

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

Sidley Austin LLP

Chicago

August 2021

BRAZIL

Angela Fan Chi Kung and Nicole Recchi Aun¹

I OVERVIEW

As part of a continuously growing and successful market, the food, beverages and cosmetics sectors of Brazil have consistently held a leading market position in the Brazilian economy. Based on recent reports, revenue from the food and beverages industry, for instance, represented 10.6 per cent of the Brazilian gross domestic product in 2020.² Ex-factory sales in the hygiene products, cosmetic and perfumery industries in 2020 represented a 5.8 per cent increase compared to 2019.³ Against the backdrop of the covid-19 pandemic, these numbers are expected to increase in 2021, with a focus on the global trend of healthy, natural, organic and sustainable products, coping with consumer convenience and digital engagement trends in these sectors.

From a legal and regulatory perspective, those dynamic sectors are subject to specific laws, as well as regulations and the oversight of different bodies in Brazil. The National Health Surveillance Agency (ANVISA) and the Ministry of Agriculture, Livestock and Food Supply (MAPA) share oversight and regulations on food and beverages. In a nutshell, while ANVISA's regulations particularly concern industrialised foods and beverages; supplements and additives; infant food; enteral nutrition; and new food products and ingredients, MAPA generally has jurisdiction over food products and beverages of animal and vegetable origin. Hygiene products, cosmetics and perfumery products are also subject to ANVISA's regulations and oversight.

II YEAR IN REVIEW

A number of updates to food and beverages regulations took place in 2020, but the most notable initiative refers to the regulatory framework on nutritional labelling, under Resolution RDC No. 429/2020 and Normative Ruling No. 75/2020. This brings significant changes to the information disclosed in food and beverage labels and calls attention to nutritional aspects of products that usually raise health concerns, such as sugar, fat and sodium, as well as defining restrictions on claims of products containing such components. The rules will enter into force in October 2022 and, depending on the product and sector, companies may have between 12 and 36 months to adapt to the new standards.

1 Angela Fan Chi Kung is a partner and Nicole Recchi Aun is a senior associate at Pinheiro Neto Advogados.

2 Brazilian Association of the Food Industry (ABIA) report available at www.abia.org.br/.

3 Brazilian Association of Personal Hygiene, Perfumery and Cosmetics Industry (ABIHPEC) report available at <https://abihpec.org.br/vendas-de-hppc-crescem-47-em-2020-e-totalizam-r-1224-bilhoes/>.

Other highlights in food and beverages regulations include Resolution RDC No. 487/2021 and Normative Ruling No. 88/2021, which have amplified the list and limits of contaminants present in food and beverages, as well as Normative Ruling No. 76/2020, which has defined the list of authorised components, limits thereto and authorised claims for supplements. A promising, but still not sufficiently exploited, topic of ANVISA's regulatory agenda is the development of nanotechnology-based foods and beverages, including packaging materials, for which there is a demand for researchers and start-ups working in the field.

In the cosmetic sector, labelling regulations have also been updated to require the description of a product's composition in Portuguese, pursuant to Resolution RDC No. 432/2020. It is also worth mentioning ANVISA's regulatory initiatives to facilitate the importation, sales and offering of antiseptic cosmetics used to fight the covid-19 pandemic. From a post-market perspective, cosmetovigilance regulations are on the rise and have been included in ANVISA's regulatory agenda.

III FOOD AND COSMETIC SAFETY

i Regulatory framework

From a legal standpoint, food and beverages are generally subject to the provisions of Decree-Law No. 986/1969, and specific provisions for:

- a* animal-derived food, under Law No. 1,283/1950 and Decree No. 9,013/2017;
- b* vegetable-derived food, under Law No. 9,972/2000 and Decree No. 6,268/2007;
- c* beverages, under Law No. 8,918/1994 and Decree No. 6,871/2009;⁴ and
- d* wine, grapes and beverages derived from them, under Law No. 7,678/1988 and Decree No. 8,198/2014.

Cosmetics are subject to the general rules provided under Law No. 6,360/1976.

