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Report Highlights:

This report is an update of GAIN report SP2019-0049. 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 Report. Compared to 2019, this report contains updated links to relevant information sources and contacts, 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.

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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.

- **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 Food Safety and Nutrition Agency (AESAN), ascribed to the Ministry of Consumption, coordinates the food chain control. However, 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**
  **Appendix II. Other Import Specialist Technical Contacts**
Executive Summary

As an EU Member State since 1986, Spain observes all EU directives, regulations, and obligations, which are either directly appliable or need to be transposed to national law. This report outlines requirements specific to Spain that differ from EU legislation. This report should be read in conjunction with the EU Food and Agricultural Import Regulations and Standards Report.

Over 50 percent of Spain’s agricultural imports are sourced from other EU Member States. In 2019, the United States was the second largest supplier of agriculture and related products outside of the EU, after Brazil. Spain’s total agricultural and related imports from the United States reached nearly $1.8 billion out of a total agricultural import figure of $44 billion. U.S. agricultural exports to Spain consist mainly of bulk commodities and consumer-oriented products, which accounted for 36 and 43 percent of the U.S. exports value during 2015-2019. Soybeans and tree nuts are the largest commodities within these export categories representing 23 and 40 percent of total U.S. agricultural trade, respectively (Graph 1).

Up to 2019, Spain’s record number of tourists, along with its strong food service sector and its competitive food processing industry provided with growing opportunities for imported ingredients and consumer-ready products. In 2019, U.S. exports of consumer-ready products to Spain grew 13 percent, hitting a record value of $879 million. However, positive economic prospects came to a halt in Spring 2020 when Spain declared a nationwide State of Alarm in response to the COVID-19 pandemic. Travel and gathering restrictions imposed have tempered economic activity particularly discouraging domestic demand for products sold through the hospitality sector.

Graph 1 U.S. Agricultural Exports to Spain in value

Source: FAS Madrid based on Trade Data Monitor, LLC data.
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) 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.

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 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) (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, 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 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 Food Safety and Nutrition Agency (AESAN), under 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 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.

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 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 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.

- 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 (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 country of origin labeling as well as GAIN report “The EU’s Country of Origin Labeling Policy” and EU: 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, by Royal Decree 1181/2008 (Spanish language only), Spain enacted country of origin labeling for dairy\(^1\) 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”. The Ministry of Agriculture recently announced its plans to extend dairy country of origin labeling until January 2023.

The EU Commission ‘Farm to Fork Strategy’ released in May 2020, foresees regulatory changes impacting food labeling legislation in the next five years. New requirements that intend to increase consumers level of awareness to make informed decisions would include aspects such as: food sustainability, labeling, animal welfare labeling, additional origin labeling, marketing standards for fishery and aquaculture products, nutrient profiles and mandatory front of pack nutrition labeling.

- **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:

- **Beef**
- **Cocoa & Chocolate Products**
- **Coffee & Chicory Extracts**
- **Dietetic or Special Use Foods**
- **Fortified Foods**
- **Wine**
- **Fruit Juice**
- **Genetically Modified Food and Feed**
- **Nutrition and Health Claims**
- **Organic Products**
- **Sugars**
- **Fruit Jams, Jellies & Marmalades**
- **Honey**
- **Wholly Dehydrated Preserved Milk**

\(^{1}\) 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.
For additional information on EU labeling requirements, please visit the FAS USEU website section on labeling requirements.

- **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.

- **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 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 (Spanish language only) 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 AESAN’s website.

- **Frozen Foodstuffs**


- **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 (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.”

- **Honey**

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


• Materials in contact with foodstuffs

European Parliament and Council Regulation 1935/2004 specifies the main requirements for all materials in 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 (Spanish language only) 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 (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 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 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 introducing plant protection products on the market replaced Directive 91/414/EEC. This piece of regulation, applied since June 14th, 2011, defines zonal authorizations. Spain is included in the Zone C (South) along with Bulgaria, Cyprus, France, Greece, Italy, Malta and Portugal. Commission implementing Regulation 540/2011 establishes a list of approved active substances. The “Pesticide Package” also contains Directive 2009/128/EC for the sustainable use of pesticides, which was transposed to national law by Royal Decree 1311/2012 (Spanish language only).

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 (Spanish language only) establishes the risk evaluation procedure in Spain.

• The Ministry of Agriculture, Fisheries and Food, is responsible for the product registration. 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 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 (Spanish language only).

• 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 “Pesticide Use and Food Safety” guide published by the European Crop Protection Association (ECPA). 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.

