

THE FOOD, BEVERAGE  
AND COSMETICS  
LAW REVIEW

THIRD EDITION

Editors

Kara L McCall and Elizabeth M Chiarello

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# PREFACE

Food, beverage and cosmetic companies provide products that are beneficial to consumers, important to the economy and in high demand. Consumers are not only seeking high-quality products at reasonable prices but also increasingly considering sustainability, methods of manufacture and use (or omission) of certain ingredients. These demands require companies to not only be looking ahead towards the ‘next big thing’ in these consumer industries but also considering how those attributes that are so important to customers (some of which have not been universally defined) can be communicated in a true and non-misleading way. Furthermore, companies need to act in compliance with the regulatory schemes of the locations in which they sell, and also make sure that their products – some of which are quite cutting edge – are safe and effective.

Regulatory, legislative and civil litigation frameworks vary dramatically from country to country and from locality to locality within each country. These laws and regulations may be similar or may be directly contradictory. Some types of products may be subject to extreme scrutiny, whereas others seem to be of less interest (and where on that spectrum your product falls may differ from day to day). Each jurisdiction is different, and advice from local legal experts is absolutely necessary before operating in (including selling into) any jurisdiction. This guide, however, is intended to provide a general overview of both the regulatory and civil legal frameworks in key countries for consideration by legal practitioners in these industries.

This is the third edition of *The Food, Beverage and Cosmetics Law Review*. It was developed because of the increase in class action litigation related to claims, particularly health benefit claims, made in the labelling and marketing of food, beverage and cosmetic products. This year brought continued litigation interest in the composition and labelling of food, beverage and cosmetic products, as well as regulatory changes in these areas, including the adoption of the Modernization of Cosmetics Regulation Act. This third edition covers nine countries and includes a high-level overview of each jurisdiction’s legal framework for food, beverage and cosmetic products, and a year in review, followed by discussions of legal frameworks related to food, beverage and cosmetic safety (including recalls); supply chain issues (including sustainability, anti-corruption, and labour and immigration); special legal issues related to sales and marketing (including whether regulatory approvals are required); general product liability and intellectual property laws; the role of trade organisations (including certifications) and unique issues related to financing and mergers and acquisitions in this space.

We hope that all readers find these chapters useful and informative. We wish to thank all of the contributors who have been so generous with their time and expertise. They have made this publication possible.

**Kara L McCall and Elizabeth M Chiarello**

Sidley Austin LLP

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August 2023

# SPAIN

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## I OVERVIEW

Spain's gastronomy is internationally renowned because of the variety and quality of its products, among other factors. The country allocates significant resources to boosting the food and beverage industry, including its protection through intellectual property rights.

Spain's agri-food legal framework is primarily based on European Union (EU) law. In particular, Regulation 178/2002 established the general principles and requirements of food law.<sup>2</sup> Regulation 178/2002 was developed by other several EU regulations, referred to as the 'Hygiene Package'.<sup>3</sup> At the internal level, Spain has approved a number of regulations contributing to the correct application of EU legislation, including Royal Decree 1086/2020.<sup>4</sup> Other laws have been enacted to regulate specific food products and beverages, including Royal Decree 4/2014, which establishes the quality standards for ham to be marketed as 'Iberian',<sup>5</sup> and Royal Decree 650/2011, applicable to the sale and marketing of soft drinks.<sup>6</sup> Worth highlighting is Law 16/2021 of 14 December on measures to improve how the food supply chain functions,<sup>7</sup> which amends Law 12/2013 on this same subject matter and implements Directive (EU) 2019/633 of the European Parliament and of the Council of 17 April 2019 on unfair trading practices in business-to-business relationships in the agricultural and food supply chain.

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- 1 Francisco Javier García Pérez is a counsel; Montiano Monteagudo, Marta Ríos, Juan Reyes and Patricia Vidal are partners; Manuel Álvarez, Cristina Ayo and Jaime Calvo are counsel; and Eduard Vila, Violeta Marinas, Yanira Miguel, Cristina Moreno and Patricia Ibárcena are associates at Uría Menéndez Abogados, SLP.
  - 2 Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 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.
  - 3 For the full list of EU Regulations being referred to as the 'Hygiene Package', see: [www.mapa.gob.es/es/ganaderia/legislacion/legislacion-comunitaria-letra-Q.aspx](http://www.mapa.gob.es/es/ganaderia/legislacion/legislacion-comunitaria-letra-Q.aspx).
  - 4 Royal Decree 1086/2020, 9 December 2020 (por el que se regulan y flexibilizan determinadas condiciones de aplicación de las disposiciones de la Unión Europea en materia de higiene de la producción y comercialización de los productos alimenticios y se regulan actividades excluidas de su ámbito de aplicación).
  - 5 Royal Decree 4/2014, 10 January 2014 (por el que se aprueba la norma de calidad para la carne, el jamón, la paleta y la caña de lomo ibérico).
  - 6 Royal Decree 650/2011, 9 May 2011 (por el que se aprueba la reglamentación técnico-sanitaria en materia de bebidas refrescantes).
  - 7 Law 16/2021, 14 December 2021 (por la que se modifica la Ley 12/2013, de 2 de agosto, de medidas para mejorar el funcionamiento de la cadena alimentaria).