In addition to the laws mentioned above, regulations issued by ANVISA and MAPA also apply to food, beverages and cosmetics. From a technical standpoint, standards of the Brazilian Association of Technical Standards or other entities accredited by the National Council of Metrology, Standardization and Industrial Quality (INMETRO) may apply.

ANVISA

Food, beverages and cosmetic products are subject to safety requirements defined by ANVISA, a Brazilian regulatory agency bound to the Ministry of Health, created with the purpose of promoting the protection of the population's health through sanitary control of the production and consumption of products and services subject to health surveillance. ANVISA's oversight is decentralised and shared with state and municipal health authorities, which usually act on the front line of audits, inspections and sanitary control activities at a local level.

From a safety perspective, ANVISA has a relevant role in defining sanitary, technical and operational criteria; specifications; and good manufacturing practices and standards to ensure that only food, beverages and cosmetic products that meet safety, efficacy and quality requirements are available for consumption on the Brazilian market.

⁴ Juices and pulp beverages produced in family rural properties must also observe Law No. 13,648/2018 and Decree No. 10,026/2019.

Importers, distributors, sellers, packagers, storage units and other establishments performing activities in connection with food, beverages and cosmetics must be duly licensed by ANVISA or local health authorities, as applicable, and a responsible technician must be in charge of the establishment's activities, in order to regularly operate in compliance with sanitary requirements.

For cosmetics, ANVISA defines the safety requirements and parameters applicable to the final product and their raw materials, including toxicology data, flammability potential, adverse reactions to exposure (such as inflammation, sensitiveness or allergies), as well as experimental and pre-clinical regulatory requirements.

Similar to foods and beverages, ANVISA sets forth the tolerable limits of contaminants and agrochemical residues, microbiological standards, levels of toxicity, pathogenicity, mutagenicity, use instructions and storage requirements, among other safety aspects that may pose risks to human health.

Additionally, certain foods, beverages and cosmetics are subject to registration with ANVISA, as a condition of being manufactured, imported, distributed and commercialised in Brazil. Under the registration process, ANVISA will review whether the relevant product conforms to the applicable sanitary requirements.

Products representing lower risks to consumer health are exempted from prior registration with ANVISA; nonetheless, the manufacturer or importer of the product may be required to formally notify ANVISA about the manufacturing and importation or commercialisation activities of such products. A list of cosmetics, food and beverage products subject to and exempted from prior registration is provided in Resolution RDC No. 7/2015 and Resolution RDC No. 27/2010, both issued by ANVISA.

MAPA

MAPA is the Brazilian ministry bound to the executive branch in charge of the management of public agricultural policies to regulate agribusiness and related activities under the scope of animal health and vegetable sanity. MAPA's policies and regulations are also directed at structuring and maintaining an adequate food supply of animal and vegetable origin.

To that effect, food and beverages are also subject to MAPA's agricultural defence initiatives and regulations, which are directed towards securing a safe and suitable environment for agricultural and livestock activities through the control of rural properties; animal and vegetable transit; plagues and diseases; epidemiology data; and facilities inspections aimed at the promotion of food safety and identity.

MAPA is responsible for the surveillance and registration of establishments performing activities with food products and beverages – in particular, products of animal or vegetable origin and producers of beverages, wine and grape derivatives.

In the context of securing safety requirements for food products, vegetable-origin food products for human consumption must undergo a classification process aimed at determining the intrinsic and extrinsic quality characteristics of a vegetable product based on official standards defined by MAPA. Classification is mandatory for all packaged vegetable food products and must be performed by the packager or processor of the product.

Animal-origin foods are subject to prior registration with the Department of Inspection of Products of Animal Origin of the MAPA Secretariat of Agricultural Defence. Additionally, the label on the animal-origin food products must have the Federal Inspection Service seal, which attests that the product is certified for the consumer, and follows national and international legislation.

