

THE FOOD,
BEVERAGE AND
COSMETICS
LAW REVIEW

Editors

Kara L McCall and Elizabeth M Chiarello

THE LAWREVIEWS

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COSMETICS
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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 seeking not only 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 not misleading way. What’s more, 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, while 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 first 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. We have also seen an increase in concern about food safety and food tracing across the world as a result of food-borne illness outbreaks. This first 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, 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

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August 2021

SPAIN

Francisco Javier García Pérez, Montiano Monteagudo, Marta Rios, Juan Reyes, Patricia Vidal, Manuel Álvarez, Cristina Ayo, Jaime Calvo, Eduard Vila, Violeta Marinas, Yanira Miguel and Cristina Moreno¹

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.² Regulation 178/2002 was developed by other several EU regulations, referred to as the 'Hygiene Package'.³ At the internal level, Spain has approved a number of regulations contributing to the correct application of EU legislation, including Royal Decree 1086/2020.⁴ 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',⁵ and Royal Decree 650/2011, applicable to the sale and marketing of soft drinks.⁶

To highlight its importance, the food and beverage industry represents 2.5 per cent of Spain's gross domestic product. Due to the impact of the covid-19 health crisis, annual turnover in the sector has decreased to approximately €130 billion and the labour force shrank by 506,200 people.⁷ Nevertheless, Spain still ranks fourth in terms of turnover at the EU level, representing 9.7 per cent of total EU turnover.⁸

-
- 1 Francisco Javier García Pérez is a senior associate, Montiano Monteagudo, Marta Rios, Juan Reyes and Patricia Vidal are partners, Manuel Álvarez, Cristina Ayo and Jaime Calvo are counsel and Eduard Vila, Violeta Marinas, Yanira Miguel and Cristina Moreno are associates at Uría Menéndez Abogados, SLP. The authors also thank Patricia Ibárcena and Adrián Vila for their contribution to the chapter.
 - 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.
 - 4 In Spanish: *Real Decreto 1086/2020, de 9 de diciembre, 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 In Spanish: *Real Decreto 4/2014, de 10 de enero, por el que se aprueba la norma de calidad para la carne, el jamón, la paleta y la caña de lomo ibérico.*
 - 6 In Spanish: *Real Decreto 650/2011, de 9 de mayo, por el que se aprueba la reglamentación técnico-sanitaria en materia de bebidas refrescantes.*
 - 7 Annual Report on the Spanish Food Industry (2020–2021), produced by the Sub-directorate General for Competitiveness of the Food Chain (Ministry of Agriculture, Fisheries and Food).
 - 8 id. at 2.

Spain also has one of the largest domestic markets for cosmetics and personal-care products in the EU, being valued at €7.7 billion in 2020. This market is also primarily regulated by EU law. In 2018, the Spanish Parliament approved Royal Decree 85/2018,⁹ which complemented the EU legislation approved on the matter, particularly Regulation 1223/2009.¹⁰

II YEAR IN REVIEW

Over the past year, marked by the covid-19 pandemic, the food and cosmetics sectors in Spain have benefited from the rise in e-commerce, as in other sectors, which has helped to weather the negative impact of the crisis.

In the food sector, we have witnessed three remarkable changes that have necessitated, in some cases, the drafting of new terms and conditions in commercial agreements:

- a* the consolidation of e-commerce distribution channels of large supermarkets;
- b* the entry of large e-commerce players into the food sector; and
- c* internet sales of products by companies that had formerly only sold their products through traditional sales channels.

In the cosmetics sector, the increase of e-commerce has had a significant impact on selective-distribution agreements, which has in turn led to increased litigation.

On a separate note, there have not been any major legislative transformations in Spain. Among the very limited legislative developments, it is worth highlighting Law 8/2020 of 16 December adopting specific urgent measures in the agriculture and food sectors to improve the functioning and structuring of the food-supply chain, which was designed to increase the efficiency and competitiveness of Spain's agri-food sector and reduce the imbalance in commercial relations between the various operators in the value chain.

Other minor legislative developments in the EU have included the authorisation for placing novel foods on the market, including the authorisation of traditional foods from third-party countries, as well as extensions of use and modifications in conditions of use or labelling of novel foods that were previously authorised.

