

Product Regulation and Safety: Overview (Spain)

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A Practice Note providing an overview of Spain's product safety and regulation for foreign retailers, distributors, manufacturers, or suppliers of goods. This Note offers information regarding product safety laws and regulations, industry-specific considerations, disclosure requirements, and enforcement in Spain.

Consumer products are highly regulated, which makes product safety and compliance an essential consideration in the global product development, distribution, and retail process. Product safety regulation typically aims to balance consumer protection with innovation and competition. In Spain, product safety regulation poses a variety of issues that product manufacturers, importers, distributors, and retailers (in principle, where they appear on the labelling of the product), must be aware of when:

- Introducing a new product into Spain.
- Developing a product safety compliance programme.
- Facing a product safety hazard situation.

For example, in Spain, defective products placed on the market give rise to liability, unless the risks of those products were already known by the injured party (the theory of assumed risks). This can apply to manufacturers, importers of products manufactured outside the EU, and the company identified on the labelling of the product or packaging.

This Note discusses:

- The legal and regulatory requirements governing product safety in Spain, including:
 - regulatory agencies;
 - key legislative acts;
 - industry-specific regulation; and
 - basic requirements for compliant products.
- Key compliance considerations related to products imported into, manufactured, or sold in Spain, including:
 - product manufacturing requirements and testing;
 - identifying and addressing key areas of risk;
 - product hazard or defect disclosure requirements; and
 - corrective action.

- Enforcement of product safety issues in Spain, including:
 - sanctions; and
 - penalties.

Product Safety Legislation and Regulation

In many countries, laws exist that are applicable to all consumer products regardless of industry. Specific types of products may be subject to further regulation and government oversight.

In Spain, the sources of consumer law applicable to consumer products are:

- State, autonomous community and EU regulations.
- Court decisions.

Regulations include:

- General state consumer law.
- Sectoral consumer law.

Articles 43 and 51 of the [Spanish Constitution](#) oblige public authorities to guarantee the safety of their citizens, making them responsible for protecting public health.

The regulatory framework is made up of:

- The [Consumers and Users Defence Act](#), which means royal legislative decree 1/2007, of 16 November, approving the restated text of the Consumers and Users Defence General Act and other supplementary acts (*real decreto legislativo 1/2007, de 16 de noviembre, por el que se aprueba el texto refundido de la Ley General para la Defensa de los Consumidores y Usuarios y otras leyes complementarias*).
- Other general regulations, such as:
 - the [Retail Trade Management Act](#), which means law 7/1996, of 15 January, on the regulation of retail trade (*Ley 7/1996, de 15 de enero, de Ordenación del Comercio Minorista*);
 - the [General Law on Advertising](#), which means law 34/1988, of 11 November 1988 on general advertising (*Ley 34/1988, de 11 de noviembre, General de Publicidad*);
 - the [General Contracting Conditions Act](#), which means act 7/1998, of 13 April, on general contracting conditions (*Ley 7/1998, de 13 de abril, sobre condiciones generales de la contratación*);
 - [Royal Decree 1801/2003](#), of 26 December, on general product safety (*Real Decreto 1801/2003, de 26 de diciembre, sobre seguridad general de los productos*); and
 - other sectoral regulations depending on the product in question.

- National laws on health and safety, such as:
 - [Law 17/2011](#), of 5 July, on food safety and nutrition (*Ley 17/2011, de 5 de julio, de seguridad alimentaria y nutrición*);
 - [Royal Decree 1945/1983](#), of 22 June, which regulates offences and penalties in matters of consumer protection and agri-food production (*Real Decreto 1945/1983, de 22 de junio, por el que se regulan las infracciones y sanciones en materia de defensa del consumidor y de la producción agro-alimentaria*);
 - [Royal Decree 820/1990](#), of 22 June, which prohibits the marketing and manufacture of products with a misleading appearance that endanger the health or safety of consumers (*Real Decreto 820/1990, de 22 de junio, por el que se prohíbe la fabricación y comercialización de los productos de apariencia engañosa que pongan en peligro la salud o seguridad de los consumidores*); and
 - [Royal Decree 227/2014](#), of 4 April, which approves the Statute of the Food Information and Control Agency (*Real Decreto 227/2014, de 4 de abril, por el que se aprueba el Estatuto de la Agencia de Información y Control Alimentarios*).

In addition, there are various regulations at regional and EU level, based on the provisions of Article 12 of the [Treaty on the Functioning of the European Union \(TFEU\)](#).

The body of sectoral legislation is comprehensive. This is due, to a considerable extent, to the adoption of the *acquis communautaire* following Spain's accession to the then European Community, and subsequent transposition of many Community provisions aimed at protecting consumers and users. Consumer protection is an issue that originated within the EU, with the Paris Summit of 1972. As a result, a series of Community programmes and directives have been approved in this area. The most important of these is the [General Product Safety Directive \(2001/95/EC\)](#).

Additional regulations apply to specific types of products, such as, toys, vehicles, food, medicines, or cosmetics (see [Industry-Specific Product Regulation](#)).

