

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

Chicago

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# CHILE

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## I OVERVIEW

In Chile, foodstuff and cosmetic products are primarily regulated by the Chilean Sanitary Code. Foodstuff and non-alcoholic beverages are also regulated by Decree No. 977/1997 of the Ministry of Health, which sets forth the Sanitary Foods Regulation (RSA), and cosmetics are regulated in detail by Decree No. 239/2003, which approves the Regulations for the National Cosmetics Control System (Decree 239).

Both the RSA and Decree 239 regulate the manufacture, import, sale and marketing of foodstuff, non-alcoholic beverages and cosmetic products in Chile.

As both cosmetic and foodstuff products are products of mass consumption, sanitary authorities exert a high level of supervision and enforcement of compliance with local regulations on this matter. Supervision and enforcement of the RSA are carried out by the regional ministerial secretariats of health for each region, and the supervision and enforcement of Decree 239 are carried out by the Chilean Public Health Institute (ISP).

The most noticeable difference between the regulatory schemes applicable to foodstuff and cosmetics in Chile is that foodstuff is not subject to registration, unlike cosmetics, which must be registered before the ISP to be commercialised in Chile.

Both cosmetic and foodstuff-imported products (including non-alcoholic beverages) are subject to a pre-marketing authorisation (in addition to registration requirements, where applicable) for their commercialisation in the country.

## II YEAR IN REVIEW

In connection to beverages, the most relevant development in the past year has been the enactment of Decree No. 98, the regulation of Law No. 21.363. This regulation sets forth the characteristics of the graphic warnings that must be included in the labelling and advertisement of alcoholic beverages and marks the beginning of the vacancy period for the actual entry into force of these obligations.

In summary, this regulation establishes that all beverages with an alcohol content equal to or greater than 0.5°, which are intended to be marketed in Chile, must include the warning set forth therein, on the back of the container or package. Manufacturers (for national products) and importers (for imported beverages) are responsible for adding the warning.

Furthermore, the label of all beverages with an alcohol content equal to or greater than 0.5° must include the energy value of the product expressed in calories (kilocalories).

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<sup>1</sup> Ignacio Gillmore is a partner and Cristina Busquets is a senior associate at Carey.

Regarding advertisement, any graphic or advertising action disseminated through written communication media, posters or advertisements of any kind, whether physical or virtual, including those placed at points of sale, must include a box containing the word 'WARNING', along with the phrases set forth in the regulation. The warning must also be incorporated in audiovisual and radio advertising, as established in the regulation.

Any form of advertising, whether direct or indirect commercial or non-commercial, of alcoholic beverages by any means, such as product packaging, computer and non-computer media, or any activity or publication, aimed exclusively at minors, is prohibited. Furthermore, any form of direct or indirect commercial or non-commercial advertising of alcoholic beverages in sporting activities is prohibited, except for mega sporting events.

Similarly, the regulation establishes a prohibition to induce minors to consume alcoholic beverages and to take advantage of their credulity. For these purposes, the regulation establishes that it will be understood that minors are induced or that their credulity is taken advantage of when, among other elements, children's or young people's characters and figures, animations, cartoons, toys or children's music are used. Furthermore, it shall be especially understood that minors are induced or their credulity is exploited when the presence of real or fictitious persons or characters that attract the interest of this group is used, such as national or international athletes recognised in their discipline or characters from movies or series aimed at children, or persons who influence minors by having a presence in written or digital media aimed at this group; or if the advertisement contains imaginative statements or fantasy plots, childish voices, language or expressions typical of minors in general, or if it presents situations that represent the daily life of minors, such as school, recreation, games, children's or teenagers' hobbies, parties or social gatherings, family or children's, teenagers' or minors' peers in general.

Moreover, sporting goods intended for mass distribution, such as t-shirts and uniforms or posters and promotional items related to all kinds of sporting activities, may not contain names, logos or images of brands of alcoholic beverages, including any sign or allusion to their brands or products.