This is particularly important because the food and beverage industry represents 2.4 per cent of Spain's gross domestic product. Annual turnover in the sector has decreased to approximately €126 billion (minus 2.2 per cent in relation to last year) and the workforce has reached 539,400 people.<sup>8</sup> Nevertheless, Spain still ranks fourth in terms of turnover at the EU level, representing 11.4 per cent of the EU's total turnover.<sup>9</sup>

Spain also has one of the largest domestic markets for cosmetics and personal care products in the EU, being valued at €9.2 billion in 2022 (plus 11.3 per cent in relation to last year).<sup>10</sup> This market is also primarily regulated by EU law. In 2018, the Spanish Parliament approved Royal Decree 85/2018,<sup>11</sup> which complemented the EU legislation approved on the matter, particularly Regulation 1223/2009.<sup>12</sup>

## II YEAR IN REVIEW

In the cosmetics sector, the amendment of Annex VI of Regulation (EC) 1223/2009 stands out as the most remarkable recent legal development. The maximum concentration rates of the substances benzophenone-3 and octocrylene have been adjusted for products in which they are used as UV filters, in light of concerns related to potential endocrine disrupting properties.

Regarding the food sector, Royal Decree 1028/2022 of 20 December represents a major development in the field of food contracts, insofar it lays down the foundations for the mandatory registration system applicable to all contracts for the supply of agricultural or food products not involving consumers.

New environmental and waste management laws have also had an impact on the Spanish food sector. Law 7/2022 of 8 April on waste and contaminated soils for a circular economy, which transposes Directives (EU) 2018/851 and 2019/904, regulates the management of food waste by compelling primary production companies, food businesses, distribution companies and mass catering enterprises to follow specific guidelines in terms of food garbage disposal. In parallel, Royal Decree 1055/2022 of 27 December on packages and packaging waste requires product producers to set up a deposit, return and refund system that operates throughout the distribution chain and includes, where applicable, the final consumer, to recover any reusable packaging used and thus reduce the rate at which packaging waste is created. The same obligation applies to producers who place on the market single-use plastic bottles for certain beverages and products with a maximum capacity of 3 litres.

There have also been other minor legislative developments in connection with certain hygiene requirements applicable to the production and marketing of food products in retail establishments, the exploitation and marketing of natural mineral waters and spring waters for human consumption, on the process of preparing and marketing prepared waters packaged for human consumption, and in the field of animal welfare in slaughterhouses.

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8 Annual Report on the Spanish Food Industry (2022–2023), produced by the Sub-directorate General for Competitiveness of the Food Chain (Ministry of Agriculture, Fisheries and Food).

9 *id.* at 2.

10 Annual Report on the Cosmetic Sector in Spain (2022), produced by STANPA (Spanish National Association of Perfumes and Cosmetics).

11 Royal Decree 85/2018, 23 February 2018 (por el que se regulan los productos cosméticos).

12 Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.



### III FOOD AND COSMETIC SAFETY

#### i Regulatory framework

The main regulatory body governing the Spanish food and beverage industry is the Spanish Agency for Food Safety and Nutrition (AESAN).<sup>13</sup> One of AESAN's main objectives is ensuring the safety of food products and beverages. AESAN is responsible for coordinating regulatory compliance control and the development of strategies to boost education and health information in the field of nutrition. In line with these functions, it offers useful information to consumers through its informative database to protect their interests.<sup>14</sup>

In turn, regulatory compliance control is highly decentralised and, as such, each autonomous region has its own agency entrusted with these matters; the agency is normally the corresponding public health department.

The lead regulatory body in the cosmetics industry is the Spanish Agency of Medicines and Health Products (AEMPS).<sup>15</sup> AEMPS systematically collects, evaluates and monitors information on the undesirable effects observed as a result of the use of cosmetics (denominated 'cosmetovigilance'). In Spain, cosmetovigilance activities are organised through a notification system. Regional agencies also have competences in the field.

#### ii Food additives and contaminants

Spain's regulatory framework on food additives and contaminants is based on EU standards. Regulation 1331/2008 establishes a common authorisation procedure for food additives,<sup>16</sup> and Regulation 1333/2008 lays down rules to achieve a high level of consumer protection and safeguarding of human health.<sup>17</sup> In order to make the corresponding rules more accessible to consumers, AESAN produces an array of resources aimed at consumers (e.g., guides, short reports and databases). Examples of these include the Guide on the Description of Food Categories in the Additives Regulation and the Guide to the European Authorisation Procedure.

EU Regulation 315/93 sets out the framework governing matters involving food contaminants.<sup>18</sup> The general rule is to ensure that contaminant levels are as low as reasonably possible. To do so, Regulation 1881/2006 sets maximum levels for specific contaminants.<sup>19</sup>

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13 Agencia Española de Seguridad Alimentaria y Nutrición.

14 The database is referred to as the General Health Register of Food Business and Foods (RGSEAA).

15 Agencia Española de Medicamentos y Productos Sanitarios.

16 Regulation 1333/2008 has been amended twice in 2022 (14 January 2022 and 21 January 2022). In this regard, Commission Regulation (EU) 2022/63 of 14 January 2022 amends Annexes II and III to Regulation (EC) No. 1331/2008 of the European Parliament and of the Council as regards the food additive titanium dioxide (E171) and Commission Regulation (EU) 2022/141 of 21 January 2022 amends Annex II to Regulation (EC) No. 1331/2008 of the European Parliament and of the Council as regards the use of sodium carbonates (E500) and potassium carbonates (E501) in unprocessed cephalopods.

17 Regulation (EC) No. 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, and Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

18 Council Regulation (EEC) No. 315/93 of 8 February 1993 laying down community procedures for contaminants in food.

19 Commission Regulation (EC) No. 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

The overarching objective is to protect public health and ensure that good manufacturing practices regulations are being followed, recognising that contaminants might enter food at any point from production to consumption.

