

THE FOOD, BEVERAGE
AND COSMETICS
LAW REVIEW

SECOND EDITION

Editors

Kara L McCall and Elizabeth M Chiarello

THE LAWREVIEWS

THE FOOD,
BEVERAGE AND
COSMETICS
LAW REVIEW

SECOND EDITION

Reproduced with permission from Law Business Research Ltd
This article was first published in September 2022
For further information please contact Nick.Barette@thelawreviews.co.uk

Editors

Kara L McCall and Elizabeth M Chiarello

THE LAWREVIEWS

PUBLISHER
Clare Bolton

HEAD OF BUSINESS DEVELOPMENT
Nick Barette

TEAM LEADER
Katie Hodgetts

SENIOR BUSINESS DEVELOPMENT MANAGER
Rebecca Mogridge

BUSINESS DEVELOPMENT MANAGERS
Joey Kwok and Juan Hincapie

BUSINESS DEVELOPMENT ASSOCIATE
Archie McEwan

RESEARCH LEAD
Kieran Hansen

EDITORIAL COORDINATOR
Alex Bagley

PRODUCTION AND OPERATIONS DIRECTOR
Adam Myers

PRODUCTION EDITOR
Jane Vardy

SUBEDITOR
Morven Dean

CHIEF EXECUTIVE OFFICER
Nick Brailey

Published in the United Kingdom
by Law Business Research Ltd
Holborn Gate, 330 High Holborn, London, WC1V 7QT, UK
© 2022 Law Business Research Ltd
www.TheLawReviews.co.uk

No photocopying: copyright licences do not apply.

The information provided in this publication is general and may not apply in a specific situation, nor does it necessarily represent the views of authors' firms or their clients. Legal advice should always be sought before taking any legal action based on the information provided. The publishers accept no responsibility for any acts or omissions contained herein. Although the information provided was accurate as at September 2022, be advised that this is a developing area.

Enquiries concerning reproduction should be sent to Law Business Research, at the address above.

Enquiries concerning editorial content should be directed
to the Publisher – clare.bolton@lbresearch.com

ISBN 978-1-80449-111-9

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following for their assistance throughout the preparation of this book:

ALLENDE & BREA

ANA LAW GROUP

CAREY

HOGAN LOVELLS

KING & SPALDING LLP

KING & SPALDING LLP IN COOPERATION WITH THE LAW OFFICE OF
MOHAMMED ALAMMAR

MLL MEYERLUSTENBERGER LACHENAL FRORIEP LTD

PINHEIRO NETO ADVOGADOS

SIDLEY AUSTIN LLP

URÍA MENÉNDEZ ABOGADOS, SLP

CONTENTS

PREFACE.....	v
<i>Kara L McCall and Elizabeth M Chiarello</i>	
Chapter 1 ARGENTINA.....	1
<i>María Morena del Río, Fernando Martínez Zuviria, Lucrecia Re and Vanesa Fernández</i>	
Chapter 2 BRAZIL.....	13
<i>Angela Fan Chi Kung and Nicole Recchi Aun</i>	
Chapter 3 CALIFORNIA.....	27
<i>Amy P Lally, Adriane Peralta, Celia H Spalding and Patrick D Rubalcava IV</i>	
Chapter 4 CHILE.....	44
<i>Ignacio Gillmore and Cristina Busquets</i>	
Chapter 5 GERMANY.....	56
<i>Ulf Grundmann and Elisabeth Kohoutek</i>	
Chapter 6 INDIA.....	67
<i>Anoop Narayanan and Priyanka Gupta</i>	
Chapter 7 MEXICO.....	87
<i>Cecilia Stahlhut Espinosa</i>	
Chapter 8 SAUDI ARABIA.....	106
<i>Nabil A Issa and Saud Aldawsari</i>	
Chapter 9 SPAIN.....	118
<i>Francisco Javier García Pérez, Montiano Monteagudo, Marta Rios, Juan Reyes, Patricia Vidal, Manuel Álvarez, Cristina Ayo, Jaime Calvo, Eduard Vila, Violeta Marinas, Yanira Miguel, Cristina Moreno and Patricia Ibárcena</i>	

Chapter 10	SWITZERLAND	134
	<i>Simon Holzer, Michael Reinle and Daniel Donauer</i>	
Chapter 11	UNITED STATES	153
	<i>Kara L McCall, Elizabeth M Chiarello, Diane C McEnroe and Alicia E Lee</i>	
Appendix 1	ABOUT THE AUTHORS	175
Appendix 2	CONTRIBUTORS' CONTACT DETAILS	189

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 be 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. 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 they 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 regulatory and civil legal frameworks in key countries for consideration by legal practitioners in these industries.

