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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Chapter 11

UNITED STATES

Kara L McCall, Elizabeth M Chiarello, Diane C McEnroe, Kevin A Sforza and Eliza M Lawless[1]

I OVERVIEW

The US Food and Drug Administration (the FDA) is the primary federal agency that regulates most food, beverage and cosmetic products pursuant, generally, to the Federal Food, Drug and Cosmetic Act (FDCA).[2] The FDA has a variety of mechanisms to address violations of the law and works with the United States Department of Justice (DOJ) and the Offices of the United States Attorneys to bring enforcement actions.

Federal responsibility for food safety and labelling is shared by the FDA and US Department of Agriculture (USDA). The FDA has authority over all domestic and imported food products (except for most meats and poultry), including seafood, fish and shellfish products. The Food Safety and Inspection Service (FSIS), an agency of USDA, regulates most meat and poultry and some egg products, as well as catfish.

The US Federal Trade Commission (FTC) regulates advertising (but not labelling) for food, beverages and cosmetics under the Federal Trade Commission Act (FTCA), which prohibits a variety of 'unfair or deceptive acts or practices', including the dissemination of false advertisements for food, beverages and cosmetics aimed at consumers.[3]

The Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates alcohol production, importation, wholesaling, distribution, labelling and advertising, primarily under the Federal Alcohol Administration Act.[4]

In the United States, regulation of products of biotechnology, which includes cell-cultivated meat and poultry products, is shared among the FDA, USDA and Environmental Protection Agency (EPA) under an inter-agency agreement known as the Coordinated Framework for the Regulation of Biotechnology. This agreement is based on an understanding that biotechnology and biomanufacturing capabilities are extensions of existing methods of production, and the agencies therefore rely on existing statutory and regulatory frameworks to regulate these innovative products. As such, regulatory authority is distributed among multiple agencies depending on the nature of the products.

State agencies administer certain licensing and labelling requirements for these products under their own state-specific statutory and regulatory frameworks.

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1 Kara L McCall, Elizabeth M Chiarello and Diane C McEnroe are partners, and Kevin Sforza and Eliza M Lawless are associates at Sidley Austin LLP. The authors would like to thank Chris Abbinante, Stephanie Koh, Marketa Lindt, Geeta Malhotra, Devin Gustafson, Kristina Martinez, Taylor Shuman, Jacqueline Pruitt and Claire Ramsey for their assistance in preparing this chapter.

2 See generally 21 USC § 301, et seq.

3 See generally 15 USC §§ 45, 52, 55; 21 USC § 352(r).

4 See generally 27 USC § 205(e); 27 USC § 8.

II YEAR IN REVIEW

i The FDA's reorganisation of its human foods programme

In the wake of the infant formula crisis of 2022, and the FDA Commissioner Robert Califf's appointment of the Reagan-Udall Foundation to assess and report on the FDA's food regulatory structure, the commissioner announced a 'new, transformative vision for the FDA Human Foods Program'.[5] The functions of the Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Policy and Response (OFPR) and certain functions of the Office of Regulatory Affairs (ORA) will be unified under a new human foods programme. According to Commissioner Califf's announcement, the overriding goal of this reorganisation is to centralise responsibility for food safety in a single leader who reports directly to the commissioner, ultimately ensuring oversight of human food in a more effective and efficient way. As detailed in the announcement, the functions of the Center for Food Safety and Applied Nutrition (CFSAN) and Office of Food Policy and Response (OFPR) and certain functions of the ORA will be unified under a new human foods programme.

ii Executive Order on Advancing Biotechnology and Biomanufacturing Innovation

On 12 September 2022, the Biden administration issued the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy (Executive Order).[6] The Executive Order is important to regulated entities in this space because it may result in streamlining the existing Coordinated Framework for the Regulation of Biotechnology, and thus ease the path to market for a range of innovative products using synthetic biology or genome editing.

The overall intent of the Executive Order is to bring a 'whole-of-government' approach to the advancement of economic activity derived from biotechnology and biomanufacturing (i.e., the bioeconomy) in the United States and to foster innovative solutions across health, climate change, energy, food security, agriculture, the supply chain and national and economic security. The covid-19 pandemic highlighted the critical role of biotechnology and biomanufacturing in addressing global healthcare needs. The Executive Order emphasises the potential application of these industry sectors across the broader bioeconomy. Of particular note for the biotechnology industry, the Executive Order aims to:

a bolster federal investment in key research and development areas of biotechnology and biomanufacturing;

b improve and expand domestic biomanufacturing production capacity and processes;

c train and support a diverse, skilled workforce, to advance biotechnology, and biomanufacturing; and

d clarify and streamline regulations.

5 The FDA Proposes Redesign of Human Foods Program to Enhance Coordinated Prevention and Response Activities, FDA (31 January 2023), https://www.fda.gov/news-events/press-announcements/fda-proposes-redesign-human-foods-program-enhance-coordinated-prevention-and-response-activities.

6 Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy (12 September 2022) https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/.

iii Foods derived from animal cell culture technology

As was announced on 7 March 2019, the FDA and FSIS signed a formal agreement to jointly oversee the production of human food products derived from the cells of livestock or poultry. The agreement provides that, among other things, the agencies will 'develop joint principles for product labelling and claims to ensure that products are labelled consistently and transparently'.[7]

On 3 September 2021, FSIS published an Advance Notice of Proposed Rulemaking (ANPR) to solicit public comments regarding the labelling of meat and poultry products produced using animal cell culture technology.[8] The ANPR followed a notice and request for information that the FDA issued on 7 October 2020 regarding the labelling of foods comprising or containing cultured seafood cells.[9] Consistent with the 2019 formal agreement, FSIS indicated that it will consider comments submitted in response to the FDA's request for information in developing rules governing the labelling of cell culture products. Currently, the issue has been placed on the USDA's Food Safety and Inspection Service's (FSIS) list of 'long-term actions' – meaning that the agency does not intend to have a regulatory action within the next year.

iv Best practices for convening a GRAS panel

Under the FDCA, any substance that is intentionally added to food is a food additive and is subject to premarket review and approval by the FDA, unless the substance is generally recognised, among qualified experts, as having been shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a 'food additive'.

In its December 2022 final 'Best Practices for Convening a GRAS Panel' Guidance (GRAS Guidance), FDA offers significant new insight on the scope and type of information that is adequate and inadequate to support generally recognised as safe (GRAS) status, when a GRAS panel is necessary or useful to support GRAS status, and what the role is for unpublished scientific data in establishing GRAS status.[10] Critically, the GRAS Guidance provides the FDA's updated thinking on the utility of published peer-reviewed primary studies, secondary literature, and findings and opinions of an authoritative body.

The GRAS Guidance introduces a two-pronged approach for assessing the weight of information used to support GRAS status. According to the FDA, this information 'is composed of both "general availability" and "general acceptance" aspects'. The FDA makes clear that the 'general availability' prong simply means 'publication in a peer-reviewed scientific journal'. In contrast, 'general acceptance' is a case-by-case analysis determined in part by the strength of the generally available evidence of safety.

7 The FDA, Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species, 7 March 2019, https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell (last visited 20 July 2022).

8 86 Fed. Reg. 49491 (3 September 2021).

9 85 Fed. Reg. 63277 (7 October 2020).

10 FDA, Guidance for Industry, Best Practices for Convening a GRAS Panel (December 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-best-practices-convening-gras-panel.