Beverages, including non-alcoholic and alcoholic wines, and grape and wine derivatives must also be registered before MAPA, as a rule. Some imported beverages are exempted from prior registration provided that the importer is duly registered before MAPA.

ii Food additives and contaminants

In the scope of its oversight activities, ANVISA is vested with jurisdiction to control, regulate and supervise food additives, technology adjuvants, limits on organic contaminants, toxic residues and other elements that may cause risk exposure.⁵

The use of additives or adjuvants in food and beverages must be justified, shall not compromise the safety or nutritional properties of the product and must be supported by a list of authorised additives and coadjutants defined under the regulations applicable for each product category. It is often subject to maximum limits based on rules and international standards, including those of the World Health Organization (WHO), the Food and Agriculture Organization (FAO), Codex Alimentarius, the European Union and the US Food and Drug Administration, among others.⁶ Food additives and adjuvants are exempted from registration with ANVISA.⁷

Additionally, ANVISA's regulations define tolerable limits of biological, chemical or physical contaminants present in food and beverages, acknowledging that complete elimination of contaminants may not be possible. Such limits are set forth based on methodologies recommended by the WHO and the FAO, and supported by a risk assessment on the characteristics of the contaminants, chain production and risk exposure data, in particular in connection with vulnerable populations. Examples of regulations issued by ANVISA in connection with contaminants include Resolution RDC No. 14/2014 (strange materials), Resolution RDC No. 42/2013 (inorganic contaminants limits) and Resolution RDC No. 331/2019 (microbiological standards).

iii Recalls

Law No. 8078 of 11 September 1990 (the Consumer Protection Code) provides that a company is required to conduct a recall when it places on the market a product or service that is hazardous to consumers.

The principle of suitability requires compliance with the requirements of safety and warranty of product quality. In addition, products and services placed on the market cannot pose risks to consumers' health and safety.⁸ Normal and foreseeable risks (which are inherent to the products) are accepted, as absolute safety is incompatible with the nature of certain products. It is mandatory, however, that suppliers provide full and clear information on their products' or services' risks.

Harmful or hazardous products cannot be placed on the market.⁹ As there is not a clear meaning of 'highly harmful or hazardous', this concept depends on case-by-case evaluation. If a supplier acknowledges the harmful or hazardous nature of the product only after it has been placed on the market, it will be responsible for informing consumers and the proper

5 Law No. 9,782/1999, Articles 7 and 8.

6 Ordinance SVS/MS No. 540/1997.

7 Resolution RDC No. 27/2010.

8 Consumer Protection Code, Article 8.

9 Consumer Protection Code, Article 10.

authorities about the evidenced danger or hazard by means of public media releases (i.e., recall). The supplier's liability is to inform about the hazard and offer the possibility of repair, replacement or reimbursement for the defective product.

In order to regulate the procedure for mandatory communication to consumers and authorities, the Ministry of Justice issued, on 1 July 2019, Ordinance No. 618, which updates the regulation of recall campaigns previously established by Ordinance No. 487 of 15 March 2012.

Recalls involve notification to authorities, investigation procedures and warnings – including a media plan, a consumer answering plan and mock-up of a recall announcement aimed at informing consumers about the product or service's risks and measures to be taken by the consumer – or withdrawal of the product from the market, as per Ordinance No. 618/2019. Notifications to authorities must include a complete and detailed report of the defect, associated risks and impacts.

After the recall communication, follow-up communication is required for at least five years as of the recall campaign.

Specific recall rules apply to products such vehicles, food and drugs.

Law No. 6,360/1976 determines that a product must be immediately withdrawn from the market in the case of evidenced harm to human health. Additional criteria for the recall of foods and beverages, for instance, are defined under ANVISA's Resolution No. 24/2015, which are required in the case of risk of harm to the consumer's health. Recall may be voluntarily performed under the responsibility of the marketing authorisation holder of the relevant product, or officially determined by ANVISA.

Recalls and notification thereof to ANVISA are required upon acknowledgement of risk of harm to consumers' health. It implies immediate suspension of sales of the respective batches of the product and the segregation of units in all companies in the production chain. ANVISA monitors the entire recall procedure in coordination with other relevant authorities, and is entitled to review market announcements in connection with the recall. Companies must maintain a recall standard procedure, as well as adequate traceability records and procedures to secure an effective recall campaign and final destination of the recalled products.