This is the second edition of *The Food, Beverage and Cosmetics Law Review*. It was developed because of the increase in class action litigation relating 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 – a result of food-borne illness outbreaks. This second edition covers 11 jurisdictions 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 relating to food, beverage and cosmetic safety (including recalls); supply chain issues (including sustainability, anti-corruption, and labour and immigration); special legal issues relating 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 relating 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

September 2022

CHILE

Ignacio Gillmore and Cristina Busquets¹

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).

Probably 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 with foodstuff products, the main regulatory development during the past year has been the modification of several regulations in connection with labelling requirements associated with gluten-free foodstuff, introduced by Law No. 21,362.

In general terms, this Law provides that processed foodstuff that does not contain gluten (i.e., that qualifies as gluten free in accordance with Articles 516 and 518 of the RSA)²

¹ Ignacio Gillmore is a partner and Cristina Busquets is a senior associate at Carey.

² Article 516 of the RSA sets forth that 'Gluten free foodstuffs are those prepared solely with ingredients that, due to their natural origin and the application of good manufacturing practices – which impede cross-contamination – do not contain prolamins from wheat, of any species of triticum such as common spelt (*Triticum spelta* L), kamut (*Triticum polonicum* L), durum wheat, rye, barley, nor their mixed varieties, as well as oat.' Further, the Article provides that 'For the inclusion of the caption "Gluten Free" on the label of the products, gluten free foodstuff manufacturers must comply with the requirements set forth in this Regulation, as well as having a good manufacturing practice program, with the purpose of ensuring the

must be labelled as such to duly inform consumers of this characteristic in the product. This information shall be provided by including the words 'gluten free' and the crossed grain symbol, which must be included on the front panel of the label to ensure visibility.

Moreover, this Law provides that commercial establishments that sell packed dry foodstuff, as defined in the RSA,³ that is labelled gluten free must place these products for sale in racks, shelves or displays that are exclusive for this category of products.

In connection with cosmetic products, and as several cosmetic products have included 'antibacterial' claims associated with the covid-19 pandemic, the ISP has issued a resolution in which it defines the scope under which such claims may be used for cosmetics in Chile.

Resolution No. 199 sets forth that products destined for hand hygiene that have ingredients with an antibacterial action are a special type of cosmetic subject to registration. In this regard, the Resolution provides that this type of product will be authorised as a hand sanitiser as long as it contains certain specific antibacterial ingredients in its formulation (e.g., isopropyl alcohol or denaturalised alcohol, among others), along with other cosmetic ingredients, such as moisturisers or excipients.

Further, Resolution No. 199 establishes that these products cannot, in any manner or language, claim actions of sanitary products or biocides for human hygiene, such as bactericide or fungicide action, which correspond solely to pharmaceutical products. In this regard, these products cannot use claims like their being antiseptic or disinfectant. In turn, the following claims are allowable for this particular category of cosmetics: 'contributes to eliminate bacteria', 'lowers bacterial load' and 'antibacterial without therapeutic action'. For the claim 'eliminates 99.99% of bacteria', this must be supported with corresponding studies.

III FOOD AND COSMETIC SAFETY

i Regulatory framework

As is explained above, 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 the course of 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.

non-contamination of wheat, rye, barley and oat by-products in their processes, from the reception of the raw materials until decommercialization of the final product'. In addition, Article 518 of the RSA provides that 'The term gluten free, and the logo or symbol of the crossed grain, can only be used when the lab analysis results for the foodstuff product do not exceed 5 milligrams of gluten, from the cereals set forth in Article 516, per kilogram of product ready for delivery to the end-consumer, in accordance with the analytic techniques that, for such purpose, are determined by the Chilean Public Health Institute.'