Consumers and Users Defence Act

The Consumers and Users Defence Act contains provisions regarding general product safety:

- Article 11 establishes a general duty of safety for products or services that are placed on the market (see [Contract: Express and Implied Terms](#)).
- Article 12(1) requires businesses to inform consumers, before contracting, of the risks likely to occur when using the goods and services that these businesses place on the market (see [Contract: Express and Implied Terms](#)).
- Article 12(2) requires chemical products and all items containing substances classified as hazardous to be packaged with the necessary safety guarantees, and carry the appropriate warnings regarding risk of use, in a prominent place.
- Article 18 regulates the labelling and presentation of goods and services.
- Article 14 sets guidelines for the content of the regulations governing the different goods and services to ensure the health and safety of consumers.

- Article 13 includes a set of specific obligations for entrepreneurs within the limits of their respective activity, aimed at protecting the health and safety of consumers. These include:
 - a prohibition on holding or storing products that are not permitted, or are prohibited, by regulations, in premises or facilities for the production, processing, storage or transport of food or beverages; and
 - maintaining the necessary control, so that the origin, distribution, destination and use of potentially unsafe goods, containing substances classified as hazardous or subject to traceability obligations, can be checked quickly and efficiently.

Product Requirements, Approvals, Registrations, and Certifications

In Spain, the basic legislation on product safety is found in [Royal Decree 1801/2003](#). This regulation transposes the [General Product Safety Directive](#).

If there are no relevant national regulations, the following apply:

- [UNE](#) (Spanish Association for Standardisation) standards.
- European Commission recommendations establishing guidelines on product safety assessment.
- Codes of good practice on product safety.
- The current state of knowledge and technology.
- The product must comply with the requirements, such as tests, registrations, licences, certifications or approvals, laid down in the relevant regulations for the type of product concerned. However, Royal Decree 1801/2003 establishes a presumption that the product is not safe if:
 - An authorisation is required for its commercialisation, but this is not obtained.
 - The manufacturing facilities do not hold an authorisation required by the corresponding legislation.
 - The product is also presumed to be unsafe when it does not have a mandatory safety mark, or lacks the manufacturer's identification data which must appear on the product labelling.

Manufacturer Safety Obligations

- Royal Decree 1801/2003 establishes a series of general obligations on manufacturers, the most important of which is to ensure the safety of the products they place on the market. These obligations for manufacturers include:
 - Informing consumers of risks which are not perceptible without adequate warnings, and which may arise from normal or foreseeable use of the products, taking into account their nature, durability and the persons for whom they are intended (Article 4, Royal Decree 1801/2003).
 - Remaining informed of the risks that their products may present.
 - Informing consumers of risks as necessary.

- In the case of indications that a product they have placed on the market could be unsafe for the consumer, taking appropriate measures to protect consumers, including:
 - informing consumers by publishing special warnings, where appropriate;
 - withdrawing the products from the market; or
 - initiating a recall.

Distributor Safety Obligations

- Royal Decree 1801/2003 also establishes a series of general obligations on distributors, the most important of which is to distribute only safe products. This generic obligation implicitly entails avoiding supplying products when distributors know, or should know, do not meet this requirement. Additionally, distributors must contribute to the safety requirements during storage, transport and display of products. (Article 5, Royal Decree 1801/2003.)
- Distributors must participate in the surveillance of the safety of products placed on the market, in particular by:
- Informing the competent administrative bodies and the manufacturers of the risks of which they are aware.
- Keeping and providing, for three years, the documentation necessary to trace the origin of the products, the identity of their suppliers, and their destination, if they are not retailers. If the competent authorities request this information, the distributors must provide it.
- When a risk incompatible with the duty of safety is detected in a product, both the manufacturer and the distributor must collaborate with the competent authority (see [Disclosure Obligations](#)).

European Union Safety Obligations

At consumer level, the EU has developed a system that allows the purchasers of certain products to have the guarantee that the product complies with the harmonised safety requirements established by the EU. This is done using "CE" marking, a certification that must be carried by products manufactured in Community territory that fall within the scope of application of one of the [new approach directives](#). These directives regulate, among other products, toys, construction products or products with electromagnetic compatibility. Failure to bear the CE marking, when required to do so, will result in the product being classified as unsafe.

Depending on the industry, some products, such as foodstuffs or medicinal products, need prior administrative approval to be put on the market. Under the [General Health Act](#), which means Law 14/1986, of 25 April (*Ley 14/1986, de 25 de abril, General de Sanidad*) and its specific regulations, this varies depending on the product and its consumers, and is time-limited in the majority of the cases.

Industry-Specific Product Regulation

There are certain products that, due to their special nature or potential danger, have restrictions on their commercialisation, and have special safety, commercialisation or manufacturing requirements.

Foodstuffs

The EU has regulated food safety in different regulations, among which are those that make up the Hygiene Package, consisting of the following Regulations:

- [Regulation \(EC\) 178/2002](#), laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- [Regulation \(EC\) 852/2004](#) on the hygiene of foodstuffs.
- [Regulation \(EC\) 853/2004](#) laying down specific hygiene rules for food of animal origin.
- [Regulation \(EC\) 854/2004](#) and [Regulation \(EC\) 882/2004](#), both repealed and replaced by [Regulation \(EU\) 2017/625](#) of the European Parliament and of the Council
- [Regulation \(EC\) 183/2005](#) laying down requirements for feed hygiene.