As regards cosmetics law, the EU has amended the annexes to Regulation (EC) 1223/2009 regarding the list of substances prohibited, substances restricted, colourants and UV filters in cosmetic products.

Nevertheless, it is expected that, in the near future, there will be an enormous legislative impact resulting from the implementation of the Recovery, Transformation and Resilience Plan for the Spanish economy prepared by the Spanish government in order to benefit from €72 billion of Next Generation EU funds. That plan foresees the implementation of measures to overcome the crisis caused by the covid-19 pandemic, and to transform Spain into an economy driven by green, digital, gender-neutral and cohesive parameters, with a special focus on fighting rural depopulation and promoting agricultural development.

9 In Spanish: *Real Decreto 85/2018, de 23 de febrero, por el que se regulan los productos cosméticos.*

10 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).¹¹ 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.¹²

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).¹³ AEMPS systematically collects, evaluates and monitors the 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, and Regulation 1333/2008 lays down rules to achieve a high level of consumer protection and safeguarding of human health.¹⁴ 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, 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.¹⁵ 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.¹⁶ The overarching objective is to protect public health and ensure good manufacturing practices, recognising that contaminants may enter food at any point from production to consumption.

11 In Spanish: *Agencia Española de Seguridad Alimentaria y Nutrición*.

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

13 In Spanish: *Agencia Española de Medicamentos y Productos Sanitarios*.

14 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.

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

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

iii Recalls

Pursuant to EU Regulation 178/2002¹⁷ and Spanish Law 17/2011, both food and feed-business operators who believe, or have reasons to believe, that a food which 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 both at the 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.¹⁸

IV SUPPLY CHAINS

i Labour and immigration

The food, drink and cosmetics industry and, more specifically, its 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 the inappropriate overuse of temporary employment contracts or employment relationships hidden under corporate agreements.

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:

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

17 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.

18 https://ec.europa.eu/food/system/files/2016-10/gfl_req_guidance_rev_8_en.pdf.

- b 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 €6,251 to €187,515. Likewise, 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, it is not an issue 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 Organisation conventions on forced labour (both 29 and 105).

ii Processing and certifications

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

The characteristics of the inspection-and-certification system are set out in European regulations (Regulation (EC) 834/2007 and Regulation (EC) 889/2008),¹⁹ which allow Member States to choose between a public or 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.

iii Sustainability

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

The consequences of climate change and the devastating effects of the covid-19 health crisis have revealed the urgent necessity of ensuring that food-chain operators (particularly producers, carriers and distributors) adapt their activities to mitigate their environmental

¹⁹ Council Regulation (EC) No. 834/2007 of 28 June 2007 on organic production and labelling of organic products 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.

impact and guarantee that consumers have access to sufficient, nutritive 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 operators in the food chain. Nonetheless, implementing the corresponding measures also requires a reasonable adjustment period, significant resources and less burdensome administrative constraints. Regardless of the potential difficulties of achieving of those goals, the European Commission is expected to present a legislative proposal for the design of a sustainable food system by the end of 2023.

Spain has unreservedly moved towards food sustainability by enacting various instruments and self-assessment tools and establishing the framework and monitoring procedures for voluntary corporate sustainability commitments regarding the food chain. Furthermore, both the Spanish Strategy for the Circular Economy and the modification of Law 22/2011 on waste and contaminated soils (currently in Parliament) incorporate requirements to reduce food loss and waste and increase food recovery, while limiting and penalising single-use plastics – a measure that may prove controversial given plastic's importance for logistics and food preservation.

It is essential for society to move further towards food sustainability. However, in pursuing this process, public authorities must take into account the interests of all affected parties and operators. As stated in the European Green Deal, it 'will transform the EU into a modern, resource-efficient and competitive economy', ensuring 'no person and no place 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 his or her 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: risk-mapping focused on corruption, anti-bribery policies and protocols in force, anti-corruption clauses in the corresponding contracts, due-diligence exercises and background checks of counterparts and foreign agents, fast detection and reaction to corruption, etc.