### **iii Recalls**

Pursuant to EU Regulation 178/2002<sup>20</sup> and Spanish Law 17/2011, both food and food business operators that believe, or have reasons to believe, that a food that it has imported, produced, processed, manufactured or distributed does not comply with food safety requirements or, in particular, appears to be unsafe must immediately communicate to the corresponding authorities the specific risk of the food product and commence any procedures or corrective actions to mitigate that risk, including the withdrawal of the food in question from the market on which the food has left the immediate control of that initial food business operator and inform the corresponding authorities thereof. If the product has reached consumers, the operator must effectively and accurately inform consumers of the reason for its withdrawal and, if necessary, recall products already made available to consumers when other measures are insufficient to achieve a high level of health protection.

In other words, operators must notify the corresponding authority of the existence of the risk and take adequate corrective measures to avoid or mitigate the risk. Among these corrective measures, which are mandatory at both domestic and European levels, the implementation of traceability systems is a basic risk management tool that increases efficiency of internal management in terms of the level of information available on products and processes, which undoubtedly contributes to increasing consumer confidence.

The guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation 178/2002 on the general food law conclusions of the standing committee on the food chain and animal health, approved on 26 January 2010, provides various guidelines in this regard.<sup>21</sup>

## **IV SUPPLY CHAINS**

### **i Labour and immigration**

The food, drink and cosmetic industries and, more specifically, their supply chains are major employers in Spain. Therefore, all trends and main issues in the Spanish labour market are reflected in this sector, such as employment relationships hidden under corporate agreements or the inappropriate overuse of temporary employment contracts, which are subject to new limitations and sanctions as a result of the 2022 labour reform.

Despite the array of issues, the most common problems in supply chains derive from the strong outsourcing component that exists in this sector, especially in logistics.

General liabilities arising from outsourcing: although outsourcing is common and legal, it may nevertheless trigger liability, particularly when the contracted-out services form

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20 Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 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 178/2002 has been subject to non-substantial amendments over the course of 2022 (amendments relating to the nomination of the management board, the scientific committee and scientific panels; the scientific studies; and confidentiality).

21 [https://ec.europa.eu/food/system/files/2016-10/gfl\\_req\\_guidance\\_rev\\_8\\_en.pdf](https://ec.europa.eu/food/system/files/2016-10/gfl_req_guidance_rev_8_en.pdf).

part of the company's core business. In these cases, the company and contractor are jointly and severally liable for the salary and social security obligations (sometimes for health and safety as well) assumed by the contractor with regard to its employees for the period during which the services are performed. If the outsourced services are not part of its core activity, the company could be liable only if the contractor becomes insolvent and limited to the social security obligations.

Unlawful assignment of employees: a distinction must be made between (1) legal outsourcing and (2) an unlawful assignment of employees where the real purpose is to assign employees to the principal, who directs, organises and manages these employees. In this case, the company and the contractor would be jointly and severally liable for all labour and social security obligations regarding the assigned employees and could be fined from €7,501 to €225,018. Similarly, the employees would be entitled to choose between becoming employees of the company or of the contractor.

Finally, although modern slavery and forced labour are two topics that are still important outside our borders, they are not issues in Spain. Despite the absence of any legal provision expressly prohibiting forced labour, the definition of 'employee' requires that the work be voluntary. Spain has also ratified the International Labour Organization conventions on forced labour (both 29 and 105).

## **ii Processing and certifications**

The inspection and certification of organic foods represent the guarantee for consumers that the provisions of European organic production regulations are satisfied. They also protect the terms used on the labelling of such products (e.g., quality of the product, animal welfare, environmental protection and sustainable production).

The characteristics of the inspection and certification system are set out in European regulations (Regulation (EU) 2018/848 and Commission Implementing Regulation (EU) 2021/1165),<sup>22</sup> which allow Member States to choose between a public or a private system for the corresponding matters. In Spain, the choice is left to the autonomous communities, 15 of which have opted for public certification (two of them resorting to a mixed public–private approach) and the two remaining autonomous communities (Andalusia and Castilla La Mancha) have opted for a certification process through private, independent organisations.

It is of the utmost importance to consumers and producers that these certification organisations be in charge of the inspection process by carrying out periodic audits that guarantee that the requirements of the regulations are met and that there is no fraud.

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22 Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No. 834/2007 Council Regulation (EC) No. 834/2007 of 28 June 2007 on organic production and labelling of organic products; Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists; and Commission Regulation (EC) No. 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No. 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.

### iii Sustainability

One of the European Union's main priorities is to transition towards a solid, resilient and sustainable food system; achieving that goal will entail significant environmental, health and social benefits and will give Member States the opportunity to boost their economies. To achieve food sustainability, the European Commission approved the Farm to Fork Strategy in May 2020, which is a crucial element of the European Green Deal and seeks to ensure that the EU becomes the 'world's first climate-neutral continent by 2050'. The Farm to Fork Strategy is consistent with the Sustainable Development Goals, specifically Goal 12, which aims to 'ensure sustainable consumption and production patterns'.