Additional Regulations include:

- [Regulation \(EC\) 2073/2005](#) regulating microbiological criteria for foodstuffs.
- [Regulation \(EEC\) 315/93](#) laying down Community procedures for contaminants in foodstuffs.
- [Regulation \(EU\) 16/2011](#) laying down implementing measures for the Rapid Alert System for foodstuffs and feed.
- [Implementing Regulation \(EU\) 2019/1715](#) laying down rules for the operation of the management system for information on official controls and its components (SGICO Regulation).

At national level, food safety is regulated by Law 17/2011. The competent authority is the [Spanish Agency for Food Safety and Nutrition](#) (AESAN). At the EU level, the [European Food Safety Authority](#) (EFSA) is the public entity in charge of food safety control. In the event of a crisis, it assists the Commission and is a key element in the risk analysis process. Its role is advisory, and it acts at the request of the Commission or a member state, but it can also act on its own initiative.

These are ultimately independent bodies responsible for the formulation of scientific opinions on all aspects of food safety, the management of rapid alert systems and risk communication. They act on the basis of the principles of excellence, independence, transparency and comprehensiveness.

Medicinal Products

Other products with special safety, marketing or manufacturing requirements include medicinal products, defined as:

"any substance or combination of substances presented as having properties for treating or preventing disease in human beings or which may be used in human beings or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" (Article 2(a), [Royal Legislative Decree 1/2015](#), of 24 July, which approves the revised text of the Law on guarantees and rational use of medicines and medical devices (*Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios*)).

In Spain, no medicinal product may be marketed without prior authorisation by the competent authority. The authorisation procedure can be carried out before the national authority, the [Spanish Agency for Medicines and Health Products](#) (AEMPS),

in which case the product can only be marketed in Spain, or before the [European Medicines Agency](#) (EMA), in which case it can be marketed in all EU member states.

At the national level, [Royal Legislative Decree 1/2015](#) is responsible for regulating the process as well as other safety guarantees, such as the registration of any medicine intended to be marketed in the [Medicines Register](#). [Royal Decree 1345/2007](#), which regulates the procedure for the authorisation, registration and conditions of dispensing of industrially manufactured medicinal products for human use (*Real Decreto 1345/2007, de 11 de octubre, por el que se regula el procedimiento de autorización, registro y condiciones de dispensación de los medicamentos de uso humano fabricados industrialmente*), establishes additional safety requirements.

Automotives

The entry into force of [Regulation \(EU\) 2019/2144](#) (on type-approval requirements for motor vehicles and their trailers and systems, components and separate technical units intended for such vehicles) brings with it special safety requirements for cars in categories M, N and O, such as ADAs (advanced driver-assistance systems), including the intelligent speed assistant, the interface for the installation of anti-idling breathalysers, the driver drowsiness and loss of attention warning system, the advanced driver distraction warning system and the emergency braking signal, among others. The Commission is also empowered to adopt delegated acts in relation to the type-approval of vehicles and safety systems, with the support of the Technical Committee on Motor Vehicles.

Electronic Equipment, Batteries and Accumulators

Other regulations apply for electrical and electronic equipment, such as:

- [Royal Decree 219/2013](#), of 22 March, on restrictions on the use of certain hazardous substances in electrical and electronic equipment (*Real Decreto 219/2013, de 22 de marzo, sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos*).
- [Law 7/2022](#), of 8 April, on waste and contaminated soils for a circular economy (*Ley 7/2022, de 8 de abril, de residuos y suelos contaminados para una economía circular*).
- The [REACH Regulation](#) ((*EC*) 1907/2006).
- [Royal Decree 993/2022](#) of 29 November, which adopts control measures for the import of electrical and electronic equipment, batteries and accumulators from third countries (*Real Decreto 993/2022, de 29 de noviembre, por el que se adoptan medidas de control para la importación de aparatos eléctricos y electrónicos, pilas y acumuladores procedentes de terceros países*).

[Royal Decree 993/2022](#) establishes the procedures for the control and inspection of electrical and electronic equipment (EEE), and batteries and accumulators from foreign countries prior to their release for free circulation in the EU. The [Official Service for the Inspection, Surveillance and Regulation of Exports](#) (SOIVRE) of the Territorial and Provincial Trade Directorates controls and inspects EEE prior to release for free circulation, to ensure compliance with the rules on restrictions on the use of hazardous substances in EEE, among other products.

Contract: Express and Implied Terms

There is no legal obligation to include express clauses in the contract with supply chain partners. However, it may be useful to analyse the nature of each product in case it is dangerous, and include specific details about the product in the contract. Therefore, it is common to include statements on the regulation of products (such as the legal obligation to market safe products), and clauses limiting liability, within the established legal framework. When products are traded, implicit assumptions are made about compliance with the regulations applicable to the particular product.

The Consumers and Users Defence Act contains terms on how products must be marketed in Spain. There is a general duty of safety, requiring all goods or services placed on the market to be safe. Goods or services are considered safe when, under normal or reasonably foreseeable conditions of use, including their duration, they do not present any risk to the health or safety of persons, or only the minimum risks compatible with the use of the good or service, and considered acceptable within a high level of personal health and safety protection (Article 11 Consumers and Users Defence Act). This article has resulted in numerous judicial interpretations.