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. Likewise, it encourages the adoption of good commercial 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.²⁰ 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.²¹

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.²²

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.²³ 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.

20 In Spanish: *Ley 34/1988, de 11 de noviembre, General de Publicidad* and *Ley 3/1991, de 10 de enero, de Competencia Desleal*, respectively.

21 In Spanish: *Ley 17/2011, de 5 de julio, de seguridad alimentaria y nutrición, 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*. 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.

22 In Spanish: *Real Decreto 1798/2010, de 30 de diciembre, por el que se regula la explotación y comercialización de aguas minerales naturales y aguas de manantial envasadas para consumo humano*.

23 www.aesan.gob.es/AECOSAN/web/seguridad_alimentaria/subseccion/procedimientos_registro.htm.

The sale and marketing of cosmetics is also highly regulated at the EU level, including through Commission Regulation 655/2013.²⁴ Likewise, domestic royal decrees addressing the sale and marketing of cosmetics, such as Royal Decree 85/2018, must be complied with.²⁵ For example, Royal Decree 85/2018 requires the labelling information of cosmetics to be, at least, in Spanish.

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,²⁶ and the Unfair Competition Law.²⁷ Both statutes provide an extensive framework governing the protection of consumer interests, including labelling, marketing and product guarantees. On the other hand, the Unfair Competition Law addresses, among other things, the regulation of unfair consumer practices, including baiting practices and misleading promotional practices.²⁸

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, 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.

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).

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 or the termination of the contract.

24 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.

25 In Spanish: *Real Decreto 85/2018, de 23 de febrero, por el que se regulan los productos cosméticos.*

26 In Spanish: *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.*

27 In Spanish: *Ley 34/1988, de 11 de noviembre, General de Publicidad.*

28 In Spanish: *Ley 3/1991, de 10 de enero, de Competencia Desleal.*

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;
- 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.²⁹ 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 3,365 European geographical indications (PDOs, PGIs and GIs), 378 are Spanish and of the 68 European traditional specialities guaranteed, four are Spanish.³⁰

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

30 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.

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.³¹

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.

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).³²

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 cosmetics sector in particular.³³ 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.

Trade organisations must comply with both European³⁴ and national³⁵ 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.

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

31 In Spanish, respectively: *Ley 3/2000, de 7 de enero, de régimen jurídico de la protección de las obtenciones vegetales* and *Ley 30/2006, de 26 de julio, de semillas y plantas de vivero y de recursos fitogenéticos*.

32 It is worth highlighting that the headquarters of the European Intellectual Property Office are based in the Spanish city of Alicante.

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

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

35 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.

itself). Infringing entities are also exposed to damages claims and reputational harm. Moreover, in some countries, individuals with a significant role in the infringing conduct may be fined (in Spain up to €60,000)³⁶ or imprisoned (e.g., in the UK).

The most common risks 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;³⁷
- b exchanging commercially sensitive information.³⁸ Exchanges of information are not per se contrary to competition rules³⁹ as it can have pro-competition effects; however, in some instances preparing statistics, reports or rankings can have the purpose or effect of coordinating or facilitating the coordination of the competitive behaviour of the trade organisation’s members. 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;
 - how old the information is and frequency of the exchange; and
 - whether the information is public; and
- 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.

36 Some employees of trade organisations have already been fined.

37 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.

38 The CNMC decision of 30 March 2004 (Case A.329/02, *Estadísticas de cerveceros*) 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.

39 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

The covid-19 health crisis, along with the corresponding restrictions on the freedom of movement, including a strict lockdown of the Spanish population, have accelerated the shift to e-commerce in these industries, which, in the short term, will likely lead to increased investment in digitalisation and new technologies and corporate partnering intended to accelerate the growth of this channel.

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: (1) share purchase; (2) merger; and (3) 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, 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 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.⁴⁰

In an asset-purchase structure, the buyer purchases specific assets of a business instead of the company itself. This structure may 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,⁴¹ as well as the Spanish foreign-direct-investment screening mechanism applicable as from 19 November 2020.⁴²

40 One example is the recent acquisition of the supermarket chain of Madrid, Sánchez Romero, by El Corte Inglés to strengthen its position in the 'premium' distribution segment. For more information on this transaction, visit: [El Corte Inglés compra Sánchez Romero para crecer en alimentación | Distribución y Consumo \(expansion.com\)](#).