Provisions of the regulation related to warning messages and graphics (including their incorporation in advertising) and energy value will enter into force one year from their publication, i.e., 7 July 2024; while the rules regulating advertising restrictions value will enter into force 36 months from the publication of the regulation, i.e., 7 July 2026.

### III FOOD AND COSMETIC SAFETY

#### i Regulatory framework

The manufacture and sale of foodstuff products are regulated mainly in the RSA, and the authority in charge of the supervision and enforcement of compliance with the Regulation is the Regional Ministerial Secretariats of Health for each region (Seremi).

In turn, the manufacture and sale of cosmetics are governed by Decree 239, the supervision and enforcement of which are under the charge of the ISP.

Both Seremi and the ISP exert strict enforcement and supervision of compliance with the aforementioned regulations through supervision campaigns during each year.

Non-compliance with the RSA and Decree 239 is subject to the same administrative procedure: the sanitary sanctioning proceeding regulated by Book X of the Sanitary Code.

In general terms, a sanitary sanctioning proceeding may be initiated *ex officio* by the sanitary authorities or through a claim filed by any interested individual or entity.



Sanctions associated with sanitary sanctioning proceedings are a fine that ranges between 0.1 and 1,000 monthly tax units (between approximately US\$7 and US\$70,000) and, if applicable, the sanitary authorities can also impose sanitary measures to avoid further damage or risk (i.e., seizure of goods, closure of establishments, mandatory recall and prohibition of sales).

Decisions issued in sanitary sanctioning proceedings may be challenged through administrative recourses (i.e., appeal for reversal and hierarchical appeal), and unfavourable decisions are also challengeable through a special judicial remedy regulated under Article 171 of the Sanitary Code.

## **ii Food additives and contaminants**

Food additives and contaminants are regulated in detail in the RSA. Furthermore, certain specific types of contamination are regulated by supplementary regulations, such as maximum permitted limits of pesticide residues in foodstuff, which are regulated in Exempt Resolution No. 892/2020 of the Ministry of Health.

In connection with food additives, Title III of the RSA regulates permitted additives, setting forth a detailed list of allowed additives for each category (e.g., acidity regulators, anti-caking and anti-humectant substances).

In this regard, the RSA sets forth an absolute prohibition on the manufacturing, import, possession, distribution, sale and transfer of any title of contaminated foodstuff.<sup>2</sup>

Regarding food contaminants, Title IV of the RSA regulates various categories of contaminants (i.e., heavy metals, radionuclides, mycotoxins, and other contaminants and residues). Furthermore, Title V of the RSA regulates microbiological parameters accepted for each category of foodstuff in detail.

## **iii Recalls**

In connection with foodstuff products, the RSA does not set forth a specific procedure for recall. However, it regulates several categories of foodstuff under which manufacturing, import, possession, distribution, sale, or transfer of any title is absolutely prohibited under Article 99 et seq. (i.e., contaminated food, counterfeit food, adulterated food and altered food). Therefore, manufacturers, importers, distributors and sellers may be liable for any of the aforementioned actions.

Article 105 of the RSA provides that foodstuff that poses a risk to health must be seized by the sanitary authorities.

For cosmetics, manufacturers, importers and distributors will be responsible for the timely and expeditious recovery of any batch or series manufactured, imported or distributed when the holder of the registration has decided to recall a cosmetic product from the market due to a suspected or confirmed quality defect (voluntary recall), or due to the cancellation of the sanitary registration by the ISP due to safety or efficacy reasons (mandatory recall).

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2 Under Article 101 of the RSA, contaminated foodstuff is any foodstuff that contains: (1) microorganisms, virus or parasites, foreign or deleterious substances of mineral, organic or biological origin, radioactive substances or toxic substances that exceed the maximum amounts permitted by applicable regulations, or that are presumed to be harmful for health; (2) any type of dirt, waste or faeces; or (3) unauthorised additives or additives that exceed the permitted maximum amounts.