The key lies in the information that the consumer receives about the product. The law establishes that "entrepreneurs shall inform the consumer and user in advance, by appropriate means, of the risks likely to arise from the foreseeable use of the goods and services, taking into account their nature, characteristics, duration and the persons for whom they are intended" (Article 12(1), Consumers and Users Defence Act). Appropriate means are considered on a case-by-case basis, taking into account the nature, characteristics and duration of the goods and services, and the persons for whom they are intended, in accordance with Article 18 and the applicable regulations. This is a preventive measure for the integrity of the health and safety of consumers.

Spanish consumer associations have filed numerous claims in recent years on the basis of Directive 93/13/EEC on unfair terms in consumer contracts, seeking a declaration of nullity for non-negotiated contract terms that are found to be unfair and therefore contrary to consumers' rights. The relief sought in these claims is the removal of the unfair term from the defendant's model contract. While a declaration of the nullity of unfair terms is binding for the defendant company as against all of its clients, most Spanish courts take the view that each consumer must individually claim compensation for damages arising from the execution of the unfair term by the defendant.

However, some courts take the position that reimbursement to consumers of payments made to the defendant under the unfair term is not a compensation issue. Instead, it is a direct consequence of the declaration of nullity of the term and, therefore, no further individual action is required, and reimbursement should form part of the relief granted in the collective action.

Product Packaging and Labelling

Product Packaging

In Spain, packaging is generally regulated by two recently approved regulations:

- [Law 7/2022](#).
- [Royal Decree 1055/2022](#), of 27 December, on packaging and packaging waste (*Real Decreto 1055/2022, de 27 de diciembre, de envases y residuos de envases*).

These transpose Directives 2018/851 and 2019/904 of the European Parliament and of the Council into national legislation.

These regulations establish a series of requirements to be met by all types of packaging. This includes:

- Maximum limits for heavy metals, such as lead and cadmium (Article 12(2), Royal Decree 1055/2022).
- Prohibition and restriction on the use of certain specific materials (Article 56, Law 7/2022).

Packaging must be:

- Manufactured in such a way that its volume and weight is the minimum acceptable level of safety and hygiene necessary for the packaged product and the consumer.
- Designed, manufactured and marketed in conditions that allow its reuse or recovery, including recycling, in such a way as to minimise the environmental impact of waste disposal.
- Composed and manufactured in such a way as to minimise the use of harmful or hazardous substances and materials.

(Annex III, Royal Decree 1055/2022.)

In addition, packaging must indicate its reusable status when it is reusable. Manufacturers who place reusable packaging on the market must:

- Charge customers a deposit for each package (Article 46 (1.a), Royal Decree 1055/2022).
- Accept the return of used packaging placed on the market by returning the same amount charged (Article 46 (1.b), Royal Decree 1055/2022).

This system is known as the deposit, refund and return system for household packaging for reusable packaging. Packaging subject to this system must be clearly distinguishable.

Packaging may be marked to identify the material from which it is made in accordance with the abbreviations set out in the Annexes to [Commission Decision 97/129/EC](#). In addition, single-use plastic packaging must comply with the marking specifications of [Commission Implementing Regulation \(\(EU\) 2020/2151\)](#) laying down rules on harmonised marking specifications on single-use plastic products.

In Spain, product manufacturers must register in the packaging section of the [Product Producers Register](#), and report annually, through this Register, the quantities in weight by type of material of the packaging they place on the market, and the number of units. They must break down packaging into the different categories, differentiating between single-use or reusable, in accordance with the options in the Register. However, in some cases, manufacturers, importers or purchasers of packaging can assume this obligation.

Under Spanish and EU legislation, chemical products and all articles containing substances classified as hazardous must be packaged with the appropriate safety guarantees, and must be visibly marked to warn of the risks involved in handling them (Article 18, [Royal Decree 363/1995 of 10 March 1995](#), approving the Regulation on the notification of new substances and the classification, packaging and labelling of dangerous substances (*Real Decreto 363/1995, de 10 de marzo, por el que se aprueba el Reglamento sobre notificación de sustancias nuevas y clasificación, envasado y etiquetado de sustancias peligrosas*); Article 35, [CLP Regulation](#)).

Plastic Packaging

Law 7/2022 introduces a tax on non-reusable plastic packaging. This is an indirect tax levied on the use in Spain of non-reusable packaging containing plastic, whether it is empty or whether it is used to contain, protect, handle, distribute and present goods. For the purposes of this tax, packaging is considered to be:

- Any product intended to contain, protect, handle, distribute and present goods, such as plastic cups or plastic rolls for packaging, or to prevent breakage during transport.
- All products included in the definition in Article 2 of Law 7/2022.

Food or beverages are subject to special rules aimed, above all, at complying with plastic waste reduction policies. For example, from 2023, single-use plastic products such as beverage cups or containers of food that is intended to be consumed in the same container or that do not need to be prepared must be charged separately.

Product-Specific Packaging Requirements

There are rules governing the packaging of certain specific products, usually because of the potential hazard of the product. For example, under Spanish and EU legislation, chemical products and all articles containing substances classified as hazardous must be packaged with the appropriate safety measures. The design of both the packaging and its closure must ensure that no contents are accidentally lost, and the packaging must be visibly marked to warn of the risks involved in handling the product.