The consequences of climate change have revealed an urgent need to ensure that food chain operators (particularly producers, carriers and distributors) adapt their activities to mitigate their environmental impact and guarantee that consumers have access to sufficient, nutritious and sustainable food at affordable prices. Reducing food systems' ecological footprint, optimising the use of natural resources and implementing circular business models are laudable goals for the leading food chain operators. Nonetheless, implementing the appropriate measures also requires a reasonable adjustment period, significant resources and less burdensome administrative constraints. Although these goals might be difficult to achieve, the European Commission is expected to present a legislative proposal for the design of a sustainable food system by the third quarter of 2023. In addition, approximately €1.8 billion from the NextGenerationEU funds allocated to Spain are being earmarked for the agri-food sector. Some of those funds are being used to promote measures to improve supply chains and the sustainability and traceability of food production. Supply chains are also likely to be affected by the Corporate Sustainability Due Diligence Directive, which is still under negotiation.

In line with this EU trend, Spain has unreservedly moved towards the goal of food sustainability by enacting various instruments and self-assessment tools as well as by establishing the framework and monitoring procedures for voluntary corporate sustainability commitments in the food chain. Furthermore, both the Spanish Strategy for the Circular Economy and Law 7/2022 on waste and contaminated soils for a circular economy include requirements to reduce food loss and waste. By 2030, Law 7/2022 aims to have reduced hospitality and domestic food waste by 50 per cent and decreased the waste generated by the supply chain by 20 per cent compared with 2010. In addition, it intends to increase food recovery, focusing on ensuring full consumption of the food produced and, failing that, improving the mechanisms to use it as a by-product in other production processes. The Spanish parliament is also debating a specific law on preventing food waste and a set of measures to reduce single-use plastics – such as a special tax on non-reusable plastic packaging – have been recently implemented. Those measures have proved controversial, given how important plastic is for logistics and food preservation. Finally, Royal Decree 1055/2022 on packaging and packaging waste entered into force in December 2022. It comprehensively regulates extended producer responsibility, which, along with the packaging waste reduction obligations it introduces, will undoubtedly have a major impact on the food sector.

It is important that we all continue to work towards food sustainability. However, in pursuing this common goal, public authorities must take into account the interests of everyone involved. As the European Green Deal states, it 'will transform the EU into a modern, resource-efficient and competitive economy', ensuring that 'no person and no place [are] left behind'.

#### **iv Anti-corruption rules**

The following are the most important anti-corruption rules applicable to supply chains in Spain:

- a* bribery of national officers, criminalised pursuant to Articles 419 to 427 of the Spanish Criminal Code (SCC): a wide array of corrupt conduct is punished under these provisions, including facilitation payments and bribes to public officers merely on the basis of their office, without the expectation of any action in return;
- b* bribery of foreign officers, criminalised pursuant to Article 286 *ter* of the SCC: this allows for prosecution in Spain of bribery committed abroad by Spanish legal persons or their directors, employees or agents, in the context of international procurement or commercial activities; and
- c* private sector corruption, criminalised pursuant to Article 286 *bis* of the SCC: bribes sought by or provided to a director, employee or associate in exchange for the unlawful performance of their corporate duties in commercial relationships in favour of the grantor and to the detriment of competitors is also a criminal offence.

These legal provisions establish penalties of imprisonment and fines for any natural person found guilty of committing the underlying offence. In the event that one of the indicated offences is committed for the company's benefit by any of its directors, managers, representatives, agents or employees, the legal person may be declared criminally liable and face penalties that include fines, debarment, closures of premises or judicial supervision, pursuant to Article 31 of the SCC. Article 31 also establishes the affirmative defence of compliance when the company had in place, prior to the underlying act of corruption, an effective compliance programme aimed at preventing criminal activity within the organisation. Among others, the following elements will be key when assessing the effectiveness of compliance programmes in this field:

- a* risk mapping focused on corruption;
- b* anti-bribery policies and protocols in force;
- c* anti-corruption clauses in the corresponding contracts;
- d* due diligence exercises and background checks of counterparts and foreign agents;
- e* effective whistleblowing channels<sup>23</sup> that lead to fast detection; and
- f* reaction to corruption.

#### **v Due diligence and monitoring**

Law 12/2013 on measures to improve the functioning of the food supply chain created the Observatory of the Food Supply Chain, a collegiate body attached to the Spanish Ministry of Agriculture, Food and Environment that replaced the Observatory of the Food Prices.

In general, the functions of the Observatory of the Food Supply Chain are the monitoring, advice, consultation, information and study of the functioning of the food supply chain and food prices. Similarly, it encourages the adoption of good commercial

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23 Law 2/2023 of 20 February on the protection of persons who report violations of the law and the fight against corruption, which entered into force in Spain on 13 March 2023, makes it mandatory for public and private entities with 50 or more employees to implement internal whistleblowing channels, which must satisfy minimum requirements and guarantees along the lines of the EU Directive 2019/1937 (the Whistleblowing Directive).

practices in food contracting by food supply chain operators and promotes the adherence of those operators to codes of good practice. It monitors the application of such codes of good practice and proposes necessary improvements or updated measures.

Finally, the Observatory of the Food Supply Chain may also inform the corresponding authorities of any breach of law by food supply chain operators that it may detect in the exercise of its functions.

## V SALES AND MARKETING

### i Regulatory framework

The Spanish regulatory framework on marketing is set out in the General Law on Advertising and in the Unfair Competition Law.<sup>24</sup> As for the marketing of food, Law 17/2011 and Royal Decree 1334/1999 establish various important provisions, such as the prohibition of the use of health professionals in food advertising and the promotion of self-regulatory systems.<sup>25</sup>

Apart from the general regulatory framework, specific regulations must be considered on a product-to-product basis. As an example, Royal Decree 1798/2010 establishes rules on the labelling and sale conditions of mineral water.<sup>26</sup>

With the exception of dietary supplements, food products generally do not require authorisation to be offered to consumers. However, depending on the sector and stage of the food chain in which they operate, Spanish food companies must be registered with the corresponding registry.<sup>27</sup> Spain has three main registries, for:

- a* companies engaged in primary production;
- b* food establishments for the sale of food products destined for consumers; and
- c* other food companies that fall outside the scope of the other two definitions.