In this respect, the holder of a sanitary registration must notify the ISP of the recall immediately upon its initiation. Similarly, all establishments that manufacture, import, export, distribute and commercialise cosmetic products in Chile must have a quality management system for handling recall activities.

Progress of the recall process must be monitored, recorded and reported to the ISP.

Finally, all products recalled from the market must be destroyed by companies authorised by Seremi for this purpose.

## **IV SUPPLY CHAINS**

### **i Labour and immigration**

Human resources are mainly regulated in Chile by the 1994 Labour Code and its related laws. These regulations are applicable nationwide. Labour and employment law in Chile is employee-protective, containing several public order provisions that may not be waived by parties. On top of these minimum regulations, parties may agree additional benefits that are regulated based on their free will.

The Labour Code defines the individual employment contract as an agreement under which the employee and the employer are reciprocally committed: the employee to personally render services under dependency and subordination, and the employer to pay the employee the corresponding remuneration. Whenever the relationship described above exists, the law implies an employment contract, even if there is no written evidence of such or the parties have agreed otherwise. This situation makes the adoption of necessary measures to avoid falling under the definition of an employment contract relevant, when outsourcing personnel or hiring independent contractors or consultants.

Labour and employment disputes need necessarily to be solved by labour courts. Consequently, it is not possible to agree arbitration clauses to modify this necessity. Remedies against labour court rulings will be solved in the relevant courts of appeals and the Supreme Court. Similarly, there is an administrative agency responsible for ensuring compliance with labour and employment laws: the Labour Board. Prior to submitting a claim before a court of law, employees may submit such a claim before an administrative agency if it is possible to reach an agreement through mediation.

The Chilean Constitution recognises the rights of employees to form unions and to bargain collectively.

The Labour Code imposes on employers the obligation to undertake all necessary measures to protect the life and health of their employees and to prevent accidents and work diseases or injuries.

When considering hiring employees in Chile, it is relevant to be aware of local laws, since labour and employment law is highly regulated, and any undermining or non-observance of employees' rights will be sanctioned by local authorities and may give rise to significant risks and liabilities.

In connection with immigration, foreigners coming into Chile for work need a work authorisation or permit that allows them to carry out remunerated activities in the country (even if the income is sourced in their home country). From a practical perspective, the recommended type of permit will depend on the length of stay and their professional or management-level occupation.

Business visitor status is not a visa category in Chile, and thus foreigners may enter the country under a transitory permanence status receiving a transitory permanence card at the

port of entry. This status will allow them to carry out limited business activities (e.g., contract negotiations and contact clients) usually for 90 days, which may be extended once in Chile for an additional 90-day period.

## **ii Processing and certifications**

The manufacturing of foodstuff must be subject to quality control procedures. Any claims or characteristics of a product highlighted in the product's packaging or advertisements must be verifiable through objective evidence.

For cosmetic products, the manufacturer or importer will be responsible for ensuring the quality of products sold in Chile. In this regard, any individual or entity that manufactures cosmetic products in Chile must adopt a quality control system that certifies compliance with manufacture specifications, raw materials and the finished product.

Importers of finished cosmetics must perform or contract an analysis that certifies the quality of the products, unless the ISP exempts them from such an obligation through a resolution in which it validates the quality control performed at origin.

## **iii Sustainability**

Chile is a signatory of the main international environmental protocols, conventions and treaties regarding sustainability, including the Rio Declaration on Environment and Development (1992), the United Nations Framework Convention on Climate Change (1994), its Kyoto Protocol (2002), the Paris Agreement (2015), the Johannesburg Declaration on Sustainable Development (2002) and the Basel Convention (1990).