Packaging must also be made of strong and solid materials, to avoid risks when handling, and which do not present a hazardous combination with the contents of the packaging. In some cases, depending on the contents, the packaging must be fitted with a child-resistant closure or bear a tactile warning. (Article 8, [Royal Decree 255/2003](#) of 28 February 2003 approving the Regulation on the classification, packaging and labelling of dangerous preparations (*Real Decreto 255/2003, de 28 de febrero, por el que se aprueba el Reglamento sobre clasificación, envasado y etiquetado de preparados peligrosos*); Article 35, [CLP Regulation \(\(EC\) 1272/2008\)](#).)

Product Labelling

A product's label presents the product and fulfils two main functions:

- To inform the consumer about its composition.
- To identify the manufacturer or distributor in the event of any type of damage and, if, as a result, it is necessary to determine liability.

Retailers and distributors, as applicable, have a duty of diligence, and must control the labelling of the products they market. Therefore, they cannot rely on ignorance to evade responsibility for the labelling of the product sold. Spain relies on the *pro consumatore* principle (Article 11(2), Consumers and Users Defence Act), which implies that the law will always be interpreted in the most favourable way for the consumer. Any exceptions should be subject to strict interpretation.

The EU does not have any rules governing labelling in general. In Spain, the Consumers and Users Defence Act establishes the minimum labelling requirements for all products, namely:

- Name and full address of the manufacturer.
- Nature, composition and purpose.
- Quality, quantity, class, grade or usual or commercial designation, if any.
- Date of production or supply and batch, where required by regulation, recommended period of use or consumption or expiry date.
- Instructions or indications for its correct use or consumption, as well as the correct sustainable management of its waste, warnings and foreseeable risks.
- Information on information and customer services and the procedures for lodging complaints and claims.

(Article 18, Consumers and Users Defence Act.)

Sectoral legislation specifies further compulsory statements to be included on the product label for certain products.

Foodstuffs Labelling

The [Food Information to Consumers Regulation \(\(EU\) 1169/2011\)](#) considers a label to be a "tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food." It defines labelling as the "words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food."

Food information is "information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication," while mandatory food information includes "particulars that are required to be provided to the final consumer by Union provisions."

In the case of foodstuffs, there are numerous rules, both at EU and national level, which regulate labelling. For example, the Food Information to Consumers Regulation, and [Royal Decree 1334/1999](#), of 31 July, approving the General Standard on labelling, presentation and advertising of foodstuffs (*Real Decreto 1334/1999, de 31 de julio, por el que se aprueba la Norma general de etiquetado, presentación y publicidad de los productos alimenticios*).

These rules set up a general legal framework for foodstuffs, and there are other rules establishing specific rules for certain types of food such as beef and organic products. All foods must be labelled with the following details:

- The name of the food.
- The list of ingredients.
- The quantity of certain ingredients or category of ingredients.
- The alcohol strength for beverages with an alcohol content greater than 1.2% by volume.
- The net quantity, for packaged products.
- The date of minimum durability or use-by date.
- The special storage conditions and conditions of use.
- Instructions for use, where this information is necessary for the proper use of the foodstuff.
- The name or business name and address of the food business operator and the batch.
- Nutritional information.
- The place of origin or provenance.
- Any ingredient causing allergies or intolerances listed in Annex II of the Food Information to Consumers Regulation.

(Article 9, Food Information to Consumers Regulation; Article 12, Royal Decree 1339/1999.)

In addition, for those products marketed in Spain, this and other compulsory information must appear, at least, in Spanish (Article 18, Royal Decree 1339/1999) and must be presented in the same field of vision, meaning in the same space within the label.

In particular, Article 30 of the Food Information to Consumers Regulation has introduced mandatory nutrition labelling for most processed foods. Energy value, fats, saturated fats, carbohydrates, sugars, proteins and salt must be declared, and must be presented in the same field of vision.

Other Products

Labelling of medicinal products is also important, due to their potential danger. Articles 29 to 40 of Royal Decree 1345/2007, which regulates labelling, are applicable.

Chemical products, and all products containing substances classified as hazardous, are also subject to special labelling requirements. Royal Decree 255/2003 and the CLP Regulation establish a detailed regime of all information that must be included on the label of these products depending on their composition or classification.

Other types of products with special labelling regulations include:

- Refrigerators, freezers and wine coolers.
- Washing machines and dishwashers.
- Electronic displays and lighting systems.

The [Energy Labelling Regulation 2017 \(\(EU\) 2017/1369\)](#) and [Commission Delegated Regulation \(EU\) 2019/2015](#) supplementing Regulation (EU) 2017/1369 of the European Parliament and of the Council with regard to energy labelling of light sources, have led to the entry into force of a new labelling standard for all these products.

Imported Products

When it comes to safety and compliance, it does not matter whether a product is manufactured in the territory of an EU member state or outside the EU. All products, whether imported or not, must follow the safety requirements established for each type of product.

Importers of Foreign Manufactured Products

Article 135 of the Consumers and Users Defence Act establishes the general principle that manufacturers are liable for damage caused by defects in the products that they manufacture or import. The Act defines a manufacturer as not only the manufacturer in the EU but also the importer of any type of product in EU territory. Importers of unsafe products are subject to the same liability as domestic manufacturers or suppliers. This results from Community directives that have subsequently been transposed in Spain, in particular the [Product Liability Directive \(85/374/EEC\)](#) and the [General Product Safety Directive \(92/59/EEC\)](#).