- **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. Some of the recommendations from the PEST Committee’s final report were also used for the final REFIT report. The European Commission adopted the final report, which outlines the main findings, on May 20, 2020 concluding the REFIT of the EU pesticide legislation.

The EU’s F2F and Biodiversity Strategies aim a 50 percent reduction of the use and risk of pesticides by 2030. For more information, check the GAIN report on the Pesticide Initiatives in the Farm to Fork Strategy.

- **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. 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 Report as well as the USEU website section on contaminants.
• **Residues in Animal Products**


For additional information on how to export food of animal origin to the EU, see:

• **Imports of food of animal origin from non-EU countries: Provisions of guarantees equivalent to EU requirements on residues of veterinary medicines, pesticides and contaminants**

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 at [http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/](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 VII “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/.

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 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. Some examples of non-fully harmonized products include collagen casings, lanolin and gelatin and composite products².

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. The components of animal origin (except gelatin and collagen) used for producing a composite product must originate from a third country with an approved residue control plan for the specific component. A detailed “Product Decision Tree” to clarify the scope of the legislation was made available by the European Commission in 2013.

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² Composite products are defined as foodstuffs intended for human consumption that contain processed products of animal origin and ingredients of plant origin.
The current certification requirements for composite products will continue to apply until April 21, 2021. Following changes in several related pieces of EU legislation, after that date entry requirements will no longer be based on percentage of ingredients of animal origin but rather on the animal health or public health risk linked to the composite product itself.

The new system that is scheduled to go into effect on April 21, 2021 establishes three categories of composite products:

- Non shelf stable composite products
- Shelf stable composite products that contain meat products
- Shelf stable composite products that do not contain meat products.

Entry requirements will be different for each of these three categories but have not been published yet.

- **Product inspection**


All consignments to be presented at the border control posts must undergo documentary checks. Identity and physical checks are carried out at a frequency depending on the risk linked to the specific animals or goods. The criteria to determine and modify the frequency of rates are established by the Commission. The list of products subject to official controls at border posts was updated with effect from Dec 14, 2019 in [Commission Implementing Regulation (EU) 2019/2007](https://eur-lex.europa.eu). For more information about new requirements, please see the [EU FAIRS Certificate Report](https://eur-lex.europa.eu).

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 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 (BIP) 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). 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. 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).

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


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 (Spanish language only). 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 (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 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 (Spanish language only), according to which, only dried aromatic herbs, spices and vegetal seasonings can be treated with ionizing irradiation.
Medicated feed


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.

For detailed information on the EU-harmonized legislation on other specific standards, please consult the EU 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.

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 (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 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. In October 2019, the Council of the EU adopted Council Decision (EU) 2019/1754 approving the EU’s accession to the “Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications.” This membership enables the EU to obtain protection for its GI’s in all 30 contracting parties to the Lisbon Agreement. Practical details on the implementation od the Lisbon Agreement in the EU are laid in Regulation 2019/1753. 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.”

Wines and Spirits are covered by specific legislation (Commission Regulation 2019/33 and Commission Regulation 2019/34 which outline detailed rules on designations of origin and geographical indications, traditional terms and labeling, and set out rules on the use of traditional terms) and do not fall within the scope of Regulation 1151/2012. The new EU database for food, 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

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 2020 Tariff Schedule was published on October 31, 2019 in the Official Journal.

The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading. 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).
Note: The Government of Spain has announced its intention to increase the VAT rate on sweetened drinks from 10 to 21 percent in 2021. The measure is intended to contribute to a healthier lifestyle, especially for minors.

• **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.

Section X. Trade Facilitation

- **Advance Rulings**

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.

The 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 EBTI-database. Administrative guidelines on the new BTI-system are published on DG Taxud’s website. As of October 1, 2019, business operators shall introduce all new applications electronically. More information is available on the EC’s website.

- **Import Control Fees**

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

- Inspection fees for animal products intended for human consumption can be consulted in the link (Spanish language only).
- Inspection fees for non-animal feed ingredients can be consulted in the link (Spanish language only).
- Inspection fees for live animals can be consulted in the link (Spanish language only).
- Inspection fees for animal products not intended for human consumption can be consulted in the link (Spanish language only).
• 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 Food Safety and Nutrition Agency (AESA), ascribed to the Ministry of Consumption, coordinates the food chain control. However, 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 Food Safety and Nutrition Agency
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: informacionaes@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

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
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 Comercio Internacional de Mercancías
Paseo de la Castellana, 162, 6a planta
28046 Madrid
Tel: +34 91 349 37 54
E-mail: sgsoivre.sscc@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
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
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@asociacionesupermercados.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

Attachments:
No Attachments