There is not a specific recall regulation issued by ANVISA for cosmetics, only general guidance provided under the applicable Good Manufacturing Practices regulations. Companies in this sector are required to keep a cosmetovigilance system in place.¹⁰

If a supplier (1) refrains from undertaking a recall and the public authorities hold that such recall is necessary; or (2) fails to report the recall within the terms provided for in Ordinance No. 618/2019, the supplier will be subject to penalties in civil, administrative and criminal spheres.

Accordingly, companies may be subject to redress damage caused to the consumer market, as well as administrative penalties including a fine of up to 11 million reais, a criminal investigation for failure to conduct the recall (which may subject the responsible individual to imprisonment from six months to two years) and a fine.

10 Resolution RDC No. 48/2013 and Resolution RDC No. 332/2005.

IV SUPPLY CHAINS

i Labour and immigration

Under Brazilian law, an employee is an individual rendering personal and ongoing services under the control of an employer. The law does not require a written employment agreement, although it is advisable to have one (specifying terms and conditions as duties and obligations) for those who hold more senior positions.

Other than in very limited circumstances (such as a temporary activity, or a temporary work permit), employments are considered arrangements effective for no particular term. Either an employee or an employer can terminate the employment at any time with notice.

Under Brazilian statutes, employees enjoy certain basic employment rights and benefits, including minimum wage, paid vacation, guarantee fund, and compensation for working overtime, which may be added by collective bargaining agreements. Severance packages and compensation usually apply in cases of termination of employees without cause.

Under Federal Law No. 13,429/2017, employers can hire services from independent contractors provided that such services are clear, determined and specific and that subcontractors and their employees do not report to the principal. In the event that an independent contractor fails to pay their employees' salaries, benefits and severance, the principal will be vicariously liable to pay them.

Foreigners require specific visas to provide services in Brazil. Among many other things, temporary and permanent visas are most commonly adopted for employment purposes.

ii Processing and certifications

The Ministry of Health led an initiative to reformulate processed food regulations and guidance for healthier and more balanced eating habits to reduce the high intake of sodium, sugar and other poor nutritional elements in the diet of the Brazilian population. Food processing in Brazil is subject to ANVISA's regulations that apply for each category of product, which have become stricter, particularly for labelling requirements.

Allied to such initiatives, certification mechanisms provide support for entrusted information on the origin, processing and industrialisation level of consumption products, and have become popular not only in the food and beverages sector, but also in the cosmetics sector, and include certification on organics, gluten-free and cruelty-free. For certification purposes, strict technical rules must apply to ensure that the certified information is true and accurate. More information related to this topic follows in Section IV.iii, below.

iii Sustainability

Brazilian rule of law draws contours to the sustainable supply chains through laws, regulations and certification parameters.¹¹ The main topics with regard to sustainability in the supply chain of the food, beverages and cosmetics sectors in Brazil relate to solid waste, animal testing and other topics such as genetically modified organisms (GMOs), and natural and genetic heritage or benefit sharing.

11 ISO 14001:2015.

Solid waste

Since the enactment of the Solid Waste Act (Federal Law No. 12,305/2010), some economic sectors are obliged to implement or participate in take-back schemes for certain products and packaging in general. Sellers, distributors, industries and importers must cooperate and take coordinated actions among themselves to implement the necessary logistics for enabling recycling or, when this is not the case, adequate and final disposal of the returned waste.

Take-back obligations applicable to packaging of food, beverages and cosmetics are in force at local, state and national levels, and still subject to several ongoing Bills.¹² Enforcement of such obligations may occur through sectorial agreements, terms of commitments entered into by companies or groups of companies and environmental authorities, or through specific regulatory acts enacted by governmental authorities. Between 2020 and 2021, several important commitments were entered into by companies on packaging take-back schemes, with the wide participation of associations representing food, beverages and cosmetics industries.

Animal testing

Federal Law No. 11,794/2008 limits the breeding and use of certain animals for academic and research purposes. Several states, though, pose stricter rules aiming at animal welfare, mostly by limiting the testing of products and components in live animals, as well as by requiring disclosure of information to consumers and labelling.¹³

With the focus on cosmetics and personal hygiene products, in 2020 and 2021 the Supreme Federal Court issued decisions aligned with majority case law on animal testing, by declaring the constitutionality of state laws in Amazonas and Rio de Janeiro that limited animal testing. In the Rio de Janeiro case, although the Supreme Federal Court recognised the constitutionality of the ban on animal testing in the state, it considered the attempt to forbid the commercialisation of such products in the state and the obligation to label to be unconstitutional.¹⁴ Increased attention has been given to the issue, and the 'Animal Law' as an autonomous branch of law. Bills¹⁵ continue to be proposed, envisioning the limiting of animal testing in cosmetics and food and providing for consumer information on the matter.