The sale and marketing of cosmetics are also highly regulated at the EU level, including through Commission Regulation 655/2013.<sup>28</sup> Similarly, domestic royal decrees addressing the sale and marketing of cosmetics, such as Royal Decree 85/2018, must be complied with.<sup>29</sup> For example, Royal Decree 85/2018 requires the labelling information of cosmetics to be, at least, in Spanish.

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24 Law 34/1988, 11 November 1988, General de Publicidad and Law 3/1991, 10 January 1991, de Competencia Desleal, respectively.

25 Law 17/2011, 5 July 2011 (de seguridad alimentaria y nutrición), Royal Decree 1334/1999, 31 July 1999 (por el que se aprueba la Norma general de etiquetado, presentación y publicidad de los productos alimenticios). In addition to other national and EU regulations such as Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

26 Royal Decree 1798/2010, 30 December 2010 (por el que se regula la explotación y comercialización de aguas minerales naturales y aguas de manantial envasadas para consumo humano). Furthermore, regarding the regulation of mineral water was approved in 2023 by Royal Decree 2/2023 of 10 January 2023, which modifies both Royal Decree 1798/2010 and Royal Decree 1799/2010. Among other amendments, Royal Decree 2/2023 introduces Article 14 *bis*, which establishes that spring water must comply with further chemical and microbiological parameters in order to preserve its quality.

27 [www.aesan.gob.es/AECOSAN/web/seguridad\\_alimentaria/subseccion/procedimientos\\_registro.htm](http://www.aesan.gob.es/AECOSAN/web/seguridad_alimentaria/subseccion/procedimientos_registro.htm).

28 Commission Regulation (EU) No. 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products.

29 Royal Decree 85/2018, 23 February 2018 (por el que se regulan los productos cosméticos).

## ii Consumer protection and false advertising

In Spain, the key mechanisms in place to prevent false advertising are Royal Legislative Decree 1/2007, which enacted the Consumers and Users Protection (Consolidation) Law and complementary regulations,<sup>30</sup> and the Unfair Competition Law.<sup>31</sup> Both statutes provide an extensive framework governing the protection of consumer interests, including labelling, marketing and product guarantees. Conversely, the Unfair Competition Law addresses, among other things, the regulation of unfair consumer practices, including baiting practices and misleading promotional practices.<sup>32</sup>

Government agencies such as AESAN and AEMPS also act as control mechanisms with regard to, respectively, the safety of food products and cosmetics. These government agencies coordinate with the regional authorities, whose powers are, broadly, limited to the specific autonomous region.

According to the Unfair Competition Law, consumer associations are entitled to start certain legal actions (e.g., cessation or rectification of misleading, incorrect or false information) acting in the defence of general, collective or diffuse interests of consumers derived from the breach of the Unfair Competition Law.

Notably, the recent amendment of the Unfair Competition Law that entered into force on 28 May 2022 has introduced a new third section to its fifth article, which states that 'it is unfair to market a good in one Member State as being identical to a good marketed in other Member States when that good has a significantly different composition or characteristics, unless justified by legitimate and objective factors'. This situation was already implicitly included within the scope of misleading practices under Article 5 of the Unfair Competition Law, but the EU legislator has considered that it should be referred to specifically. This Article is a response to the issue of the dual quality of products that EU institutions have reported in recent years. For example, according to the Commission, consumers from various EU countries have complained that the composition of products such as soft drinks, coffee or fish sticks in the country where they were originally sold differs from that of the products sold under the same trademark and with very similar packaging in other Member States. This has been confirmed by several comparative investigations, which have evidenced the existence of products in the EU market with a similar trademark and presentation but that contain, for example, differing amounts of meat or fish or a higher fat content or different types of sweeteners depending on the Member State where they are sold. The corresponding authorities will now assess and address such practices on a case-by-case basis according to Directive 2005/29/EC.<sup>33</sup> These assessments will take into account:

*a* whether such differentiation is easily identifiable by consumers;

30 Royal Legislative Decree 1/2007, 16 November 2007 (por el que se aprueba el texto refundido de la Ley General para la Defensa de los Consumidores y Usuarios y otras leyes complementarias).

31 Law 3/1991, 10 January 1991, de Competencia Desleal.

32 Law 3/1991, 10 January 1991, de Competencia Desleal. In this regard, this legal text has been modified by Law 15/2022 of 12 July 2022 and by Royal Decree-Law 24/2021 of 2 November 2021.

33 Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No. 2006/2004 of the European Parliament and of the Council (Unfair Commercial Practices Directive).

- b* traders' right to adapt goods of the same brand to different geographical markets due to legitimate and objective factors, such as national legislation, the availability or seasonality of raw materials, or voluntary strategies to improve access to healthy and nutritious food; and
- c* traders' right to offer goods of the same brand in packages of distinct weights or volumes in different geographical markets.

## VI PRODUCT LIABILITY

Placing a product into circulation can also generate other types of liability under Spanish law if:

- a* the product is not suitable or effective or it differs from the conditions agreed (lack of conformity liability); or
- b* it does not sufficiently guarantee the level of safety expected of it (product liability).<sup>34</sup>

Both types of liability are currently governed by Royal Legislative Decree 1/2007.