National environmental protection is based on Article 19 No. 8 of the Chilean Constitution, which recognises the right to live in a pollution-free environment and allows the restriction of certain constitutional rights to achieve this objective. Law No. 19,300, on the General Bases of the Environment, concretises this guarantee through the creation of the Ministry of the Environment (responsible for the creation of environmental policies, including quality and emission standards), the Environmental Assessment Service (entrusted with the evaluation of the environmental impact of projects and activities) and the Superintendency of the Environment (responsible for the supervision and sanction of infractions of the environmental regulations). Recently, Congress has approved the creation of a Biodiversity and Protected Areas National Service, and the regulation of several environmental infringements as criminal offences.

Conversely, Law No. 20,920 and subsequent regulations set forth a special waste management regime. This regime addresses reducing waste generation and promoting its reuse, recovery and recycling. In this regard, Supreme Decree No. 12/2020, which sets collection and recovery goals associated with containers and packaging, has significant relevance. In addition, Law No. 21,368 limits the delivery of single-use products to food establishments and in disposable plastic bottles.

Finally, to improve production and environmental conditions in terms of occupational health and safety, energy and water efficiency, emissions reduction and waste recovery, among other things, several private companies and public agencies have signed clean production agreements (APLs), including the eco-labelling of containers and packaging, which seeks to provide consumers with certified information on the recyclability of containers and packaging of mass consumption products. These APLs have been validated by the United Nations as a nationally appropriate mitigation action.

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

Legal entities and individuals are exposed to acts of corruption and money laundering in their supply chains, which can have legal and reputational consequences, even if misconduct or illegal acts are not committed directly by a company's employees but by contractors, subcontractors, suppliers, distributors or other agents under the supervision and control of the legal entity. Under this framework, in Chile, there are two main regulations to be considered:

- a* the Corporate Criminal Liability Act (CCLA),<sup>3</sup> which imposes criminal liability on legal entities when the relevant behaviour is a crime of bribery of a local or foreign public official, money laundering, terrorism financing, or the reception of stolen goods, unlawful negotiation, commercial bribery, disloyal management or embezzlement; and
- b* the Anti-Money Laundering Act (AML Act),<sup>4</sup> which penalises anyone who possesses, hides or otherwise conceals assets while knowing that they directly or indirectly originate from certain crimes, including drug trafficking, terrorist acts, violation of the securities law, bribery, embezzlement of public funds or other crimes committed by public officials.

Under the CCLA, it is essential that companies adopt and implement compliance programmes or crime prevention models to manage their own anti-bribery compliance and to mitigate risks. The CCLA refers to representatives to trigger criminal liability for a company. Within this scope, contractors, subcontractors, suppliers, distributors and agents can be included. Thus, an offence committed by a contractor, subcontractor, supplier or distributor could criminally expose the legal entity if the company benefits from a corrupt act and its measures were insufficient to prevent the risk of the offence being committed.

The AML Act requires certain industries to implement an AML compliance programme and to report to the Financial Analysis Unit suspicious money laundering transactions, including those detected in the supply chain.

In May 2023, the Chilean Congress approved a bill that Systematises Economic Crimes and Attacks against the Environment. The objectives of this bill are, inter alia:

- a* to incorporate new penalties for individuals and legal entities that incur in economic crimes; to establish a new and more severe system for determining and executing penalties; and
- b* to reformulate the liability imputation model for legal entities.

Hence, companies will have to take even more measures within their supply chain, in order to comply with the new legal requirements to address corruption. This bill is currently under review by the Chilean Constitutional Court, awaiting enactment.

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

As other regulated products, the most common issues in this regard are related to permits required to develop relevant activities, due handling and storage of products, and adequate traceability in the supply chain. This will be particularly important in the case of cosmetics, whereby the holder of the registration will be ultimately responsible for any breaches of the applicable regulations.

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<sup>3</sup> Law No. 20,393.

<sup>4</sup> Law No. 19,913.