Other topics: GMOs and natural and genetic heritage

In view of the wide supply chain for the food, beverages and cosmetics sectors and the highly regulated environment in Brazil, naturally, other relevant topics such as GMOs¹⁶ and natural and genetic heritage or benefit sharing¹⁷ lead to consolidated rules and ongoing discussions. Federal Law No. 11,105/2005 establishes the legal framework on safety measures and

12 At least nine main Federal Bills under analysis regarding packaging for food, beverages and cosmetic sectors, plus food waste.

13 State Laws from Rio de Janeiro, Minas Gerais, São Paulo, Federal District, Pernambuco, Amazonas, Pará, Paraná, Santa Catarina and Mato Grosso do Sul forbidding the utilisation of animals for testing of cosmetics and personal hygiene, perfume and their components.

14 Supreme Federal Court, ADI Nos. 5996 and 5995 – decided on 15 April 2020 and 25 May 2021, respectively.

15 Currently at least four main Federal Bills.

16 Federal Law No. 11,105/2005 and related.

17 Federal Law No. 13,123/2015 and related.

inspection mechanisms for several activities with GMOs, including the need for obtaining authorisations from controlled entities such as the National Technical Biosafety Commission, aside from other specifications provided in the constantly updated regulations.

Federal Law No. 13,123/2015, among others, implemented international treaties on genetic heritage or associated traditional knowledge¹⁸ with a view to conserving biological diversity and the integrity of the Brazilian genetic heritage. This Law and related regulations provide for rules on:

- a* access to the Brazilian genetic heritage and associated traditional knowledge (i.e., indigenous and traditional people's knowledge);
- b* access to technology and technology transfer;
- c* economic exploitation of finished products or reproductive materials arising from such access;
- d* the benefit of sharing of such exploitation; and
- e* the remittance of related organisms abroad.

iv Anti-corruption rules

The main act governing anticorruption enforcement in Brazil is Federal Law No. 12,846/2013 (the Anti-corruption Law), which foresees corporate, civil and administrative liability for misconduct against Brazilian or foreign government entities. The Anti-corruption Law came into effect on 29 January 2014, and does not address criminal liability, nor does it penalise individuals.

Before the entry into force of Anti-corruption Law, which is broad and covers practices that are harmful (1) to the public administration or the public property; (2) to the principles of the public administration; or (3) to the international commitments entered into by Brazil, there was no specific law in Brazil dealing with the subject. What had always existed were a few laws that, in one way or another, aimed at maintaining probity in public administration, such as the Brazilian Criminal Code and the Improbability Law.

One of the major innovations introduced by the Anti-corruption Law was the adoption of objective liability of the legal entity, which does not exclude the individual liability of officers, administrators or co-offenders. Thus, companies will be held liable regardless of the conduct of the involved individuals. Likewise, there is no need to prove the intention of a company's officers in causing damage to the public treasury.

Companies that violate the provisions of the Anti-corruption Law may be subject to severe penalties, via administrative or judicial proceedings, including a fine of up to 60 million reais, publication of the judgment, forfeiture of property and interdiction of activities.

Last, in relation to anti-money laundering legislation, the Money Laundering Act, Law No. 9,613, of 3 March 1998 (Law 9,613/98), not only criminalises laundering or concealment of assets, rights and money, but also establishes mechanisms to prevent the Brazilian financial system from being used in the commission of those crimes by creating a number of obligations that entities engaged in business that in any way relates to the financial industry are required to fulfil, exposing violators to severe penalties.

18 Part of the Convention on Biological Diversity, internalised in 1998 by the enactment of Federal Decree No. 2,519.

v Due diligence and monitoring

Issues on due diligence and the monitoring of companies, especially in the food and beverages supply sector, are mostly related to compliance with licensing requirements, as well as traceability and management of quality throughout the supply chain.

