For detailed information on FDA regulated products certified by Other U.S. agencies, please consult the latest [EU FAIRS Country Report](#).

Attachments:

No Attachments