Thus, according to the FDA, 'general availability' and 'general acceptance' should be evaluated together, along a continuum, in a weight-of-the-evidence approach. Notably, FDA makes clear that the outcome of a GRAS panel's analysis may have limited use in this weight-of-the-evidence assessment, depending on the membership and expertise of the panel. In the GRAS Guidance, the FDA offers several illustrative examples of the weight of types of published literature.

v Proposed rule exempting marketed foods, dietary supplements and cosmetics from IND requirements

On 9 December 2022, the FDA issued a proposed rule that would create an exemption from investigational new drug (IND) requirements for certain clinical investigations of lawfully marketed human foods (e.g., conventional foods and dietary supplements) and cosmetics.[11] Under the proposal, clinical studies to evaluate a 'drug' endpoint for such products would not require an IND when, among other things, the study is not intended to support a drug development plan or a labelling change that would cause the product to become an unlawfully marketed drug, and as long as the study does not present a potential for significant risk to the health, safety or welfare of subjects.

The FDA's proposed rule responds in part to lingering uncertainty after the FDA published a 2013 guidance (Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards (IRBs) on Investigational New Drug Applications – Determining Whether Human Research Studies Can Be Conducted Without an IND) which stated that all studies with a drug endpoint on food and dietary supplement products would require an IND, even if there was no intent to develop or market the product for a drug use. In October 2015, the FDA stayed the portions of the guidance that were at issue.

The proposed rule explains the FDA's position by offering exemptions from the IND requirement for investigations of foods, dietary supplements and cosmetics if they meet the exemption criteria for either a sponsor self-determined exemption or an FDA-determined exemption, the requirements of which are described in the proposed rule. Comments from industry have been submitted.

vi Healthy rule

In September 2022, after seven years of consideration and addressing one of the first updates to the FDA's Nutrition Labeling and Education Act (NLEA) of 1994 as applied to nutrient content claims, the FDA's proposed rule updates the 'healthy' implied nutrient content claim by introducing a food group-based approach, rather than focusing on the presence or absence of specific nutrients in a product.[12] The proposed rule seeks to align the definition of 'healthy' with current nutrition science, the updated nutrition facts label, and the 2020 to 2025 Dietary Guidelines for Americans (Dietary Guidelines). Under the proposed rule, a food product may bear the 'healthy' claim if it contains certain amounts of specific 'food group equivalents,' as defined by the Dietary Guidelines groupings of foods:

a vegetables of all types:
- dark green;

11 87 Fed. Reg. 75536 (9 December 2022).

12 FDA, Guidance for Industry, Best Practices for Convening a GRAS Panel (December 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-best-practices-convening-gras-panel.

- red and orange;
- beans, peas and lentils;
- starchy; and
- other vegetables;

b fruits, especially whole fruit;

c grains, at least half of which are whole grain;

d dairy, including:

- fat-free or low-fat milk, yogurt and cheese; or
- lactose-free versions and fortified soy beverages and soy yogurt alternatives;

e protein foods, including:

- lean meats, poultry and eggs;
- seafood;
- beans, peas and lentils; and
- nuts, seeds, and soy products; and

f oils, including vegetable oils and oils in food, such as seafood and nuts.

The proposed rule also requires food products bearing the claim 'healthy' to be limited in certain nutrients, including saturated fat, sodium and added sugars.

vii Labelling of plant-based milk alternatives

In February 2023, the FDA released draft guidance on the labelling of plant-based milk alternative products.[13] The draft guidance provides recommendations regarding naming principles for plant-based milk alternatives and voluntary nutrient statements. The draft guidance details the FDA's conclusions regarding consumer understanding of plant-based milk alternatives, and notes that consumers are not confused as to the ingredients used in producing the products: namely, that consumers do not misunderstand plant-based milk to contain any ingredients sourced from cows, despite use of the term 'milk'. However, the FDA concluded consumers do not appear to understand the nutritional differences between plant-based milk and cow's milk. These conclusions informed the FDA's recommendations for (1) naming principles and (2) voluntary nutrient statements.

'Non-standardized foods', or foods that do not have a standard of identity, must be labelled using the common or usual name, which can be established though regulation or common usage. The guidance recognises there is no standard of identity for plant-based milk products; however, some common names have been established, such as 'soy milk' or 'almond milk.' Additionally, the plant source of the product should be identified in the product name. The term 'dairy-free milk' is insufficiently descriptive to identify the plant source but may be used as additional information on product labels to inform consumers.

The FDA recommends that plant-based milk alternatives that use the term 'milk' in their name and differ nutritionally from milk bear a voluntary nutrient statement describing how the product is nutritionally different. The FDA recommends the voluntary nutrient statement appear prominently on the principal display panel near and visually connected to the name of the product if space allows. A symbol may also be placed next to the name of the product, directing consumers to the voluntary nutrient statement on the principal display

13 87 Fed. Reg. 75536 (9 December 2022).

panel. The FDA recommends using USDA's Food and Nutrition Service's nondairy beverages nutrient criteria to determine whether plant-based milk has a different nutrient composition than milk from cows.

viii White House Conference on Hunger, Nutrition and Health

On 28 September 2022, the Biden administration held the White House Conference on Hunger, Nutrition and Health. The Conference laid out the administration's goals to end hunger in America and increase healthy eating and physical activity by 2030. The Conference discussed initiatives to be led by FDA to help meet the administration's goals. The FDA will develop a front of package labelling system to quickly and easily communicate nutrition information.[14] The FDA will also publish a request for information to 'gather public input regarding industry practices, technology, and current challenges to inform guidance for the food industry on nutrition, ingredient, and allergen information that should be available for groceries sold online'.[15]

ix Cosmetics

In December 2022, Congress passed the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) as part of the Consolidated Appropriations Act of 2023.[16] MoCRA amended the FDCA to bring the regulation of cosmetics in line with other FDA-regulated consumer products. MoCRA established new requirements for cosmetic companies, including serious adverse event reporting, GMPs, and facility and product listing requirements. These requirements are discussed in further detail in Section III.iv.

III FOOD AND COSMETIC SAFETY

i Foods and beverages

The United States has a comprehensive statutory and regulatory framework that covers all stages of food production, processing, holding, distribution and marketing of food intended for human consumption.

ii FDA-regulated food products

In general, food products[17] subject to the FDA's jurisdiction that are sold in the US must not be adulterated or misbranded under the FDCA.[18] A food is 'adulterated' if, for example, it contains poisonous or deleterious substances that might render it injurious to health, if it is manufactured under unsanitary conditions or if it contains unsafe ingredients.[19] A food is misbranded if, among other things, its labelling (due to affirmative statements or omissions) is false or misleading.[20]

14 Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health (September 2022), https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf.

15 id. at 22.

16 H.R. 2617, 117th Cong. (2022).

17 Dietary supplements are a subset of foods and are regulated differently from conventional foods.

18 21 USC § 331.

19 id. § 342(a).

20 id. § 343(a).