This is particularly critical in Brazil, given the joint liability risk exposure of all of the players in the supply chain, from a consumer protection perspective (as further described in Section VI, below), and may be addressed by the adoption of more substantive control and governance measures.

V SALES AND MARKETING

i Regulatory framework

Sales, marketing and advertisement relating to products subject to health surveillance, including food, beverages and cosmetics, must follow the provisions of Law No. 6,360/1976, Law No. 9,294/1996, the Consumer Protection Code and specific ANVISA regulations for that product, as applicable. In addition, advertising activities are also subject to the guidelines defined by the National Council of Self-Regulated Advertising (CONAR), especially under the Brazilian Code of Self-Regulated Advertising.¹⁹

As a general principle, sales, advertising and promotion activities in connection with food, beverages and cosmetics may not contain indications that may lead the consumer to error, confusion or misinterpretation of the actual qualities, origin and properties of the product, nor should they contain therapeutic claims.

Nonetheless, some special categories of food products, such as supplements, may have specific and restricted health or functional related claims as authorised and defined under ANVISA's regulations, in particular Resolution RDC No. 18/1999, Resolution RDC No. 243/2018 and Resolution RDC No. 241/2018. Concerns about abusive consumption of alcoholic beverages, unhealthy or under-nutritional products by adults and infants, or weight-control diets, have also triggered specific sales, promotion and labelling regulation on such products.

ii Consumer protection and false advertising

Consumers are entitled to full and accurate information about products and services, including information on pricing, and have the right to be protected from misleading or abusive advertisements.

An advertisement will be considered misleading if it transmits untrue information or misses out relevant information. An abusive advertisement refers to one inciting to violence, discrimination or other prejudicial and harmful behaviour. Under Article 38 of the Code, suppliers have the burden of proof to evidence that advertisements are truthful and accurate.

Accordingly, under the Consumer Protection Code, an advert should be placed in such a way that the consumer can easily and immediately identify it as such. Offers and presentations of a product must contain information that is clear, direct, precise, comprehensive and in

19 Available at www.conar.org.br/codigo/codigo.php.

Portuguese regarding the characteristics, qualities, quantity, composition, price, warranty, validity and origin, among other pieces of information, as well as any risks that the product or service may pose to the consumer's health and safety.²⁰

The control system for advertising is mixed (through governmental regulation and self-regulation). While governmental regulation of advertisements may be undertaken by relevant agencies and authorities, including the Brazilian Federal Consumer Protection Agency, the State and Local Consumer Protection Agencies and the Public Prosecutor's Office, self-regulation is conducted by CONAR, as guided by ethical advertisement principles, including social responsibility, fair competition and human dignity.

It is important to note that advertising directed at children is a sensitive matter, considering children's potential lack of judgement.²¹ Thus, advertising involving or directed at children is frequently challenged by associations and public prosecutor offices throughout the country.

In addition to consumer protection rules and CONAR guidelines, food, beverages and cosmetics are subject to specific regulations, such as those specified by ANVISA (mentioned above).

Failure to comply with labelling and regulatory requirements is regarded as a violation of the Consumer Protection Code, entailing civil, administrative or criminal penalties. Irregularities are usually challenged by consumer protection bodies, CONAR, relevant agencies (such as ANVISA) or even competitors.

VI PRODUCT LIABILITY

Suppliers' liability arising from manufacturing defects (including packaging issues and food-borne illnesses and contaminants) is governed by the Consumer Protection Code. Thereunder, service and product suppliers have strict and joint liability for the imperfections and defects of products and services they place on the market. Consumers do not have to prove suppliers' negligence, recklessness or unskillfulness. The existence of damage per se connected to the supplier's action by a chain of causation is sufficient to entail the duty of indemnifying the consumer.