3 The RSA has not been modified to date to include this definition.

Once a proceeding has been initiated, the defendant will be summoned to a hearing in which it will have to provide its defence arguments and evidentiary means. If this proceeding is initiated through a claim, the claimant will also be summoned to a hearing to confirm the terms of the claim.

Sanctions associated with sanitary sanctioning proceedings are a fine that ranges between 0.1 and 1,000 monthly tax units (between approximately US\$6 and US\$60,000) 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. Further, 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 for foodstuff and non-alcoholic beverages, setting forth a detailed list of allowed additives for each category (e.g., acidity regulators, anti-caking and anti-humectant substances, antioxidants and sweeteners, among others).

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.⁴

As to food contaminants, Title IV of the RSA regulates different categories of contaminants (i.e., heavy metals, radionuclides, mycotoxins, and other contaminants and residues). Further, 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.

Further, 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

4 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.

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).

In this respect, the holder of a sanitary registration must notify the ISP of the recall immediately upon its initiation. Likewise, 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 Subdepartment of Inspection of the national medicines agency, Anamed, of the ISP. Additionally, a final report must be issued, including a reconciliation between the amount of products distributed and those recalled from the market, which must also be sent to the aforementioned Subdepartment.

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. Likewise, 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. According to recent statistics, approximately 20 per cent of employees are affiliated to a union.

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. In terms of regulatory requirements, the following are the most relevant.

- a* Every company, establishment or economic unit, whether commercial or industrial, needs to adopt internal health and safety regulations that must set down the prohibitions and obligations imposed on employees in regard to their jobs, permanence and life in

the respective company or establishment. In companies with 10 or more employees, it is also mandatory to have order regulations in addition to health and safety regulations, materialised through one document: internal order, hygiene and safety regulations.

- b* In companies that employ more than 25 employees, it is mandatory to have a parity health and safety committee.
- c* In companies that employ more than 100 employees and that have mining, industrial or commercial operations, it is mandatory to create a work-related risk prevention department.
- d* Employers are required by law to provide timely information to all employees regarding the hazards entailed in their jobs, preventive measures and adequate work methods, and to provide to employees all required protection elements at the employer's cost.
- e* Employers having contractors and subcontractors on their premises shall also have in place a site safety programme and a special regulation for contractors and will be directly liable for such contractors' employees' health and safety.
- f* Every employer must also enrol its employees in, and pay for, works accidents and professional diseases statutory insurance.

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, Law No. 21,325 and Decree No. 296 of the Ministry of Interior and Public Safety on Immigration were enacted this year. Although it is too soon to come to conclusions regarding the impacts of this law on immigration in Chile, it is possible to highlight that the intention of the recent law is to avoid foreigner tourists coming to Chile to render remunerated services without a valid visa previously issued. This way, all tourists who enter the country are not able to change their immigration status while they are in Chile, it being necessary for them to return to their place of residence to apply for a Chilean visa. Indeed, an important change in this respect is that, based on the new law, the visa must be requested from an employee's place of residence through the online platform that the Chilean Immigration Service has implemented for this purpose.

ii Processing and certifications

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

For cosmetic products, the manufacturer or importer of a product 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, the raw materials and the finished product.

Importers of finished cosmetics must perform or contract an analysis that certifies the quality of these 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, inter alia, the Rio Declaration on Environment and Development (1992), the United Nations Framework Convention on Climate Change (1994), its Kyoto Protocol (2002) and 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. Further, Law No. 19,300, on the General Bases of the Environment, concretises this guarantee through the creation of the Ministry of the Environment (i.e., the authority responsible for the creation of environmental policies, including quality and emission standards), the Environmental Assessment Service (i.e., the agency 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).

On the other hand, 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 the risk of acts of corruption and money laundering in their supply chains. In that context, these activities can have legal and reputational consequences, even if illegal acts or misconduct are not committed directly by a company's own 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),⁵ which imposes criminal liability on legal entities when the relevant behaviour is, inter alia, 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),⁶ which penalises anyone who possesses, hides or otherwise conceals assets while knowing that they directly or indirectly

5 Law No. 20,393.

6 Law No. 19,913.

originate from certain crimes, including, inter alia, 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 benefited from a corrupt act and the company's measures were insufficient to prevent the risk of the offence being committed.