Food safety

Most domestic and foreign facilities that manufacture, process, pack or hold food must register with the FDA every two years, and failure to register can lead to refusal of an import.[21] The FDA may suspend a facility registration if it determines that food manufactured, processed, packed, received or held by the facility has a reasonable probability of causing serious harm to humans.[22] Registered foreign facilities must designate a US agent who lives or maintains a place of business in the United States and is physically present in the United States.[23] Farms are exempt from registration, as are foreign facilities if food from a foreign facility undergoes further manufacturing or processing (including packaging) by another facility outside the United States.[24]

Current good manufacturing practices (CGMPs) establish the minimum requirements for methods, equipment, facilities and controls for producing safe and wholesome food.[25] Under the FDCA, as amended by the FSMA, food facilities may be subject to the following key requirements, among others.

a Under the Hazard Analysis and Risk-Based Preventive Controls (HARPC) rule, registered facilities must create and implement a food safety plan – which includes a hazard analysis, preventive controls, a risk-based supply chain programme, a recall plan and monitoring, corrective action and verification procedures – and must maintain required records.[26]

b A registered food facility must make a report to the FDA through the Reportable Food Registry within 24 hours of determining that there is a reasonable probability that food manufactured, processed, packed or held by the facility will cause serious adverse health consequences.[27]

c At the FDA's written request, a company must permit the agency timely access to all relevant records when the FDA has a reasonable belief that a food manufactured, processed, packed, distributed, received, held or imported by the company is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.[28]

d Most registered facilities must comply with a rule requiring mitigation strategies to protect food against intentional adulteration from acts of terrorism targeting the food supply and other acts intended to harm the public health.[29]

21 21 CFR §§ 1.225, 1.285.

22 21 USC § 350d(b).

23 21 CFR §§ 1.227, 1.232.

24 21 USC § 350d(c); 21 C.F.R. §§ 1.226(a), (b), 1.227. Farms, however, may be subject to requirements for produce safety. 21 CFR part 112. A foreign facility is not exempt from registration if the further manufacturing or processing (including packaging) conducted by the subsequent facility consists of adding labelling or any similar activity of a *de minimis* nature. 21 CFR § 1.226(a).

25 21 CFR part 117, subpart B. Certain categories of foods, including acidified foods and low-acid canned foods, and infant formula, are subject to their own CGMPs that provide enhanced safety provisions. See 21 CFR parts 113, 114 and 106.

26 21 CFR §§ 117.126, 117.190, 117.315.

27 See 21 USC § 350f.

28 id. § 350c. The FDA also enforces general record-keeping requirements to enable tracing of manufactured foods along the supply chain; foreign facilities are exempt unless they transport food in the US. 21 CFR § 1.327(h).

29 21 CFR part 121.

e Shippers, receivers, loaders and carriers who transport food in the United States by motor or rail vehicle are subject to requirements to ensure the sanitary transportation of food.[30]

The FDA has the authority to inspect domestic and foreign facilities that manufacture, process, pack or hold food for introduction into the United States to assess compliance with CGMPs and HARPC, and might require production of records when the FDA reasonably believes that a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.[31] Indeed, the FSMA mandates that the FDA increase the frequency of inspections of food facilities, with a specific focus on foreign facilities.[32] If a foreign facility refuses to permit an FDA inspection within 24 hours of the FDA's request to inspect, food from the facility will not be admitted.[33]

If the FDA observes violative conditions during a facility inspection, the agency will issue an FDA Form 483 to notify management. Should the FDA determine that the conditions are serious, it may issue a warning letter to the facility.[34] The facility must respond to the FDA and explain how it has remedied (or will remedy) the objectionable conditions. The FDA also has other enforcement powers, including administrative detention or seizure of an article that is adulterated or misbranded, recalls (as is discussed further below), injunctions and criminal prosecutions.[35]

As a result of the covid-19 pandemic, the FDA was forced to pilot new and unfamiliar inspectional initiatives. One of the tools used for oversight has been remote regulatory assessments (RRAs). On 22 July 2022, the FDA released a new draft guidance, 'Conducting Remote Regulatory Assessments Questions and Answers' (the Draft RRA Guidance), describing the agency's plan to continue to use these alternative inspectional initiatives beyond the pandemic.

The Draft RRA guidance includes further insight into mandatory RRAs, including requests for Foreign Supplier Verification Program (FSVP) records.[36] These requests can include records related to hazard analysis, the importer's determination of appropriate supplier verification activities, performance of supplier verification activities and corrective actions.

Even though the FDA generally does not consider RRAs to be replacements for inspections, the draft guidance indicates that these FSVP record requests function as inspections in that FDA uses these records requests to evaluate a food importer's compliance with the programme.

Imported foods

Food imported into the United States generally must meet the same laws and regulations as food produced domestically. The FDA must receive prior notice of imported foods; food imported or offered for import without prior notice may be refused admission.[37] Imported

30 id. part 1, subpart O.

31 21 USC §§ 374, 350c(a)(1).

32 id. § 350j.

33 id. § 384c(b).

34 FDA, Regulatory Procedures Manual, Section 4-1.

35 21 USC §§ 334, 332, 333, 350l; 21 CFR part 1, subpart K.

36 21 CFR. 1.510(b)(3) and 1.512(b)(5)(ii)(C).

37 21 CFR part 1, subpart I.

food products are subject to FDA review at US ports of entry, and the FDA may refuse admission of imported foods if it 'appears from the examination of such samples or otherwise' that the product:

a was manufactured, processed or packed under unsanitary conditions;
b was forbidden or could not be sold in the country where it was produced or from which it was exported; or
c is adulterated or misbranded.[38]

The FDA does not certify, license or otherwise approve individual food importers, products, labels or shipments prior to importation. Under the Foreign Supplier Verification Program (FSVP) rule, importers must verify that the food they import from foreign suppliers complies with the FDCA's food safety requirements – including having processes and procedures that provide at least the same level of protection as those required under HARPC, if applicable – and is not adulterated or misbranded.[39]

In January 2023, the FDA issued its final guidance, 'Foreign Supplier Verification Programs for Importers of Food for Humans and Animals'. The guidance provides the FDA's thinking on how to comply with the regulations to analyse hazards in food, evaluate a potential foreign supplier, and to determine and conduct appropriate foreign supplier verification activities.

iii USDA-regulated products

Food products subject to USDA's jurisdiction must comply with the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA) or Egg Products Inspection Act, as applicable. Generally, the PPIA requires inspection of establishments that 'process' 'poultry products',[40] and the FMIA requires inspection of establishments that 'prepare' 'meat food products'.[41] Both the PPIA and the FMIA provide exemptions from federal inspection for certain types of establishments if certain criteria are met.[42] Establishments that are subject to inspection must obtain a grant of inspection from FSIS and must meet associated requirements, including establishing and implementing a hazard analysis critical control point plan and sanitary standard operating procedures. There are additional requirements for imports of meat, poultry and egg products, which are limited to eligible countries and establishments in those countries that meet requirements equivalent to those established by FSIS.[43]

Cell-cultivated meat and poultry products

The United States has made substantial headway in regulating food products derived from cell culture. Cell-cultivated meat and poultry products are regulated collaboratively between the FDA and USDA. Under a March 2019 memorandum of understanding, both agencies

38 21 USC § 381(a); FDA, Regulatory Procedures Manual 9-8 (Detention without Physical Examination) (citing FDCA Section 801(a)).
39 21 CFR part 1, subpart L.
40 21 USC §§ 453(f), 455(b).
41 id. §§ 601(j), 606(a).
42 id. §§ 454(c)(2), 661(c)(2).
43 USDA, FSIS Guidance for Importing Meat, Poultry, and Egg Products into the United States 1 (September 2020).

agreed to a joint regulatory framework wherein the FDA oversees cell collection, cell banks, cell growth and differentiation. At the harvest stage, regulatory oversight then transfers to USDA, which oversees the processing and labelling of human food products derived from cell culture. Both the FDA and USDA are expected to provide guidance for future potential cell-cultivated meat and poultry products.