Whenever a product does not conform to the corresponding contract or agreement – due to qualitative, quantitative or delivery reasons, among others – the consumer has the right to seek a remedy from the seller and, under specific circumstances, from the manufacturer. The consumer will be entitled to choose between demanding the repair or replacement of the good, unless the latter is disproportionate. If either of these possibilities is feasible, the consumer may choose between the price reduction and the termination of the contract.

Apart from this legal guarantee, the seller may grant additional (commercial) guarantees, which usually offer greater conditions and advantages.

In turn, whenever a product causes bodily harm or damage to things other than the product itself as a consequence of the product not offering the expected safety, the consumer is also entitled to seek compensation.

The law specifically establishes the statutory prescription period of actions brought pursuant to this law to three years as from the time of the injury or damage. It also establishes that the rights of the injured party will prescribe 10 years after the date on which the product was put into circulation (provided that no legal action has been instigated in that period).

Finally, Royal Legislative Decree 1/2007 establishes that manufacturers and importers are not subject to liability insofar as evidence of any of the following circumstances is provided:

- a* the product was not put into circulation by the manufacturer or importer;
- b* in view of the circumstances, it was foreseeable that no defect existed at the time the product was placed into circulation;

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<sup>34</sup> Product liability regulation is being amended at a European level and there may be vast modifications in the future. As at the time of writing, there is only a draft directive; however this directive makes important changes on the current regime, such as the inclusion of artificial intelligence within the scope of the directive, such as the presumption of damage and causation. Furthermore, with the need to implement in Spain Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers, repealing Directive 2009/22/EC (Representative Actions Directive), the course of action of both types of liability – product liability and lack of conformity – will undergo some changes before our courts. A draft law has been published with important changes, but it is still pending discussion in parliament and approval.



- c* the product was not manufactured for sale or for any other method of distribution for an economic purpose, or was neither manufactured nor imported, supplied nor distributed in the course of a professional or business activity;
- d* the defect was the result of manufacturing the product in accordance with mandatory rules in force; and
- e* the state of scientific and technical knowledge at the time the product was put into circulation did not permit the discovery of the defect (denominated the ‘state-of-the-art’ defence).

However, this exemption cause does not apply to drugs and foodstuffs intended for human consumption.

## VII INTELLECTUAL PROPERTY

As an EU Member State, Spain has transposed Directive 2004/48 into domestic law.<sup>35</sup> The result is that Spain has a highly complete, modern system for enforcing intellectual property rights that is harmonised at the EU level. Spain has also adhered to the most important international treaties and conventions on the enforcement of intellectual property rights, with the notable exception of the agreements on the European patent with unitary effect (also known as the Unitary Patent), to which Spain has refused to become a party.

Within this framework, intellectual property related to the agricultural sector stands out. In fact, Spain is one of the European countries that affords the highest legal protection to food products and beverages. This protection is achieved through the EU quality schemes: designations of origin (PDOs), geographical indications (PGIs) – collectively denominated ‘geographical indications’ – and traditional specialities guaranteed (TSGs). Among the 3,436 European geographical indications (PDOs, PGIs and GIs), 394 are Spanish and of the 69 European traditional specialities guaranteed, four are Spanish.<sup>36</sup>

Another extremely relevant intellectual property issue in the field of food in Spain is plant varieties. Law 3/2000 of 7 January establishes the legal framework for the protection of plant varieties and the requirements and procedures with which breeders must comply to apply for intellectual property protection. Law 30/2006 of 26 July on seeds, nursery plants and genetic resources sets out the domestic legal system for the management and protection of plant genetic resources.<sup>37</sup>

Two separate registries result from these two separate pieces of legislation: the Register of Protected Plant Varieties, which grants its holder a special intellectual property right limited in time (the Plant Variety Certificate), and the Register of Commercial Varieties, which provides farmers with access to seeds and nursery plants that are more productive and better adapted to the various Spanish climate and soil conditions.

These two registries, which are linked, constitute an innovative system that recognises and protects intellectual property rights and trade authorisations. It also harmonises the protection system of the rights of breeders, producers, farmers and consumers.

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35 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

36 Data extracted from GIview, the EU database for geographical indications and eAmbrosia, the EU database for guaranteed traditional specialities: GIview (tmdn.org) and eAmbrosia (europa.eu), respectively.

37 Law 3/2000, 7 January 2000 and Law 30/2006, 26 July 2006, respectively.

One of the main features of the Spanish system is the highly specialised nature of the courts that hear enforcement cases of intellectual property rights. The enforcement of intellectual property rights falls under the jurisdiction of commercial courts (which handle intellectual property, antitrust, unfair competition and bankruptcy proceedings). Only courts specifically designated by the Spanish General Council of the Judiciary are entitled to hear cases concerning the enforcement of patents, trademarks and design rights. The commercial courts of Alicante have exclusive jurisdiction over all disputes related to EU trademarks and EU designs (i.e., the commercial courts of Alicante act as European trademark and European design courts in Spain).<sup>38</sup>

## VIII TRADE ORGANISATIONS

Trade organisations bring together undertakings with common commercial interests to contribute to achieve their goals. They play a valuable and legitimate role in modern economies in general, and in the food, beverage and cosmetic sectors in particular.<sup>39</sup> However, trade organisations are by their very nature exposed to risks of unlawful antitrust behaviour (they are a competitors' forum) and regularly attract the attention of competition authorities, even in respect of apparently less risky behaviours such as the preparation of sectorial statistics of benchmarking systems.<sup>40</sup>

Trade organisations must comply with both European<sup>41</sup> and national<sup>42</sup> competition rules, which prohibit agreements between undertakings, as well as decisions, recommendations and concerted practices that have as their object or effect the prevention, restriction or distortion of competition.