41 See more in Section VIII: 'Trade organisations'.

42 Article 7 *bis* Law 19/2003 of 4 July on the legal framework governing capital movements and economic transactions abroad and on specific measures to prevent money laundering, as introduced by the fourth final provision of Royal Decree Law 8/2020 of 17 March on urgent extraordinary measures to address the social and economic impact of COVID-19, as amended by the third final provision of Royal Decree

With regard to 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.

Over the past year, companies have significantly reduced their investment activities due to covid-19. So far, efforts have focused on maintaining companies' liquidity, by extraordinary measures approved by the Spanish government to mitigate the economic effects of covid-19 (e.g., ICO (Instituto de Crédito Oficial) loans) or by reducing their costs (e.g., collective dismissal, divestments of non-core business). As a consequence of the pandemic, many companies have carried out restructuring operations and have been forced to refinance their debt following the economic slowdown that has jeopardised some companies' viability.

X SPECIAL ISSUES FOR CERTAIN PRODUCTS

i Alcohol

Within the EU, spirits are regulated by Regulation 2019/897.⁴³ At the domestic level, Royal Decree 164/2014 has unified all previously approved royal decrees on the matter in order to align itself with the structure of the Regulation.⁴⁴

A primary issue regarding alcohol in Spain is advertising. The General Law on Advertising and the General Law on Audio-visual Communication, as well as various regional laws, prohibit television advertisements for spirits exceeding 20-proof.⁴⁵ With some exceptions, advertising spirits under 20-proof between 6am and 8.30pm is also prohibited.

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 is prohibited.

ii Cannabis

In Spain, private consumption of cannabis and growing marihuana 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. It must be taken into consideration that regulations combating drug addiction are entrusted to the autonomous regions, and therefore vary among them.

Law 11/2020 of 31 March on additional urgent measures to address the social and economic impact of COVID-19; by the single transitory provision of Royal Decree Law 34/2020 of 17 November on urgent measures to support business solvency and the energy sector, and in relation to tax matters; and by Royal Decree Law 12/2021 of 24 June on urgent measures in the field of energy taxation and energy generation and on the regulation fee management and the water rate.

43 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.

44 In Spanish: *Real Decreto 164/2014, de 14 de marzo, por el que se establecen normas complementarias para la producción, designación, presentación y etiquetado de determinadas bebidas espirituosas.*

45 In Spanish: *Ley 34/1988, de 11 de noviembre, General de Publicidad and Ley 7/2010, de 31 de marzo, General de la Comunicación Audiovisual.*

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.

However, under specific conditions, cannabis may be used to produce cosmetic products. In order to commercialise a cosmetic that contains cannabis as an ingredient, it is mandatory to (1) make a sworn declaration; and (2) register the product at the domestic and European level. This is a requirement of AEMPS.

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 – 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. Due to the potential risk that some miracle products may pose to consumers, Royal Decree 1907/1996 specifically regulates their advertising.⁴⁶

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. Despite being hit particularly hard by the covid-19 health crisis and the measures implemented to prevent its spread, these sectors have nevertheless shown great potential to maintain a position of leadership in comparison with other industries. However, studies predict that the food industry will start its recovery in the first quarter of 2022, but will not return to normal levels of activity until at least the first quarter of 2023.⁴⁷

Moreover, the rise of online commerce represents a significant opportunity for both the food and beverage and cosmetics industries. Yet, with great opportunities come greater (legal) challenges, particularly in connection with consumer rights, means of payment, enforcement of distribution contracts, etc. This is why, in the near future, there will likely be regulatory changes in the field.

46 In Spanish: *Real Decreto 1907/1996, de 2 de agosto, sobre publicidad y promoción comercial de productos, actividades o servicios con pretendida finalidad sanitaria.*

47 Data extracted from the following website: Industria de alimentación. Impacto del Covid-19 en las empresas del sector y horizonte de recuperación (www-randstadresearch-es.s3.amazonaws.com).

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