While the US system is still in its infancy, two US companies received landmark grants of inspection from USDA on 21 June 2023, which is the final hurdle that allows cultivated chicken products to be sold in the United States. Immediately after receiving the final grants of inspection approvals by USDA, both companies announced that they had begun production of cultivated chicken products.

The FDA completed its voluntary premarket consultation process for both companies in November 2022 and March 2023, respectively, and USDA approved labels for two cultivated chicken products earlier in June. Although USDA approved use of the labelling term 'cell-cultivated' chicken for both companies, use of that term is not yet standardised. USDA is tasked with determining the final name for these products produced using cell culture technology. However, USDA has not finalised any labelling regulations. Its September 2021 advance notice of proposed rulemaking, which remains open and sought comments from interested stakeholders on the labelling terms, notes that '[l]abels approved for cell cultured meat and poultry products prior to the conclusion of this rulemaking may need to be changed for compliance with the requirements of final regulations'.[44]

The completion of the regulatory review and approval for the cultivated chicken products is a milestone for industry, and provides significant insight into the key criteria necessary for the development of further cultivated meat products in the United States.

iv Cosmetics

Congress enacted the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) in the Food and Drug Omnibus Reform Act of 2022, as part of the Consolidated Appropriations Act of 2023 on 29 December 2022. MoCRA established new requirements for cosmetic manufacturers, including adverse event reporting, GMPs, and facility and product listing requirements.

Pharmacovigilance

Under MoCRA, the 'responsible person' (i.e., the manufacturer, packer or distributor whose name appears on the product label) is required to report to the FDA any 'serious adverse events' associated with the use of a cosmetic product in the United States.[45] 'Serious adverse events' means an adverse event that 'results in death, a life threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, an infection, or significant disfigurement (including serious and persistent rashes, second or third degree burns, significant hairloss, or persistent or significant alteration of appearance)', which requires medical intervention. Reports must be made within 15 business days. Pharmacovigilance requirements are effective 29 December 2023.

44 86 Fed. Reg. 49491, 49496 (3 September 2021).

45 Modernization of Cosmetics Regulation Act of 2022 (MoCRA) in the Food and Drug Omnibus Reform Act of 2022, Pub. L. No. 117-328, § 3502 (Sec. 605(a) Serious Adverse Event Reporting Requirements) (2022).

GMPs

FDA will be promulgating regulations establishing GMPs for cosmetic products before 29 December 2025. Prior to issuing regulations, the Secretary of Health and Human Services must 'consult with cosmetic manufacturers, including smaller businesses, consumer organizations and other experts'.[46] These regulations may build on the FDA's 2013 Draft Guidance, Cosmetic Good Manufacturing Practices or International Organization for Standardization (ISO) standards used in Europe.[47] The FDA is tasked with publishing a related notice of proposed rulemaking by 29 December 2024.

Pursuant to FDA's anticipated rulemaking, on 1 June 2023, the FDA held a listening session on 'Good Manufacturing Practice for Cosmetics', which was an opportunity for industry members to provide oral comments on any 'national or international standard (e.g., International Organization for Standardization (ISO) standard 22716:2007) and the extent to which it would be practicable for good manufacturing practice regulations for cosmetic products to be consistent with such standard'. The most common request from listening session participants was for GMPs to follow ISO standard 22716 as a guide, and there were some requests from participants to continue following the 2013 guidance.

Facility registration and product listing

MoCRA requires registration of facilities that manufacture or process cosmetics for distribution in the United States.[48] Existing facilities must register within one year of the statute's enactment, or by 29 December 2023. New facilities must do register within 60 days of beginning manufacturing operations. Similarly, under MoCRA, cosmetic products must be listed with FDA. Product listing includes a list of all product ingredients, including fragrances, flavours and colours, and updates are required annually. Listings for products currently marketed must be submitted to the FDA within one year of the statute's enactment, or 29 December 2023. New product listings must be submitted within 120 days of placing the product in interstate commerce.

Other requirements

Manufacturers are required to have a 'responsible person' maintain records supporting adequate substantiation of the safety of a cosmetic product.[49] Adequate substantiation means:

> *tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.*

The FDA will be issuing regulations designating certain substances as 'fragrance allergens', and requiring them to be listed on a product's label via proposed notice of rulemaking, by 29 June 2024. Current regulations restrict the use of certain ingredients in cosmetics that the FDA has determined are poisonous or deleterious, including mercury compounds and

46 Pub. L. No. 117-328, § 3502 (Sec. 606(a) In General).

47 FDA, Draft Guidance for Industry, Cosmetic Good Manufacturing Practices (June 2013), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices.

48 Pub. L. No. 117-328, § 3502 (Sec. 607 Registration and Product Listing).

49 Pub. L. No. 117-328, § 3502 (Sec. 608 Safety Substantiation).

methylene chloride.[50] The FDA may inspect cosmetic establishments to determine whether cosmetics are safe and properly labelled. If the agency identifies a violation of the FDCA, it may issue a warning letter, require that the firm conduct a recall under mandatory recall authority established in MoCRA (effective 29 December 2023),[51] seize violative products, seek an injunction or seek criminal penalties.[52]

Additionally, MoCRA contains a 'Sense of Congress' provision stating that animal testing should not be used to test the safety of cosmetic products and should be phased out with the 'exception of appropriate allowances'.[53] MoCRA contains a preemption clause prohibiting states and their agencies from establishing or continuing laws that differ from MoCRA's with respect to registration and product listing, GMPs, recall, adverse event reporting or safety substantiation.[54]

v Food additives and contaminants

Under the FDCA, any substance that is intentionally added to food is a food additive and is subject to premarket review and approval by the FDA[55] unless the substance is generally recognised, among qualified experts, as having been shown to be safe[56] under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a 'food additive'.[57] The use of a food substance may be generally recognised as safe (GRAS) either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.[58] GRAS status is established through notification by an applicant to the FDA of the applicant's own conclusion that a substance is GRAS, or self-affirmation of the GRAS status of a substance without notification to the FDA. The FDA has also recognised certain substances as GRAS, as set forth in the FDA's regulations, and the agency maintains a GRAS Notice Inventory containing information regarding substances for which the FDA has received a notification.[59] Packaging materials for FDA-regulated products must also comply with the FDA's food additive regulations if the packaging contains food contact substances that are reasonably expected to migrate into food.[60] FSIS and the FDA have a joint ingredient approval process for meat, poultry and egg products, under which the FDA authorises safety and FSIS determines suitability and efficacy for use.[61]

Unlike food additives, there is no GRAS (or similar) exemption for colour additives in food. All substances that impart colour are colour additives and are subject to premarket

50 21 CFR part 700, subpart B.

51 Pub. L. No. 117-328, § 3502 (Sec. 611 Mandatory Recall Authority).

52 21 USC §§ 334, 332, 333; 21 CFR part 7, subpart C; FDA, Regulatory Procedures Manual, Sec. 4-1.

53 Pub. L. No. 117-328, § 3507 (Sense of the Congress on Animal Testing).

54 Pub. L. No. 117-328, § 3502 (Sec. 614 Preemption).

55 21 USC §§ 321(s), 348.