## V SALES AND MARKETING

### i Regulatory framework

In terms of marketing, cosmetics and foodstuff products are subject to the same general rules, which are, mainly:

- a* information must be provided in Spanish;
- b* prohibition of misleading or deceitful advertisements; and
- c* prohibition of curative or therapeutic claims (permitted only for pharmaceutical products).

No registration or permit is required to advertise foodstuff or cosmetic products in Chile.

Any information or claims on a product's label or in an advertisement that contain or suggest a benefit or characteristic, or both, of a product (e.g., '100% natural', '#1 product' or 'vegan') must be verifiable through scientific or objective support.

Manufacturers, sellers and distributors of foodstuff and non-alcoholic beverages may highlight a product's characteristics in terms of vitamins, minerals, proteins, and other nutrients and dietary fibre by using thoroughly regulated claims denominated 'nutritional descriptors' (e.g., 'light', 'low in'). The RSA sets forth the conditions to use each nutritional descriptor.

The use of certain health claims<sup>5</sup> is permitted for foodstuff products and non-alcoholic beverages under the stringent parameters set forth in Exempt Resolution No. 860/2017.

Furthermore, certain types of foodstuff (i.e., those with added sugars, sodium or saturated fats, or a combination thereof, that, due to their nutritional composition, exceed the maximum limits set forth in Article 120 *bis* of the RSA in connection with said critical nutrients and energy) are subject to specific restrictions and obligations in terms of advertising and sales as introduced by Law No. 20.606, which sets forth front of pack (FOP) nutritional labelling requirements and advertisement restrictions for this type of foodstuff ('high in' foodstuff).

High in foodstuff must include a warning sign, consisting of a black octagon with white letters, on their labels stating the nutrient (or nutrients) in which such food is high. However, certain categories of high in food are exempted from the obligation to include this FOP nutritional information on their labels, regardless of their nutritional composition. High in foodstuff have a prohibition of making advertisements addressed to children under 14 years old, which includes the use of commercial hooks,<sup>6</sup> contests, raffles and free samples addressed to such an age group.

In addition, advertisements of high in products broadcast on television or exhibited in cinemas are completely prohibited between 6am and 10pm and are restricted to advertisements that are not addressed towards children under the age of 14 outside such a time frame.

Furthermore, a mandatory message must be included in any advertisement of high in foodstuff that are made in mass media (i.e., television, radio, written press, billboards and other advertisements displayed on public roads and on the internet).

<sup>5</sup> Health claims in connection with foodstuff are defined as 'Any representation that states, suggests or implies the existence of a relationship between a food, a nutrient or other substance contained in a food and a health-related condition' (Article 106 No. 9 of the RSA).

<sup>6</sup> In other words, toys, stickers or other elements provided for free with the purchase of a product that are unrelated to the consumption of such and that are targeted for children.

The sale of high in foodstuff is absolutely forbidden in educational establishments, with the exception of higher education institutions (e.g., universities and vocational colleges). Any type of advertisement for infant milk formulas is forbidden. According to the RSA, infant milk formulas are those addressed towards infants of up to 12 months of age.

In the case of cosmetics, the information provided in advertisements must be in accordance with the nature, cosmetic purpose and other characteristics of the product declared for its registration before the ISP.

## **ii Consumer protection and false advertising**

Misleading and deceitful advertisements are prohibited both by the RSA and by Decree 239. Therefore, non-compliance with this prohibition is subject to the initiation of the sanitary sanctioning proceeding described above.

When a product is subject to a special regulation as a foodstuff or cosmetic, Law No. 19.496 on the Protection of the Rights of Consumers (CPA) has a residual application only for those matters that are not expressly addressed in the special regulation.

Therefore, and due to the level of detail in which an advertisement is addressed under the sanitary rules – particularly in connection with foodstuff – the CPA is applicable in terms of, *inter alia*, compensation for damages caused by misleading or deceitful advertisements. In this regard, compensation for damage caused may be sought, under the CPA, through individual claims or class actions.