In Spain, the importer of a product into the EU can be considered the manufacturer. The producer of any element that makes up a finished product, or raw material, is also considered a manufacturer. If the actual manufacturer cannot be identified, the supplier of the product will be considered to be the manufacturer, unless, within a period of three months, they indicate to the damaged or injured party the identity of the actual manufacturer, or of the person who has supplied or provided them with that product. The same rule applies in the case of an imported product if the product does not indicate the name of the importer, even if the name of the manufacturer is indicated.

Foreign Manufacturers

Any product marketed in Spain must be safe and compliant with local regulations regardless of its origin or the home country of its manufacturer. Products can be marketed either through a distributor in the EU who can charge VAT or, alternatively, by setting up a permanent establishment in the EU to be registered for VAT (and charge it directly).

All manufacturers must ensure that they rely on the latest scientific knowledge and research related to the safety of the products they produce. This places an implicit obligation on manufacturers to carry out research into the safety of their products, regardless of their location, market position or financial resources.

Product Safety Compliance and Risk

An effective compliance programme must remain up-to-date with the extensive regulation in place at both national and European level, to limit criminal liability. It must also be tailored to each branch of industry, as there are numerous regulations that apply on a sectoral basis. Therefore, a compliance programme should be tailor-made for each company, depending on its operations.

Root Cause Analysis and Risk Assessment

A product is defective when it presents an unreasonable or unforeseeable health or safety risk. Therefore, the law requires an assessment of the degree of knowledge by the consumer of the potential risks associated with a particular product to establish whether sufficient safety information has been provided. For this purpose, the courts use the degree of safety test, which is an assessment of the safety of each product in comparison with others.

Even if the manufacturer conducts a diligent safety analysis, carries out random sample tests, and responds to consumer complaints, they will still be liable if they have placed an unreasonably or unforeseeably unsafe product on the market. It is therefore advisable that controls are carried out prior to the marketing of the product, to avoid risks for consumers and, therefore, avoid liability.

In the absence of legislation the type of safety controls needed by a manufacturer is a discretionary decision, taking into account:

- The type of product.
- Its method of use.
- Its intended purpose.
- What hazards it presents to consumers.

When designing a compliance programme and the controls it will put in place to validate the safety of a product, the manufacturer should consider all possible scenarios in which the product will be used. The manufacturer should determine what risks the consumer should be aware of, and how those risks are best communicated, whether through warning statements, instructions, or labelling.

The manufacturer must make an assessment of the risks inherent in the product that are not required to be communicated through labelling, general warnings, or instructions attached to the product. If consumers know, or should know, the risks of a product, or if a product presents risks that are an integral part of what is to be expected from it (for example, a knife), then the liability of the manufacturer is greatly reduced (the theory of assumed risks). However, it is always better to inform the consumer of any risks, to ensure adequacy of information.

There are also certain mandatory standards (see [Product Safety Legislation and Regulation](#)).

Article 137 of the Consumers and Users Defence Act lists some of the parameters that must be taken into account to assess the safety of a product:

- A defective product is one that does not offer the safety that could legitimately be expected, taking into account all the circumstances and, especially, its presentation, its reasonably foreseeable use and the time when it was placed on the market (Article 137(1), Consumers and Users Defence Act).
- A product is defective in all cases if it does not offer the safety normally offered by other specimens of the same series (Article 137(2), Consumers and Users Defence Act).
- A product is not considered defective merely because an improved version is put onto the market (Article 137(3), Consumers and Users Defence Act).

This list is not exhaustive, which allows for a broad interpretation when adapting the rule to the specific fact.

Similarly, Royal Decree 1801/2003 sets out considerations for assessing the safety of products put into circulation. These include:

- The characteristics of the product, including its composition and packaging.
- The effect on other products, when the use of the former together with the latter can reasonably be foreseen.
- The information, presentation and advertising accompanying the product.
- The categories of consumers who are at risk when using the product, in particular children and the elderly.

This rule is administrative, with no direct impact on the field of product liability (see [Product Liability](#)), but can serve to better delimit the "safety that could legitimately be expected," since the list of circumstances in Article 137 of the Consumers and Users Defence Act is not exhaustive.

Since several of these circumstances have already been analysed by the courts in relation to the product liability regime of the Consumers and Users Defence Act, this case law also explains how they influence the classification of a product as defective.

The manufacturer has an on-going duty to remain informed of how the product is being used by consumers and the risks a product may present in relation to how it is being used. The manufacturer also has a duty to keep distributors informed of new risks (see [Product Requirements, Approvals, Registrations, and Certifications](#)). Royal Decree 1801/2003 does not establish how the manufacturer should be kept informed of risks. It only mentions the study of consumer complaints and random sampling. Sectoral legislation can regulate the way in which risks should be investigated.

Disclosure Obligations

When manufacturers or distributors know, or should know, that a product on the market does not meet the safety requirements, they must notify the competent authority of this immediately (Article 6, Royal Decree 1801/2003).

This notification, which is made using an [online form](#) on the website of the Ministry of Health, Consumer Affairs and Social Welfare, contains:

- Details identifying the product or batch of the product.
- A full description of the risk.

- All available information for tracing the product.
- A description of the action taken to prevent risks to consumers.

The notification is not public, but the competent authority can issue an alert to the general public, in response to the risk, and to enable any corrective measures to be taken.