56 'Safe' means 'a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use'. 21 CFR § 170.3(i).

57 21 USC §§ 321(s), 348.

58 id; 21 CFR §§ 170.3, 170.30.

59 21 CFR parts 182, 184, 186; FDA, GRAS Notice Inventory, www.accessdata.fda.gov/scripts/ fdcc/?set=GRASNotices.

60 21 USC § 348(a)(3).

61 Memorandum of Understanding Between the US Department of Agriculture, Food Safety and Inspection Service and the United States Department of Health and Human Services, Food and Drug Administration, MOU 225-00-2000 Amendment 1 (January 2015).

approval unless they are used solely for a purpose other than imparting colour.[62] Colour additives must comply with individual listing requirements.[63] The same requirements for colour additives apply to cosmetics as well, and a cosmetic containing a colour additive that does not comply with the applicable FDA regulation is considered adulterated.[64]

vi Recalls

FDA-registered food facilities generally must comply with HARPC requirements, which include creating and implementing a recall plan. Most companies have a recall policy to address situations whereby the company must voluntarily recall a product. The FDA also has the authority to issue a mandatory recall for food when the agency believes that there is a 'reasonable probability' that a food is adulterated or misbranded and its use or exposure will cause serious adverse health consequences.[65] The agency must provide the responsible party with an opportunity to cease distribution and recall the food, but if the party does not institute a voluntary recall, the FDA can order the recall.[66] The FDA has no authority under the FDCA to mandate a recall of a cosmetic, but the agency may request that a firm recall a product. For both food and cosmetics, once a firm initiates a recall, the FDA takes an active role in the recall process, including monitoring its progress, evaluating the health hazard presented by the product being recalled, issuing a public notification if the recalling firm is unwilling to do so and ensuring that the product is destroyed or suitably reconditioned.[67] USDA does not have the authority to mandate a recall, but official establishments do have an obligation to notify FSIS of adulterated or misbranded products.[68]

IV SUPPLY CHAINS

i Labour and immigration

The US immigration system is administered primarily by the US Citizenship and Immigration Services (USCIS) agency to permit employers to request work visas and permanent residency for scientists, engineers, executives and managers, technology professionals, intracompany specialists and other occupations in the food, beverage and cosmetics industries. Most employer petitions are initially filed with USCIS followed by visa issuance at a US consulate abroad. In 2022, the Biden Administration announced new actions to attract STEM talent to the United States by updating policy guidance for a number of visa classifications. These updates provide employers with more flexibility in pursuing certain visa categories for STEM employees, including students, trainees, researchers, and extraordinary ability and national interest waiver applicants. Furthermore, under the US free trade agreements with Canada and Mexico, there are special expedited immigration options for certain specific food industry-related professions, including agriculturalists, biologists, chemists, poultry and dairy scientists, and animal and plant breeders. Agricultural operations and other seasonal non-agricultural employers may be able to use some of the US temporary worker programmes.

62 21 USC §§ 321(t)(1), 379e(a).
63 id. § 379e(b); 21 CFR part 70.
64 21 USC § 379e(a).
65 id. § 350l.
66 id.
67 21 CFR part 7, subpart C.
68 21 USC §§ 612, 459(b); 9 CFR § 418.2.

Enforcement of employer compliance with immigration regulations is conducted by a range of agencies, including USCIS, the Department of Labor and US Immigration and Customs Enforcement.

ii Processing and certifications

Organic

The FDA does not define the term 'organic', but both foods and cosmetics may be certified as organic by USDA through its National Organic Program. USDA guidelines outline how certified organic food products are grown and processed, including, among other factors:

a requirements for soil quality;
b animal-raising practices;
c pest and weed control; and
d use of additives.

Organic producers generally rely on natural substances and physical, mechanical or biologically based farming methods.[69] Processed foods labelled as organic generally may not contain artificial preservatives, colours or flavours.[70] Products labelled as having been made with organic ingredients must contain at least 70 per cent organically produced ingredients and, as with all other organic products, must identify the USDA-accredited certifier, but 'made with organic ingredients'-labelled products may not bear the USDA organic seal.[71]

Non-GMO

USDA prohibits genetically modified organisms (GMOs) in organic products by banning the use of excluded methods.[72] USDA defines 'excluded methods' as:

> *[a] variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.*[73]

The FDA has issued guidance discouraging the use of the claim 'non-GMO', as opposed to 'not developed using bioengineering', for example. The FDA has said, however, that it does not intend to take enforcement action against 'non-GMO' and similar claims as long as the food is, in fact, not derived from a genetically engineered plant and the food's labelling is not otherwise false or misleading.[74]

69 See 7 CFR part 205.
70 See id. §§ 205.605, 205.606.
71 See id. § 205.304.
72 See id. §§ 205.105(e), 205.301(f)(1).
73 7 CFR § 205.2.
74 See FDA Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants 7, 8 (rev. March 2019).

In the public more broadly, the use of non-GMO claims remains an industry issue. In December 2021, a class action lawsuit was filed against Gerber Products Company, alleging that the company's labelling and marketing of certain products as non-GMO are false, misleading and deceptive to consumers because the products contain ingredients derived from genetically modified crops, protein or dairy sources derived from animals raised on genetically modified feed, and numerous artificial ingredients that were genetically engineered in a laboratory setting using biotechnologies.[75] The litigation is part of a larger trend of class action litigation surrounding the use of non-GMO claims.[76]

iii Sustainability

Although US consumers are interested in sustainability as a goal for food, beverage and cosmetics products, the initiatives on this front are generally led by company business practices rather than rules and regulations. For example, The Coca-Cola Company has announced a number of initiatives relating to packaging, recycling and water stewardship; in February 2022, the company announced a global goal to sell at least 25 per cent of all beverages across its portfolio of brands in reusable packaging by 2030.[77] Ben & Jerry's, a popular ice cream producer, began a project in 2019 to eliminate single-use plastic and instead use wooden spoons and paper straws. It has also focused on biodegradability of its ice cream containers.[78]

In the United States, the development of marketing guidelines relating to sustainability is likely to be considered in the context of legal disputes.[79] For example, in August 2021, one company was sued by a non-profit environmental advocacy group that challenged the company's marketing around its environmental stewardship and commitment to sustainability.[80] The term 'greenwashing' has been coined to refer to the process of conveying a false impression or providing misleading information about how a company's products or processes are sustainable or environmentally sound.

In December 2022, the FTC opened a comment period on its Guides for the Use of Environmental Marketing Claims (Green Guides).[81] The Green Guides outline general principles applicable to all environmental marketing claims and provide specific guidance regarding many common environmental benefit claims. For each claim covered, the Guides:

a explain how reasonable consumers will likely interpret it;

b describe the basic elements necessary to substantiate it; and

c present options for qualifications to avoid deception.

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75 Complaint, *Norman v. Gerber Products Company*, Case No. 4:21-cv-09940 (N.D. Cal.) (Complaint filed on 22 December 2021).

76 See, e.g., *Stewart v. Kodiak Cakes, LLC*, 537 F. Supp. 3d 1103 (S.D. Cal. 2021); *Schneider v. Chipotle Mexican Grill, Inc*, Case No. 16-cv-02200-HSG (N.D. Cal. 12 February 2019).

77 The Coca-Cola Company, Sustainability, https://www.coca-cola.co.uk/sustainability (last visited 20 July 2022); The Coca-Cola Company, The Coca-Cola Company Announces Industry-Leading Target for Reusable Packaging, 10 February 2022, https://www.coca-colacompany.com/news/coca-cola-announces-industry-leading-target-for-reusable-packaging.