On the other hand, 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.

v Due diligence and monitoring

As with 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.

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, that:

- a* information must be provided in the Spanish language;
- b* there is a prohibition on misleading or deceitful advertisements; and
- c* there is a prohibition on making curative or therapeutic claims (claims that are permitted only for pharmaceutical products).

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

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

For foodstuff and non-alcoholic beverages, manufacturers, sellers and distributors may highlight a product's particular characteristics in terms of vitamins, minerals, proteins, and other nutrients and dietary fibre by using thoroughly regulated claims that are denominated 'nutritional descriptors' (e.g., 'light', 'low in' or '0%'). The RSA sets forth the conditions that must be met for a product to use each nutritional descriptor.

Moreover, the use of certain health claims⁷ is permitted for foodstuff products and non-alcoholic beverages under the stringent parameters set forth in Exempt Resolution No. 860/2017.

Further, 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 on the Nutritional Composition of Foodstuff and its Advertisement, 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) such food is high in.

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.⁸ Foodstuff products with added sugar, sodium or saturated fats that, due to their nutritional composition, exceed the maximum levels of critical nutrients have a prohibition of making advertisements addressed towards children under 14 years of age, which includes the use of, *inter alia*, commercial hooks,⁹ contests, raffles and free samples addressed to this protected age group.

In addition, advertisements of high in products broadcast on television or exhibited in film theatres 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 foodstuff with added sugar, sodium or saturated fats that exceeds the maximum concentration levels that are made in mass media (i.e., television, radio, written press, billboards and other advertisements displayed on public roads and the internet), even in advertisements for food that is exempt from the obligation of including FOP signs on its labels.

The sale of products with added critical nutrients that exceed the maximum levels of concentration of such is absolutely forbidden in educational establishments, with the exception of higher education institutions (e.g., universities and vocational colleges).

Article 5 of Law No. 20,869 on the Advertisement of Food sets forth that 'Any type of advertisement of infant milk formulas is forbidden.' According to the RSA, infant milk formulas are those addressed towards parents of children 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.

7 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).

8 This exception does not exempt these products from having to comply with other obligations and restrictions imposed on food with added sugars, sodium or saturated fats that exceed the maximum permitted levels.

9 i.e., 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 addressed towards children.

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 shall be subject to the initiation of the sanitary sanctioning proceeding described above.

In this context, it is relevant to consider that, 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) will have residual application only for those issues that are not expressly addressed in the special regulation.

Therefore, and due to the level of detail to which advertisements are subjected under the sanitary rules – particularly in connection with foodstuff – the CPA shall be applicable, in terms of compensation, only for any damage caused by misleading or deceitful advertisements, and not regarding non-compliance with regulations.

In this regard, compensation for damage caused may be sought, under the CPA, through individual claims or class actions.

VI PRODUCT LIABILITY

As is described above, with regard to liability for non-compliance, the sanitary sanctioning proceeding will be applicable in connection both with foodstuff products and with cosmetics. In connection with foodstuff, the Sanitary Code sets forth a definition of defective sanitary products, which includes foodstuff, pharmaceutical products and medical devices, in Article 111 H.¹⁰

Further, in the case of cosmetics, the holder of the corresponding registration will be the primary party responsible for any sanitary liabilities arising from non-compliance with Decree 239, notwithstanding the responsibility that each other member of the supply chain may have in their corresponding role in such. In the case of 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, as neither the RSA nor Decree 239 contemplates any procedures for requesting compensation for damage suffered due to defective products, the CPA shall be applicable only in connection with the procedure for claiming payment of damages.

VII INTELLECTUAL PROPERTY

The 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 more strict substantive analysis.

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

10 Defective sanitary products are defined as those products that do not offer sufficient safety, taking into account all circumstances relating to the product, especially its presentation and reasonably foreseen use. In addition, a sanitary product shall be deemed defective if it does not offer the same safety normally offered by other units of the same series.