The supplier is only exempted from liability if it is proven that (1) the service or product defect does not exist; (2) the fault rests exclusively on the consumer or on third parties; or (3) it has not marketed the product.²²

Moreover, all suppliers making up the supply chain of a product or service are jointly and severally liable for the damage caused to consumers. The law ensures full redress for damage suffered by consumers, who are entitled to claim indemnification for such damage from any supplier that has participated in the product supply chain. If it is possible to determine which of the suppliers was liable for the damage, the supplier compelled to indemnify the consumer will have the right of recourse against the party actually liable, which does not affect the consumer's right in any way.

20 Consumer Protection Code, Articles 31 and 36.

21 Consumer Protection Code, Article 36, paragraph 2.

22 Consumer Protection Code, Article 12, paragraphs 3 and 14.

Furthermore, Brazilian law provides for the concept of ‘apparent supplier’. This means that any company that is reasonably perceived by the customer as a supplier of the product or service is held to be part of the supply chain for such product or service, thus holding strict and joint liability for any damage caused to consumers.

Investigations of possible violations may be conducted by consumer protection agencies, or filed as a public civil action in connection thereto. Individuals may also file claims for damage redress, including compensation for moral damages arising from food unfit for consumption, as recently judged by the Superior Court of Justice, regardless of the effective consumption of the product.

Finally, as per the Consumer Protection Code, certain conduct that violates consumers’ rights should be regarded as a crime (e.g., failure to perform a recall, disclose a abusive or misleading advertisement, etc.).

VII INTELLECTUAL PROPERTY

Intellectual property protections from the Brazilian Industrial Property Law (Law No. 9,279/1996), such as trademark, patent and industrial design protection, apply generally to food, beverages and cosmetic products. Litigation involving manufacturers of such products that use a trade name or marks similar to previously registered trademarks is common in Brazilian courts.

Additionally, the Brazilian Industrial Property Law prohibits acts of unfair competition, which concept has a broad definition that may comprise imitating a competitor product’s trade dress or visual identity to pass off as such competitor or to create confusion among consumers, or even marketing pieces and advertising. Litigation involving unfair competition claims are also frequent for consumables such as food and beverages, and for cosmetic products.

The Brazilian Industrial Property Law also provides for the registration and protection of geographical indications, which comprise both indication and designation of origin, and have increased in importance in the past few years. The use of such geographical indications is restricted to the producers, manufacturers or service providers established in the place and, for designations of origin, to those who meet the quality standards.²³

VIII TRADE ORGANISATIONS

There are several trade organisations in Brazil in the food, beverages and cosmetics sectors. In the food sector, certain trade organisations, such as the Brazilian Food Industry Association, encompass all the different branches and focus on general issues, while others, such as the Brazilian Association of Animal Protein, focus on the issues of specific branches. In the beverages sector, the Brazilian Beverage Association is one of the main trade organisations, whereas the Brazilian Association of Personal Hygiene, Perfumery and Cosmetics is a key organisation for the cosmetics sector. There are also several trade organisations that focus on the state and municipal spheres.

When it comes to antitrust, the Administrative Council for Economic Defense (CADE) is the governmental body responsible for the enforcement of competition law. CADE dealt with relevant cases in the food, beverages and cosmetics sectors during 2020. While

23 A list of geographic indications, which mostly comprise food and beverages, can be found at <https://www.gov.br/inpi/pt-br/servicos/indicacoes-geograficas/pedidos-de-indicacao-geografica-no-brasil>.

CADE acknowledges that trade organisations and associations play an institutional role, it also provides general guidelines to prevent associates in trade organisations from behaving in an anticompetitive manner (e.g., forming cartels or exchanging competitively sensitive information). CADE recommends that discussions occurring within trade organisations be limited to their legitimate goals; that the collection of data from associates be focused on historical information rather than actual or future information, and preferably disseminated in aggregate; among other things.

IX FINANCING AND M&A

Over the past few years, there has been an increase in M&A activity with the purpose of promoting growth, restructuring and consolidation of the food, beverages and cosmetic sectors in Brazil. Examples abound of strategic players coming together to face ever-increasing global competition, and also financial investors looking for unique opportunities.