78 Ben & Jerry's, 'Sustainable Packaging', www.benjerry.com/values/how-we-do-business/responsibly-sourced-packaging.

79 See generally Andrew Jacobs, Lawsuits Over 'Misleading' Food Labels Surge as Groups Cite Lax U.S. Oversight, N.Y. Times (7 September 2021), https://www.nytimes.com/2021/09/07/science/food-labels- lawsuits.html.

80 *Earth Island Inst. v. Bluetriton Brands*, Civil Action 21-2659 (JEB) (D.D.C. 27 January 2022).

81 87 Fed. Reg. 77766 (20 December 2022).

The FTC seeks to ensure that the Green Guides reflect changes in the marketplace over time, given changes in consumer perception and increased attention to environmental concerns, including climate change and issues driven by the covid-19 pandemic. Pursuant to the FTC's periodic review of its rules and guides, the FTC is soliciting comments about the efficiency, costs, benefits and regulatory impact of the Green Guides to determine whether to retain, modify or rescind them.

iv Anti-corruption rules

Supply chain participants should also remain sensitive to corruption and money-laundering risks as well as the accompanying laws in this area. Such risks are often exacerbated in the context of supply chains as a result of the significant use of and reliance on third parties (e.g., consultants, vendors and suppliers) – for which control and oversight are more difficult – as well as the increasingly complex set of global supply chain interactions that often include government touchpoints. Relevant anti-corruption laws in this area include the Foreign Corrupt Practices Act (which, in general terms, prohibits corrupt payments to foreign officials to obtain or retain business and imposes record-keeping and internal controls obligations on certain entities), the Travel Act, and federal bribery, mail and wire fraud statutes, as well as local anti-bribery and anti-corruption laws in the foreign countries in which the companies and supply chains operate (e.g., the UK Bribery Act and the Brazilian Clean Company Act). Relevant anti-money laundering regulations include:

a the Anti-Money Laundering Act of 2020;
b the Bank Secrecy Act; and
c the Office of Foreign Assets Control enforcement regulations.

Domestic and international supply chain participants should ensure adequate practices to identify and mitigate third-party risks, including through the use of third-party due diligence, defensive contractual provisions, training and monitoring.

v Due diligence and monitoring

The FDA generally requires registered food facilities that manufacture or process a raw material or other ingredient that they receive from a supplier to establish and implement a risk-based supply chain programme, through which the facilities must approve suppliers, determine and conduct appropriate verification activities, and document their supply chain programme.[82] Supplier approval is based on various factors, including the hazard analysis for the food and the supplier's food safety history relevant to the raw materials and ingredients.[83] Importers generally must conduct similar approval and verification activities for their foreign suppliers.[84] To comply with these requirements, covered facilities will need to evaluate the risks associated with the ingredients provided by suppliers and distributors, work with their suppliers to obtain relevant information and, in some cases, conduct on-site audits.

82 21 CFR § 117.410.
83 id. § 117.410(d)(1).
84 id. part 1, subpart L.

V SALES AND MARKETING

i Regulatory framework

In general, food labels must bear the following required information:

a statement of identity (the name of the food);[85]
b the name and address of the manufacturer, packer or distributor;[86]
c the net quantity of contents;[87]
d an ingredient declaration;[88]
e nutrition labelling;[89] and
f allergen labelling.[90]

The FDA does not pre-approve labels for food products; manufacturers are responsible for ensuring that their product labelling is compliant. The FDA has regulatory requirements for certain types of claims, including nutrient content claims (which characterise the level of a nutrient in the food) and health claims (which characterise the relationship of any substance to a disease or health-related condition).[91] Health claims are limited to claims about disease risk reduction and cannot claim to diagnose, cure, mitigate or treat a disease.[92]

The FDA requires food allergen labelling on products.[93] In 2022, the FDA updated the requirements to include sesame as a new major food allergen, and answered questions clarifying the requirements for allergen labelling for bulk foods, spice mixes, genetically engineered foods, ingredients containing allergen proteins, allergen statements for dietary supplements and exemptions to allergen labelling requirements.[94] The FDA may review product labelling during an inspection or otherwise, and may issue a warning letter when it identifies serious non-compliance with labelling requirements under the FDCA.

The FDA requires menu labelling of calorie information in restaurants and similar retail food establishments, and the requirements apply to standard menu items offered for sale in covered establishments. A 'covered establishment' is defined as 'a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership (e.g., individual franchises)) and offering for sale substantially the same menu items'.[95]

85 21 CFR § 101.3.
86 id. § 101.5.
87 id. § 101.7.
88 id. § 101.4.
89 id. § 101.9.
90 21 USC § 343(w).
91 21 CFR §§ 101.13, 101.14.
92 id. § 101.14.
93 21 U.S.C. 343(w).
94 FDA, Guidance for Industry, Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5) (5 November 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5.
See also FDA, Draft Guidance for Industry, Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5) (5 November 2022), https://www.fda.gov/media/163454/download.
95 id. § 101.11.

Unlike the FDA, USDA and FSIS have the authority to approve product labels before the products may be offered for sale. USDA has established requirements for the content and design of labels to ensure that they are truthful, accurate and not misleading, and that products are not misbranded. Product labels must generally bear the following features:

a product name;
b inspection legend;
c handling statement;
d net weight;
e ingredient statement;
f name and place of business of manufacturer, packer or distributor; nutrition labelling; and
g safe handling instructions.[96]

FSIS has also issued guidance documents to assist firms in understanding when special statements and claims may be used. Although allergen statements are not mandatory, FSIS supports the voluntary addition of such statements on meat and poultry labels immediately following the ingredient statement.[97]

As of 1 January 2022, food manufacturers, importers and other entities that package and label foods for retail sale or sell bulk food items (regulated entities), subject to certain exceptions, must disclose information about bioengineered foods and bioengineered food ingredients in accordance with the National Bioengineered Food Disclosure Standard (the Standard).[98] The Standard defines 'bioengineered food', in part, as 'food that contains [detectable] genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature'.[99] The Standard also requires regulated entities to maintain customary or reasonable records to demonstrate compliance with the disclosure requirements.[100]

A cosmetic product must have a truthful, non-misleading label that:

a indicates that it is for cosmetic use;
b lists ingredients;
c states the product contents of the package by weight; and
d states manufacturer, distributor or packer information.[101]

The presence of PFAS in cosmetics has been under increased scrutiny, and a recent class action litigation trend is for plaintiffs to allege that companies falsely advertised cosmetic products containing PFAS by using terms such as 'pure', 'safe' and 'sustainable'.[102] These plaintiffs sue under state business and consumer protection statutes.

96 9 CFR §§ 317.2, 317.300, 317.309, 381.117, 381.118, 381.121, 381.122, 381.125, 381.400, 381.409, 381.123.

97 USDA, FSIS Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labelling (November 2015).

98 7 CFR part 66; 83 Fed. Reg. 65814 (12 December 2018).

99 7 CFR § 66.1.

100 id. part 66, subpart D.

101 21 CFR §§ 701.3, 701.11, 701.12, 701.13.

102 See, e.g., Complaint, *Onaka, et al, v. Shiseido Americas Corporation*, Case No. 1:21-cv-10665 (S.D.N.Y.) (Complaint filed 14 December 2021); *Solis v. Covergirl Cosmetics, et al*, Case No. 3:22-cv-00400 (S.D.