## **VI PRODUCT LIABILITY**

As to liability for non-compliance, the sanitary sanctioning proceeding will be applicable in connection with both foodstuff products and cosmetics. Regarding foodstuff, the Sanitary Code sets forth a definition of defective sanitary products, which includes foodstuff, pharmaceutical products and medical devices, in Article 111 H.<sup>7</sup>

Furthermore, in the case of cosmetics, the holder of the registration will be the primary responsible for any sanitary liabilities arising from non-compliance with Decree 239, notwithstanding the responsibility that members of the supply chain may have in their corresponding roles. For foodstuff, any actor in the supply chain may be subject to a sanitary summary proceeding for its specific liability in the manufacture, import, distribution or sale of defective products.

As to compensation, neither the RSA nor Decree 239 contemplates procedures for requesting compensation for damage suffered due to defective products.

## **VII INTELLECTUAL PROPERTY**

Registration of trademarks and patents relating to food, beverage and cosmetic products does not have a special procedure, nor is it subject to additional requirements or a stricter substantive analysis.

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<sup>7</sup> Defective sanitary products are defined as those products that do not offer sufficient safety, considering all circumstances relating to the product, especially its presentation and reasonably foreseen use. In addition, a sanitary product is deemed defective if it does not offer the same safety normally offered by other units of the same series.

The only exception corresponds to trademarks relating to Class 31 of the Nice Classification (mainland and sea products not having been subjected to any form of preparation for consumption, live animals and plants), for which the Chilean Patent and Trademark Office (PTO) will request a report from Chile's Agricultural and Livestock Service to confirm whether a product corresponds to the name of a plant variety that could impede its registration. Another important point regarding trademark matters is that when a good or service has been accepted for registration, the Chilean PTO specifically states in its resolution that grants the registration number of the particular trademark or in its verdict – in cases in which an opposition or nullity action has been involved – that said granting does not exempt such a good or service from compliance with the rules concerning distribution, sale, marketing, labelling, origin, health measures and any other special regulations applicable to the good or service that the trademark is intended to distinguish in Chile.

## VIII TRADE ORGANISATIONS

For foodstuff products, the main trade organisations in Chile are AB Chile AG<sup>8</sup> and Chilealimentos AG<sup>9</sup> notwithstanding that there are other trade organisations for certain specific categories of foodstuff, such as ALIMSA AG,<sup>10</sup> which represents manufacturers and importers of dietary supplements.

For cosmetics, the main trade organisation is the Cámara de la Industria Cosmética AG.<sup>11</sup> As with any trade organisation, companies should avoid any conduct that could be considered a breach of the above organisations' antitrust or competition regulations and thus limit industry-wide issues and concerns.

## IX FINANCING AND M&A

The food industry in Chile is still an important industry after mining in terms of contribution to national gross domestic product (GDP) and exports. However, the agricultural and livestock sector has decreased by 4.1 per cent to the GDP in 2023's first trimester analysis. Main food segments involving financing and M&A transactions in Chile are fruit and nuts and seafood products, which include aquaculture, fishing products and food and other suppliers (e.g., packaging, storage and distribution). Regarding the cosmetics and personal healthcare market, it has been constantly growing in recent years and, currently, market players have noticed a shift in Chilean consumers' behaviour and their preference to purchase natural and organic-based personal care products rather than conventional products.

The main emphasis in financing and M&A transactions involving the foodstuff and cosmetic industries is placed on sanitary, regulatory and advertisement compliance. As such, due diligence and representation and warranty negotiations are focused on the relevant products' registration, permits and authorisations, and label or advertisement matters, which legal review requires qualified lawyers with deep knowledge of the numerous regulations and local public bodies governing the foodstuff and cosmetic industries. If a target's products are sold to the public at large, compliance with the consumer protection regulations is also

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8 <http://abchile.cl/>.