Corrective Action

If the general safety obligations in Royal Decree 1801/2003 are not complied with, the Regulation empowers the competent authority to adopt a series of measures to guarantee the safety and health of potential purchasers. These measures include:

- Temporary prohibition on supply until checks have been carried out.
- Prohibition on sale.
- Inclusion of warnings about the risks.
- Withdrawal from the market.
- Product recall from consumers.

These measures, which must be proportionate to the risk, may be preceded by warnings, or requirements on manufacturers and distributors who have breached any of the duties to carry out the necessary actions to comply with the law.

Corrective measures, which are mandatory, may affect any of the participants in the supply chain, such as:

- The manufacturer (including the manufacturer's representative when the manufacturer is not established in the EU or the importer of the product).
- The distributor.
- Service providers, meaning any other person involved in the supply chain.

The competent authority can assume the management of the corrective measures imposed, in which case the costs will be charged to those who have caused them through their illegal actions (Article 12, Royal Decree 1801/2003).

The competent regional authority must notify the Ministry of Consumer Affairs of:

- The corrective measures adopted.
- The requirements placed on manufacturers or distributors.
- Any voluntary actions undertaken.

In Spain, this communication is carried out through the *Sistema de Intercambio Rápido de Información* (SIRI) (rapid exchange of information system), a system that allows communication between the regional authorities and the State.

At Community level, the [General Product Safety Directive \(2001/95/EC\)](#) created a system for the exchange of information on product safety, known as [Safety Gate](#).

The main purposes of this European system are:

- Exchange of information between the authorities of the member states and the Commission on product safety.
- Communication of the adoption, modification or suspension of measures taken by the member states to prevent, restrict or impose special conditions in their territory for the marketing of certain products, due to a serious risk.

Safety Gate is integrated with different authorities designated by the member states. In Spain, the designated authority is currently the Directorate General for Consumer Affairs.

There are specialised agencies, both at Community and national level, for certain types of products. In the field of food safety, for example, Spain has the Spanish Agency for Food and Nutrition Safety (*Agencia Española de Seguridad Alimentaria y Nutrición*) (AESAN), which in turn has the *Sistema Coordinado de Intercambio Rápido de Información* (SCIRI) (coordinated rapid exchange of information system), an alert system that aims to guarantee consumers that food and food contact materials are safe, and do not present health risks. SCIRI is integrated into the Rapid Alert System for Food and Feed (RASFF) of the European Union, and The International Food Safety Authorities Network (INFOSAN) of the [UN Food and Agriculture Organisation](#) (FAO) and [World Health Organization](#) (WHO), respectively.

Enforcement and Liability

While government agencies are in charge of monitoring compliance and imposing sanctions at the administrative level, the courts have competence to enforce product safety regulations, in accordance with Spanish procedural rules, at the request of:

- Individuals or consumers.
- Associations whose purpose is to defend consumer rights (such as the Spanish Consumers and Users Organisation).
- Public bodies and authorities in charge of product safety, such as AESAN in the food field or AEMPS in the field of medicines and medical devices.

Liability for damage caused by a defective product lies with the manufacturer, including the importer into the EU of the product in question (Articles 138 and 146, Consumers and Users Defence Act). However, the supplier or distributor will be liable as the manufacturer in those cases in which they have supplied the product in the knowledge that it was defective. It is common for certain product safety issues to be submitted to the jurisdiction of the Court of Justice of the European Union (CJEU) through preliminary rulings by national courts. This was the case in *Bundesverband der Verbraucherzentralen und Verbraucherverbände v. Teekanne GmbH & Co. KG* (Case C-195/14) EU:C:2015:361.

Product Liability

If the buyer is considered to be a consumer, the Consumers and Users Defence Act regulates liability for defective products. Manufacturers are liable for damage caused by defects in the products they manufacture or import (Article 135, Consumers and Users Defence Act). The importer of a product into the EU can also be considered a manufacturer, as well as those that produce an element integrated into a finished product, or a raw material. The distributor or supplier of the product may also be considered a manufacturer when the actual manufacturer of a product cannot be identified, and the distributor does not identify them (Article 138, Consumers and Users Defence Act).

Manufacturers are not liable for damages suffered as a result of a defective product where they can prove that:

- They did not put the product into circulation.
- Given the circumstances, it can be presumed that the defect did not exist at the time the product was put into circulation.
- The product was not manufactured for sale or any other form of distribution for economic purposes, nor manufactured, imported, supplied or distributed in the course of a trade or business.
- The defect is due to the fact that the product was manufactured in accordance with existing mandatory standards.
- The state of scientific and technical knowledge existing at the time when the product was put into circulation did not allow the existence of the defect to be assessed.

(Article 140, Consumers and Users Defence Act.)

The manufacturer is liable for a period of ten years from the date on which the product causing the damage was put into circulation.

Distributors of the defective product are liable as if they were the manufacturer, when they have marketed the product with knowledge of the defect. However, they can claim liability costs from the manufacturer.

Manufacturers may also be liable for non-conformity of the products with the contract, and any public statements made (such as advertising or labelling). The Consumers and Users Defence Act establishes three cases where the seller's liability for lack of conformity may be excluded:

- The seller proves that they were unaware and could not reasonably be expected to be aware of the statement.
- The seller proves that the statement had been corrected at the time of entering into the contract.
- The seller proves that the statement could not have influenced the decision to purchase the product.