Although the FDA exercises primary authority over food and cosmetics labelling, the FTC exercises authority over advertising of foods and cosmetics, among other products.[103] The FTCA prohibits 'unfair or deceptive acts or practices'; advertising must be truthful, non-misleading and adequately substantiated.[104] FTC's Health Products Compliance Guidance[105] provides the view of FTC's staff on the advertising of consumer products, with a particular focus on health claims of such products.[106] Under the Guidance, claims must be substantiated with 'competent and reliable scientific evidence'.[107] FTC's staff has expressed an interpretation of the standard that is quite high, suggesting for some claims that substantiation will need to be in the form of randomised, controlled human clinical testing.[108]

In some cases, the FDA and the FTC conduct joint enforcement efforts. Examples of recent efforts include sending warning letters to companies marketing cannabidiol-containing products that claim to treat covid-19, as well as products containing delta-8 tetrahydrocannabinol (THC) in packaging that is almost identical to that of many snacks and types of candy that are eaten by children.[109]

The TTB requires pre-approval of alcoholic beverage labels within its jurisdiction but does not require pre-approval of alcoholic beverage advertisements. The TTB does offer a voluntary pre-clearance service and monitors advertising through referrals and complaints, industry member requests for pre-clearance and internal selections of advertisements for review. Advertising regulations generally prohibit statements that are false, statements that are inconsistent with the approved product labels, false or misleading statements that are disparaging of a competitor's product, health-related statements that are false or misleading, and misleading guarantees.[110] Certain alcohol products are required to follow FDA labelling regulations: low-volume alcohol wines, beers that are made from substitutes for malted barley and beers made without hops.

Cal.) (complaint filed 25 March 2022); *Hicks, et al v. L'Oreal USA, Inc*, Case No. 1:22-cv-01989 (S.D.N.Y.) (Complaint filed 9 March 2022).

103 Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, MOU 225-71-8003 (1971).

104 15 USC § 45(a).

105 FTC, Health Products Compliance Guidance (December 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/ Health-roducts-Compliance-Guidance.pdf.

106 id. at 3.

107 id. at 11.

108 id. at 12.

109 See FTC, FTC, FDA Send Warning Letters to Seven Companies about Unsupported Claims that Products Can Treat or Prevent Coronavirus (9 March 2020), https://www.ftc.gov/news-events/news/press-releases/2020/03/ftc-fda-send- https://www.ftc.gov/news-events/news/press-releases/2020/03/ftc-fda-send-warning-letters-seven-companies-about-unsupported-claims-products-can-treat-or-prevent. See also FTC, FTC Sends Cease and Desist Letters with FDA to Companies Selling Edible Products Containing Delta-8 THC in Packaging Nearly Identical to Food Children Eat (5 July 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-sends-cease-desist-letters-fda-companies-selling-edible-products-containing-delta-8-thc.

110 27 CFR § 4.64 (wine); 26 CFR § 5.65 (distilled spirits); 27 CFR § 7.54 (malt beverages).

ii Consumer protection and false advertising

Personal injury or class action plaintiffs may point to advertising or label statements as the basis for misrepresentation, warranty and consumer fraud claims. In those claims, plaintiffs generally aim to prove that company statements were false and misleading, and they might attempt to use the FDA's communications to support these claims. When the FDA sends a warning letter to a manufacturer based on a review of labelling or promotional materials, the FDA's letter generally contains assertions that certain claims language might misbrand the product or be 'false or misleading'. Although such letters are neither formal findings by the FDA nor final agency actions, they can be admitted in litigation and used against manufacturers defending these suits. Even without an FDA letter, plaintiffs may sue (usually in class actions) under state consumer protection acts that prohibit false or misleading advertising. Competitors may also sue for false or misleading advertising under the US Lanham Act or state law equivalents.

Claims that may be subject to Lanham Act or private civil actions include:

a a false claim about the characteristics or the benefits of the goods or service (including, in particular, health benefits of the product);

b the way the price is represented (e.g., products are advertised at sale prices but turn out not to be on sale);

c the way the goods or services are supplied or manufactured is misrepresented (e.g., made in the United States or 'eco-friendly'); and

d claims that leave out or hide material information.

VI PRODUCT LIABILITY

The United States permits product liability claims, and state law provides the elements of those claims that may be filed in state or federal court. Plaintiffs can bring several different types of product liability claims, the most common of which is negligence, which requires proof that the defendant's breach of a general duty to product users proximately caused the plaintiff's injuries. The negligence may be related to, generally, the design of the product, the manufacturing process or failure to warn.

State law governs strict liability claims and therefore the availability of such a claim will depend on the jurisdiction in which the plaintiff sues. However, most states recognise strict liability claims in product liability cases. A strict liability claim does not require that a plaintiff show that the defendant breached a duty, but the plaintiff will still have to show a product defect that proximately caused the plaintiff's injuries. In certain cases involving products that cannot be made completely safe, failure to warn about the risks of using the product may be considered the 'defect', even if the product itself is not defective.

Any type of recall or government action relating to a food, beverage or cosmetics product will almost always result in civil product liability litigation as well. Similarly, litigation arising out of a food-borne illness or contaminant will be brought under the same product liability claims discussed above. A food-borne contaminant will almost always be considered a 'defect' in the product if it was not intended to be in the product and if it creates a risk of personal injury.

Personal injury and product liability claims involving physical injury or property damage typically are brought in the United States as individual claims, or in some cases aggregate claims. Class actions are uncommon because these types of physical injuries are generally too individualised to permit class certification; however, a class action may be filed

if the class members are seeking refunds only and not seeking any damages for physical injury. Personal injury and product liability actions filed in federal court are often coordinated in federal courts under the Judicial Panel for Multidistrict Litigation rules. State courts also have their own various methods for coordination of cases filed within the same state.

VII INTELLECTUAL PROPERTY

Intellectual property (IP) offers a wide array of tools to set companies apart and edge out competition in the food, beverage and cosmetics industries. IP protection includes trademarks, trade dress, trade secrets and patents – all of which have advantages and disadvantages in securing a competitive advantage in the marketplace.

A trademark is a non-functional, distinctive sign used by a business to differentiate its goods from those of its competitors.[111] Trademark protection is how customers recognise a product in the marketplace and distinguish it from those of competitors. Trade dress is a subset of trademark law that protects the design, shape, colour, packaging or appearance of a product, where these characteristics help customers to distinguish a product in the marketplace. Elements of trade dress are protectable under the Lanham Act and most parallel state laws, only if they are both distinctive and non-functional.[112]

A trade secret may consist of any formula, pattern, physical device, idea, process or compilation of information that provides the owner with a competitive advantage in the marketplace and is treated in a way that can reasonably be expected to prevent the public or competitors from learning about the secret.[113] Many food, beverage and cosmetics companies also leverage the secretive nature of trade secrets as a marketing tool. However, trade secrets do not prevent independent discovery or reverse engineering.

Patents cover technical inventions, such as chemical compositions or machine designs that are new and unique.[114] Patent protection can add significant value to an emerging brand by keeping competitors at bay, serving as an asset or collateral to secure financing, or as leverage to license across different industries or markets. However, establishing the novelty of a food, beverage or cosmetics patent limits the availability of patent protection in many instances.[115]

111 See 15 USC § 1051 et seq. The Lanham Act (also known as the Trademark Act of 1946) is the federal statute that governs trademarks, service marks, and unfair competition.