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 in the procedure – 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 AG¹¹ and Chilealimentos AG,¹² notwithstanding that there are other trade organisations for certain specific categories of foodstuff, such as ALIMSA AG,¹³ which represents manufacturers and importers of dietary supplements.

For cosmetics, the main trade organisation is the Cámara de la Industria Cosmética AG.¹⁴ 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 the second most important industry after mining in terms of contribution to national gross domestic product (GDP) and exports. Overall, according to official information, the food industry represents approximately 18 per cent of GDP, 25 per cent of exports, 20 per cent of internal sales, 23 per cent of employment and 31 per cent of companies. Main food segments involving financing and M&A transactions in Chile include fruit and nuts and seafood products, which include aquaculture, fishing products and food and other suppliers (e.g., packaging, storage and distribution). On its part, the cosmetics and personal healthcare market has been constantly growing in recent years and, at present, market players have noticed a shift in Chilean consumers' behaviour in 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

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

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

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

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

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 relevant and is included in the legal assessment of the transaction.

The covid-19 pandemic has produced several challenges that, all taken together, have seen the negotiation of financing and the number of M&A transactions slowing down or even reaching a standstill. However, this has not halted an increase in venture capital and fintech investments. A successful example of an innovative start-up in the food segment is embodied by Not Company (NotCo), a Chilean alternative start-up. In 2019, NotCo closed a US\$30 million round. 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. A notable 2021 M&A deal concerning the cosmetics industry was the acquisition by musician Ricky Martin of a 25 per cent stake in the local dermo-cosmetic company Kumiko Skincare.

X SPECIAL ISSUES FOR CERTAIN PRODUCTS

i Alcohol

In Chile, alcoholic beverages are not deemed a foodstuff and therefore are subject to completely diverse and independent regulation as to their manufacturing and import processes, as well as in connection to their distribution, sale and marketing. Until recently, the advertisement of alcoholic beverages did not have major restrictions in Chile. However, Law No. 21,363, enacted in August 2021, introduced certain restrictions to the advertisement of alcoholic beverages in connection with sports and sports equipment brands, as well as labelling requirements, to include warnings relating to the harmful effect of excessive consumption of this type of product.¹⁵

ii Cannabis

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.

With regard to cosmetics, in Chile, cannabidiol is forbidden for use as a cosmetic ingredient as 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*, which must not contain tetrahydrocannabinol according to the techniques used by the ISP: high-performance thin-layer chromatography or confirmatory gas chromatography/mass spectrometry.

¹⁵ Although this Law was enacted on 6 August 2021, it has not yet entered into force in Chile, because the issuance of regulations that will make it applicable is still pending.

iii '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 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 and non-alcoholic beverages have been not only extensive but also groundbreaking in a lot of senses during the past five 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.

ABOUT THE AUTHORS

IGNACIO GILLMORE

Carey

Ignacio Gillmore is a partner of Carey and co-head of the firm's life sciences and biotechnology and public law groups. His practice focuses on life sciences, biotechnology and public law, advising companies on intellectual property issues relating to the pharmaceutical industry, cosmetics, medical devices, commercialisation and advertisement of these products, scientific research, clinical studies, regulation of medical professions, privacy, data protection, public and private procurement and biddings, licences, distribution and franchises. He also represents clients in administrative processes and in sanitary, administrative and judicial litigation derived from those operations.

CRISTINA BUSQUETS

Carey

Cristina Busquets is a senior associate at Carey and part of the firm's life sciences and biotechnology group. Her practice is focused mainly on advising clients regarding food and beverages, alcoholic beverages and animal food regulation, including their import, commercialisation and advertisement. She also provides assistance regarding other regulated products, such as cosmetics, pharmaceutical products for human and veterinary use, medical devices, pesticides and fertilisers. Furthermore, she advises clients in contracts associated with said industries, such as distribution and storage, among other things. Moreover, she has relevant experience in data protection and consumer protection matters.

CAREY

Isidora Goyenechea 2800
43rd Floor Las Condes
Santiago
Chile
Tel: +56 2 2928 2200
Fax: +56 2 2928 2228
igillmore@carey.cl
cbusquets@carey.cl
www.carey.cl

ISBN 978-1-80449-111-9