(Article 116(1)(d), Consumers and Users Defence Act.)

The legislator separates here from the traditional distinction between hidden vices or defects and apparent defects (Articles 1484 and 1485, Civil Code; Articles 336 and 342, Commercial Code). It clearly establishes that the seller will not be liable for the original defect of the product sold, provided that the seller can prove that either:

- The buyer was aware of the lack of conformity (for example, if the seller warns the buyer of the defects or shortcomings of the product sold).
- The buyer could not reasonably have been unaware of the lack of conformity at the time of entering into the contract (because it is presumed that the buyer should be fully aware of the defects, even if there is no proof that they were aware).

A buyer who knows of the defect or who cannot reasonably be unaware of it, accepts the product as it is, and there is no lack of conformity.

The manufacturer is not exempt from liability for defective products if the good is resold. Therefore, if the second-hand buyer is a consumer, they are also entitled to claim from the manufacturer for damages that occur as a result of a defective product.

Sanctions and Penalties

The Consumers and Users Defence Act establishes a complete system of consumer penalties to prosecute infringements related to product safety. These penalties range from EUR150 to EUR1 million and can be extended to exceed these quantities, up to eight times the illicitly obtained profit. In addition, accessory penalties can be imposed, such as confiscation of the goods which are the object of the infringement, or publicising of the penalties. (Articles 49 and 50, Consumers and Users Defence Act.)

The natural or legal person who committed the offence is liable. In the event that there are several perpetrators for the same infringement, the corresponding penalty will be imposed on each one according to their degree of guilt.

With regard to consumers and foodstuffs, Royal Decree 1945/1983 establishes a series of offences in relation to alteration, adulteration or fraud relating to consumer goods. It also includes a series of infringements in sanitary matters, including non-compliance with:

- The regulations contained in [Decree 2484/1967](#), approving the text of the Spanish Food Code, of 21 September (*Decreto 2484/1967, de 21 de septiembre, por el que se aprueba el texto del Código Alimentario Español*),
- Technical-sanitary regulations which include the manufacturing standards and the sanitary and hygienic conditions to be followed in any handling or packaging process.
- Quality standards.

The penalties are up to EUR601,012.10, which can be increased to ten times the value of the products that are the object of the infringement. Accessory penalties can also be imposed (Article 10, Royal Decree 1945/1983).

In addition, Law 17/2011 also imposes penalties of up to EUR600,000 for food safety and nutrition offences. Accessory penalties can also be applied.

In the health field, in general, and more specifically regarding drug safety, Royal Legislative Decree 1/2015 includes a series of offences, among which are the placing on the market of medicines without authorisation, or the manufacture, distribution or marketing of counterfeit medicines. The penalties are up to EUR1 million and may exceed this amount by up to five times the value of the goods or services which are the subject of the infringement. In the case of the most severe infringements, the competent authority may order the temporary closure of the establishment (Article 10, Royal Decree 1/2015).

Other Considerations

Liability Associated with Marketing and Label Claims

The Federal Association of Consumer Centres and Associations (BVV), brought an action against Teekanne before the Landgericht Düsseldorf (Regional Court in Düsseldorf). The basis of the claim was that the ingredients listed on the packaging of a fruit infusion were misleading as to the composition of that infusion. It claimed that, because of the packaging, the consumer could expect the fruit infusion to contain vanilla and raspberry components or flavourings, which it did not. The BVV therefore requested that Teekanne be ordered to cease promoting the fruit infusion, actively or passively, in the context of commercial activities, with the imposition of a coercive measure in the event of non-compliance. By judgment of 16 March 2012, the Landgericht Düsseldorf upheld that action, and subsequent rulings applied the same approach in *Bundesverband der Verbraucherzentralen und Verbraucherverbände - Verbraucherzentrale Bundesverband e.V. v Dr. August Oetker Nahrungsmittel KG (Case C-388/20) EU:C:2021:913*.

Upon appeal by Teekanne, the *Oberlandesgericht* (Higher Regional Court) of Düsseldorf, by judgment of 19 February 2013, annulled that judgment and dismissed the BVV's claim, holding that there had been no misleading of the consumer.

The BVV lodged an appeal against the latter judgment, with the Bundesgerichtshof (Federal Court of Justice), and referred the following question to the CJEU for a preliminary ruling:

"Is it permissible for the labelling, presentation and advertising of foodstuffs to create, by means of the appearance, description or a figurative representation, the impression that a particular ingredient is present, when in fact it is not, but this is inferred solely from the list of ingredients referred to in Article 3(1)(2) of Directive 2000/13?"

According to the referring court, a number of elements suggested that the flavour of that infusion was determined by flavourings obtained from raspberries and vanilla flowers:

- The repetition of images of raspberries and vanilla flowers on the packaging of the fruit infusion, which attracts the eye.
- The wording "with natural flavourings."
- A graphic stamp containing the wording "only natural ingredients."

The presentation of that fruit infusion was therefore designed to create, even in the case of an average consumer who is reasonably well-informed and reasonably observant and circumspect, a false impression as to its composition. It added that the presentation of the fruit infusion was liable to dissuade the consumer from being aware of the real list of ingredients, presented on the packaging in smaller lettering. Therefore, the court considered that, in light of sections 6 and 8 of Directive 2000/13, it was not necessary for the consumer to be aware of the list of ingredients on the packaging.

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