9 <https://chilealimentos.com/>.

10 <http://www.alimsag.cl/>.

11 <https://camaracosmetica.cl/>.

relevant and is included in the legal assessment of the transaction. The covid-19 pandemic has produced several challenges that, along with the global economic conditions, have seen the negotiation of financing and the number of M&A transactions slowing down. Nevertheless, we have seen successful transactions in the industry. An example of an innovative start-up in the food segment is embodied by Not Company (NotCo), a Chilean alternative start-up. After it launched in the US market, in July 2021 NotCo wrapped up a US\$235 million round of funding that gave it a US\$1.5 billion valuation. Another example of increased interest in the foodtech-related industry is the online shopping and delivery space Cornershop, of which 53 per cent was acquired by Uber in 2020 and the remaining 47 per cent in 2021, giving the platform a US\$3 billion valuation. More recently, Canadian Public Sector Pension Investment Fund (PSP Investments) acquired more than a 49 per cent of Hortifrut, a Chilean company dedicated to the production, export and commercialisation of berries in Chile and abroad.

## X SPECIAL ISSUES FOR CERTAIN PRODUCTS

### i Cannabis and derivatives

Pharmaceutical specialties containing cannabis, cannabis resin, or extracts and tinctures of cannabis may be sold to the public in pharmacies or laboratories by means of a ‘retained prescription’ with records of all units received and dispensed. The ISP may authorise, in qualified cases and for scientific research purposes, the use of cannabis, cannabis resin, or cannabis extracts and tinctures. The ISP may also authorise and control the use of cannabis, cannabis resin, or cannabis extracts and tinctures for the manufacture of pharmaceutical products for human use.<sup>12</sup>

Regarding cosmetics, in Chile, cannabis seed oil is an ingredient that can be part of a cosmetic product. Cosmetic products may not contain THC (any of its stereoisomers and derivatives) as an ingredient.<sup>13</sup>

However, the use of cannabidiol as a cosmetic ingredient has been controversial, since it has been classified as an active pharmaceutical ingredient.

For foodstuff, the use of edible oil is allowed only from the seeds of hemp, *Cannabis sativa* L, which must not contain tetrahydrocannabinol according to the techniques used by the ISP: high-performance thin-layer chromatography, or confirmatory gas chromatography or mass spectrometry.

### ii ‘Cosmeceuticals’

To date, cosmeceuticals are not specifically defined or regulated in Chile. Therefore, any products that may qualify under this category are subject to the generally applicable regulation for cosmetic products – Decree 239 – particularly regarding the limitations on the use of therapeutic and unverifiable claims.

In cases in which a cosmetic or foodstuff product’s nature is questioned due to claims made on its labels or in an advertisement, or both, the ISP may initiate, *ex officio* or at the

12 To date, the ISP has only authorised the registration of one pharmaceutical product containing extract of leaves and flowers of *Cannabis Sativa* L and one containing Cannabidiol.

13 Nevertheless, it has been reported that the ISP is working on guidelines for the use of cannabidiol in cosmetic products under certain conditions, such as the formulation of the product prevents the absorption of CBD and the consequent passage into the bloodstream. To date, the full content and progress status of these guidelines are unknown.



request of an interested party, an applicable control regime proceeding in which the authority will establish the regulatory regime applicable to the specific product. This decision of the ISP has general effects on all products with the same characteristics.

## **XI OUTLOOK AND CONCLUSIONS**

The modifications introduced into the regulatory landscape for foodstuff, non-alcoholic and alcoholic beverages have been not only extensive but also groundbreaking in many senses during the past few years.

Even though the regulation of cosmetics has not been subject to as many developments in the past few years, it is likely that this could change, considering all the latest developments and new challenges seen in the industry.

Notwithstanding the above, it is safe to say that the regulation of foodstuff and cosmetic products in Chile is thorough and extensive and presents certain unique challenges to the industry, particularly regarding the former.