In Spain, the infringement of these provisions can result in fines of up to 10 per cent of the worldwide turnover of the infringing entity or entities (the members or the organisation itself). Infringing entities are also exposed to damages claims and reputational harm. Moreover, individuals with a significant role in the infringing conduct may be fined (in Spain up to €60,000).<sup>43</sup>

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38 Notably, the headquarters of the European Intellectual Property Office are based in Alicante, Spain.

39 For instance, in Spain, the National Perfumery and Cosmetics Association (STANPA) and the Spanish Federation of Food and Drink Industries (FIAB).

40 A recent example of such interest can be found in the European Commission's investigation into Insurance Ireland Limited, the association of Irish insurers. In this case, the European Commission questioned certain conditions of access to the association's statistic information exchange system. In order to address the European Commission's concerns, the association offered a set of compromises. See also the section concerning exchanges of information between competitors of the new guidelines on horizontal agreements and concerted practices of the European Commission that have recently been published (the Revised Horizontal Guidelines).

41 Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).

42 Mainly, Articles 1 and 2 of Law 15/2007 of 3 July 2007 on the Defence of Competition that mirror Articles 101 and 102 of the TFEU at a national level.

43 Some employees of trade organisations have already been fined.

The most common risks that trade organisations face include:

- a Issuing (binding) decisions or (non-binding) recommendations concerning prices, market allocation or other strategic conditions. This conduct can influence the independent behaviour of their members, favouring price alignment. Even an ‘innocent’ press release can be problematic.<sup>44</sup>
- b Exchanging commercially sensitive information.<sup>45</sup> Section 6.2.4.2 of the Revised Horizontal Guidelines indicate that trade organisations can participate in the indirect information exchange by facilitating or enforcing the collusion. Exchanges of information are not per se contrary to competition rules<sup>46</sup> as they can have pro-competitive effects; however, in some instances, preparing statistics, reports or rankings can have the effect of coordinating or facilitating the coordination of the competitive behaviour of the trade organisation’s members. An information exchange can be also considered a restriction of competition by object in certain instances (which means that the conduct is problematic per se and can be sanctioned without the need of it having an anticompetitive effect). Exchanging information relating to future conduct on prices or quantities is particularly likely to be considered an infringement by object. Whether an exchange of information can raise competition concerns should be analysed on a case-by-case basis, considering, inter alia:
  - the nature of the information;
  - market characteristics;
  - whether the information is truly aggregated or allows undertakings to be identified; and
  - the age of the information and frequency of the exchange.
- c Agreeing commercial conditions, contract templates that include economic aspects, agreeing (or even discussing) what to do with a common client or supplier, or discussing how to boycott new entrants or competitors.

Trade organisations’ exposure to these antitrust risks makes it highly advisable to consult with specialised counsel and implement strict and tailored compliance programmes.

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44 The decision of 14 October 2009 of the Spanish competition authority (CNMC) (Case S/0053/08, FIAB y Asociados) fined FIAB and eight of its members for an alleged collective price recommendation published in several press releases. The CNMC considered that the combination of content and language between the publications gave the impression that a price increase in raw materials had to be passed on to consumers. This contributed to a price alignment between competitors and predisposed consumers to accept the increase. The infringement was confirmed on appeal.

45 The CNMC decision of 30 March 2004 (Case A.329/02, Estadísticas de cervecedores) did not authorise the collection of statistical data on beer production and commercialisation in Spain, as it considered that the concentration of the market and the nature of the information generated a risk of collusion between undertakings. See also the CNMC decision of 7 February 2011 (Case S/0155/09, STANPA), which sanctioned STANPA for exchanging commercially sensitive information that included intended price increases.

46 See the current Communication from the EC Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements.

## IX FINANCING AND M&A

Over the past year, the geopolitical uncertainty caused by the armed conflict in Ukraine has led to disruptions in the supply chain, an increase in interest rates and inflationary pressures. There has also been a trend for new consumer food and lifestyle preferences, meaning consumers seek food that not only is considered healthy but also has a positive environmental impact. This new scenario demands companies to continue taking advantages of growth opportunities to accelerate the consolidation of their brands in this highly competitive market. Although there is a wide array of M&A structures, M&A transactions can be classified depending on the manner in which a business is acquired. There are three main alternatives to structure an acquisition transaction:

- a* share purchase;
- b* merger; and
- c* asset purchase.

In a share purchase, the buyer purchases shares of a company that operates a business, together with the assets and liabilities that the target company owns. In a merger, two or more companies join together to become a single combined entity. As the process of a merger in Spain is reasonably simple, it is the preferred approach for companies and particularly common in intra-group transactions (which benefit from simplified procedures); however, given that shareholders of the target company usually receive shares of the acquirer company, in some cases it is not the most suitable option.

In both of these types of M&A transactions, due diligence exercises are crucial to identify risks and contingencies of the target company and determine how they should be addressed by the parties involved in the transaction. Given the highly regulated nature of the food, beverage and cosmetics industries, it is essential to confirm that the target complies with applicable laws and regulations (e.g., food safety, product labelling and design, and maintenance of the cold chain) when the structure chosen to acquire a company in these sectors is a share purchase. Negotiation of representations and warranties regarding the assets and liabilities of the target and of subsequent specific indemnities (as the case may be) is also important in share deals to ensure that all information provided by the seller is accurate and all identified contingencies are properly covered.