One could consider that two of the main reasons for the recent consolidation and activity are related to (1) constant pressure on the sectors, as worldwide demand for food is on the rise and cosmetics and beauty-related sectors in Brazil are historically one of the most flourishing and diverse in the world, with continued growth expectation; and (2) as global markets are suffering enormous pressure to innovate on sustainability and diversity, the food, beverages and cosmetics sectors are certainly on the very edge of such trend, having to adapt to rapid changes in consumer behaviour, searching for products that protect and conserve natural resources while achieving a healthier lifestyle, in terms of healthy food, products that are not animal tested and manufactured with natural ingredients, for instance, converged with a more inclusive business and society.

Recently, the agricultural inputs resale market has been flooded with investments by strategic players, with the market changing gear and moving to a higher level.

Licensing regularity, product liability concerns and compliance with environmental laws are of the utmost importance from a legal perspective when analysing M&A transactions in the sector, as non-compliance with any of the foregoing may lead to, in a worst-case scenario, embargo of the activities of a particular establishment. Also, Brazil has very complex tax legislation, especially when it comes to transportation of products within the different states of the federation, as each state has its own tax regulations and particularities related to the import, export and manufacturing of cosmetics, agricultural products and organic and processed food and beverages.

Consolidation of sectors also tends to raise concern for approval by the antitrust authorities; therefore, it is important to thoroughly analyse the particularities of the specific products and the niche of a particular target company prior to entering into any definitive agreements in order to mitigate any competition risks.

X SPECIAL ISSUES FOR CERTAIN PRODUCTS

i Alcohol

Alcoholic beverages are generally ruled under Law No. 8,918/1994, regulated by Decree No. 6,871/2009, except for wines and derivatives thereof, which are subject to specific ruling under Law No. 7,678/1988, regulated by Decree No. 8,198/2014.

General alcoholic beverages are divided into fermented, distilled, rectified and mixed beverages. All of them, including wines and derivatives, must observe the applicable technical

and regulatory standards to be offered in the market, including manufacturing control, classification, denomination, alcoholic grade and labelling requirements. Registration of the product with MAPA is a sales condition and, once granted, is valid for 10 years.

ii Cannabis

Although *Cannabis sativa L* is a prohibited plant in Brazil, since 2015, substances derived from *Cannabis sativa L*, tetrahydrocannabinol (THC) and cannabidiol (CBD) are allowed for medicinal use under certain restrictions imposed by ANVISA. To qualify for ANVISA's clearance, cannabis-based pharmaceuticals must comply with ANVISA's Resolutions, which include clinical data demonstrating the pharmaceuticals' safety and efficacy for their intended indication and the Good Manufacturing Practice certification of the manufacturer, among other things.

Such products are governed under RDC No. 327/2019, which provides for a special clearance path for such products with ANVISA, valid for five years, until the product receives marketing authorisation to be a commercialised pharmaceutical product. This resolution is under review and changes thereto should be expected in the near future. Cannabis-based cosmetics, tobacco products, healthcare products or food items do not qualify as cannabis products for medical purposes and, thus, their importation or manufacturing are still not allowed by Brazilian legislation.

iii 'Cosmeceuticals'

'Cosmeceuticals' is not a term recognised under Brazilian regulation, since cosmetics may not have therapeutic indications or claims. Accordingly, products that contain medicinal substances, and have prophylactic, curative or palliative purpose, will qualify as medicines and will be subject to medicines regulations.

iv Others

A recent change in Brazilian regulation has identified supplements as a range of food products that are subject to specific regulation, simplifying the regulatory framework thereof. Supplements are subject to Resolution RDC No. 243/2018 and the authorised ingredients and claims in connection thereto are defined pursuant to Normative Ruling No. 28/2018, both issued by ANVISA.

XI OUTLOOK AND CONCLUSIONS

From the production and distribution of inputs for agriculture to the industrialisation and export of food, Brazil is a global leading producer of several agricultural commodities and, allied with a growing local consumer market, has become a magnet for local and international investment. The cosmetics sector does not fall behind, and has been continuously receiving investor attention.

Although comprising different products in nature, these sectors are now converging into the recent spread of the self-care trend, consumers' convenient access and digital marketing, and are highly driven by innovation, which consequently requires an eye on the development of regulation, particularly regarding safety aspects. Future developments present an exciting challenge to the players in these markets, as well as a lot of opportunities to be exploited.

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