Share purchases and mergers are structures often used by companies seeking to increase market share or gain access to new brands. In these cases, the companies may opt to acquire competitors to reduce the number of players in a segment or industry, thereby consolidating their market position.

In an asset purchase structure, the buyer purchases specific assets of a business instead of the company itself. This structure might be attractive when acquiring a single business division within a company or when the buyer wants to avoid specific liabilities related to the target. However, this alternative is not particularly common given that it ensures neither the continuity of contracts with third parties nor the maintenance of compulsory licences.

Other legal considerations to bear in mind in connection with M&A structures relate to antitrust regulations in Spain and the European Union, as well as the Spanish foreign direct investment screening mechanism applicable as from 19 November 2020.

Regarding financing in these industries, companies often turn to traditional financing sources, including banks, credit lines, and factoring and lease agreements. However, in recent years, companies have taken a gamble on venture capital investment to finance the growth and expansion of companies as an alternative to bank financing.

Currently, the environment is not favourable for companies looking to raise liquidity, due to the high level of interest rates. Despite the venture capitalists having more capital to spend than in the past years, they are being more selective in what companies they invest, prioritising profitable and established companies. Financial entities are also being cautious when lending funds. The economic uncertainty generated by the Ukrainian war has not prevented companies from continuing to raise funds, although the financing that they obtain is less than in the past few years.

## **X SPECIAL ISSUES FOR CERTAIN PRODUCTS**

### **i Alcohol**

Within the EU, spirits are regulated by Regulation 2019/787.<sup>47</sup> At the domestic level, Royal Decree 164/2014 has unified all previously approved royal decrees on the matter to align itself with EU law.<sup>48</sup>

A primary issue regarding alcohol in Spain is advertising. The General Law on Advertising and the General Law on Audio-visual Communication limit television advertisements for spirits exceeding 20 proof to a strict time frame.<sup>49</sup> Advertising spirits under 20 proof is permitted, however, between 8.30pm and 5am.

The sale of spirits to minors (in Spain, under 18) is banned. Advertisement legislation attempts to prevent underage drinking; irrespective of alcoholic content, advertisements for spirits aimed at minors are prohibited.

### **ii Cannabis**

In Spain, private consumption of cannabis and growing marijuana plants, as long as they are not visible from a public street, are legal. In contrast, consumption in public places, trade and possession in large quantities are illegal, and therefore may be subject to administrative or criminal sanctions.

At the time of writing, cannabis cannot be marketed for human consumption in Spain because it has not been classified by AESAN as a food supplement. In fact, cannabis has yet to be registered as a food supplement on AESAN's list of authorised food supplements.

Under specific conditions, however, cannabidiol may be used to produce cosmetic products. In order to commercialise a cosmetic that contains cannabidiol as an ingredient, it is a requirement of AEMPS, and thus mandatory:

- a* to make a sworn declaration; and
- b* to register the product at the domestic and European levels.

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<sup>47</sup> Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No. 110/2008.

<sup>48</sup> Royal Decree 164/2014, 14 March 2014 (por el que se establecen normas complementarias para la producción, designación, presentación y etiquetado de determinadas bebidas espirituosas).

<sup>49</sup> Law 34/1988, 11 November 1988, General de Publicidad and Law 13/2022, 7 July 2022, General de Comunicación Audiovisual.

In June 2022, the Health Committee of the Spanish Congress approved an opinion that proposed regulating cannabis use for therapeutic purposes for the first time in Spain.

### iii 'Cosmeceuticals'

Straddling the line between cosmetics and pharmaceuticals, cosmeceuticals are products that continue to generate confusion among consumers. There is no European or Spanish legislation on cosmeceuticals, making it necessary to classify these products as either cosmetics or drugs, which is a choice that takes into account factors such as the product's purpose or the part of the body to which the product is applied.

Special mention should also be made of products that claim to have health benefits, known as miracle products. Owing to the potential risk that some miracle products might pose to consumers, Royal Decree 1907/1996 specifically regulates their advertising.<sup>50</sup>

## XI OUTLOOK AND CONCLUSIONS

Of the 27 EU Member States, Spain has some of the highest production levels in the food, beverage and cosmetics markets, and this will most likely continue in the future. With the Russo-Ukrainian War, new challenges have emerged. Indeed, the data related to the food and beverage industry has been abnormally affected by the inflationary effect generated by the armed conflict. In particular, in 2022 the inflation on the cost of the products has been quantified as the highest in the past 14 years, reaching 15.6 per cent.<sup>51</sup>

Moreover, the rise of online commerce represents a significant opportunity for both the food and beverage and cosmetics industries. However, with great opportunities come greater (legal) challenges, particularly in connection with consumer rights, means of payment and enforcement of distribution contracts. This is why the Spanish legal framework in the field of food, beverages and cosmetics has been modernised considerably in 2023, and further regulatory changes in the field are expected in the future.

NextGenerationEU funds allocated to Spain will also help to modernise the industry and increase its efficiency, reducing, in turn, its environmental impact. This evolution will come together with new legal challenges to be faced in the next years.

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50 Royal Decree 1907/1996, 2 August 1996 (sobre publicidad y promoción comercial de productos, actividades o servicios con pretendida finalidad sanitaria).

51 Data extracted from the Economic Report by the Spanish Federation of Food and Drink Industries (FIAB), available at: [https://fiab.es/es/archivos/documentos/INFORME\\_ECONOMICO\\_2022.pdf?](https://fiab.es/es/archivos/documentos/INFORME_ECONOMICO_2022.pdf?)