112 Ezaki Glico Co. Ltd., maker of the Pocky cookie sticks, petitioned the US Supreme Court to resolve a circuit split relating to the unlawful copying of 'functional' trade dress. In a petition for certiorari, Ezaki Glico Co. Ltd. urged the Court to reverse the Third Circuit, which said the design of the cookie sticks was too 'functional' to be locked up under federal trademark law. *Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp*, 986 F.3d 250, 255 (3d Cir. 2021), as amended (10 March 2021), cert. denied sub nom. *Kaisha v. Lotte Int'l Am. Corp*, 142 S. Ct. 420 (2021), reh'g denied, 212 L. Ed. 2d 345, 142 S. Ct. 1402 (2022).

113 Trade secret laws are governed by state and federal laws. The Defend Trade Secrets Act of 2016 (DTSA), codified at 18 USC § 1836, et seq., is a US federal law that allows an owner of a trade secret to sue in federal court when its trade secrets have been misappropriated. The Uniform Trade Secrets Act (UTSA) is a Uniform Act promulgated for adoption in the United States. To date, 48 states and the District of Columbia have adopted the UTSA.

114 35 USC §§ 100–105.

115 A patent for a claimed invention may not be obtained if the differences between the claimed invention and the prior art would have been obvious to a person having ordinary skill in the art to which the claimed invention pertains. 35 USC § 103.

Although trademark protection is the tool most used by businesses in the field of food and cosmetics, traditionally underutilised branches of IP protection are seeing a resurgence. For example, this year has seen a continued boom in patent filings for commercialised substitute meat products – food products having structures, textures and other properties similar to those of animal products.

IP protection for cannabis-infused food, beverages and cosmetics is also on the rise, but companies seeking to protect these products face challenges because many forms of cannabis are illegal at the federal level.[116] For example, federal trademark protection mandates that the protected subject matter be lawful.[117] However, federal trademark laws do not pre-empt state trademark laws, and thus many cannabis-infused brands can still rely on geographically limited state protections. Conversely, established brands seeking to curb the sale of infused products in packaging that mimic famous brands are also faced with limited IP protections. Any contact with money that can be traced back to state marijuana operations could be considered money laundering and expose a bank to significant risk. The uncertainty of collecting from companies that cannot rely on traditional finance services means that brands seeking to stop cannabis-infused copycats might be limited to seeking injunctive relief for trademark infringement.

Even so, food, beverage and cosmetics companies rely on IP protections to differentiate themselves in the market and protect innovations. Those that take advantage of both traditional and underutilised branches of IP protection will likely secure a competitive advantage in the market.

VIII TRADE ORGANISATIONS

Several voluntary organisations have developed best practices and other guidelines that can assist regulated entities in demonstrating that they have complied with industry standards, or in otherwise mitigating potential liability.

Consumer product marketing (including food and beverages) is subject to industry self-regulation through the National Advertising Division (NAD) of the Better Business Bureau. NAD evaluates national advertising across all media types for truthfulness and accuracy. Specific challenges to a company's advertising can be made by a business, a trade association or consumers. The NAD may also review advertising on its own initiative. Generally, NAD seeks voluntary compliance with its determinations regarding the truth and accuracy of challenged advertising. In cases in which an advertiser declines to participate or to abide by the terms of an NAD decision, the issue is referred to the FTC. In some cases, NAD will also reach out to the FDA on an issue.

The Consumer Brands Association is the national trade association for the consumer-packaged goods industry in the United States, representing food, beverage, household and personal care product companies. For dietary supplements, the Consumer Healthcare Products Association, a member-based association representing manufacturers

116 Cannabis is classified as a Schedule I drug under the Controlled Substance Act (CSA). 35 USC §§ 100–105.

117 The federal trademark lawful use requirement mandates that 'use of a mark in commerce must be lawful use to be the basis for federal registration of the mark'. TMEP §907, citing 37 CFR §2.69 and §§1, 45 of the Lanham Act.

and distributors of over-the-counter drugs and dietary supplements, has adopted guidelines on advertising practices. The Personal Care Products Council is one of the leading national trade associations representing cosmetics and personal care products companies.

FMI, The Food Industry Association, is a national trade association for the entire food industry and supply chain (including retailers, suppliers, wholesalers and companies that provide services to these entities) in the United States. The Plant Based Food Association (PBFA) was created in 2016 to represent the US plant-based food industry. PBFA has adopted voluntary labelling standards and has helped to develop merchandising and marketing programmes and promote plant-based foods in the media. The American Frozen Food Institute is a national trade association for the frozen food industry in the United States.

The American Beverage Association is a government lobbying group that represents the beverage industry in the United States, including producers and bottlers of soft drinks, bottled water and other non-alcoholic beverages.

IX FINANCING AND M&A

The historic deal activity seen in 2021 continued to fade throughout 2022, as record levels of inflation, rising interest rates and geopolitical tension persisted. High inflation and interest rates, coupled with slow economic growth, increased scrutiny from regulators, and equity market volatility resulted in the downturn seen in 2022, in terms of deal volume and average deal price, especially when compared to 2021.[118]

In the food and beverage industry, the second half of 2022 was one of the worst periods in the past five years in terms of the number of deals closed, yet the third highest in terms of aggregate deal value, estimated at US$11.5 billion.[119] The branded packaged goods and the beverage segment led the way in terms of the number of deals closed in the second half of 2022.[120] Notable 2022 deals include Mondelez International's acquisition of Clif Bar & Company, Ferrero Group's acquisition of Wells Enterprises, and Royal DSM and Firmenich's US$21 billion merger.[121] Despite the slowdown during the first half of 2023 – in terms of deal value and numerosity – experienced across the market,[122] changing industry conditions such as the war in Ukraine and its effect on the supply chain, and the end of the federal covid-19 pandemic, may position companies for strategic M&A in the food and beverage space.[123] The food and beverages market is projected to grow from US$7,221 billion in 2023 to US$9,225 billion in 2027.[124] Deals in the beauty industry in 2022 were similarly down from the previous year, but the number of deals is otherwise impressive, when properly accounting for the record-breaking year of M&A in 2021.[125] Skin and hair care led the way for the beauty industry in 2022, most notably by the acquisition of Amika and Eva NYC by the Bansk Group in May of 2022, and Church and Dwight's purchase of Hero Acne's 'Mighty Patch' for US$630 million in the second half of 2022. The first half of 2023 showed

118 Mediha DiMartino, PE Firms Face 'Intriguing' Investment Climate, L. A. Bus. J., 1 February 2023.

119 Food and beverage M&A update: H2 2022, BAKERTILLY, 27 March 2023.

120 Food and beverage M&A update: H2 2022, BAKERTILLY, 27 March 2023.

121 Christopher Doering, 2022's top M&A deals in the food and beverage industry, FOODDIVE, 3 January 2023.

122 Food & Beverage: Industry Insights, KROLL, Spring 2023.

123 Nicole Sheynin, M&A Trends and Outlook for 2023, ALPHASENSE, 5 May 2023.

124 Food and Beverages Global Market Report 2023, REPORTLINKER, 21 April 2023.

125 Beauty Deals: Investment + M&A Transactions Year End 2022, BeautyMatter, 2022.

an increase in minority investments in the beauty industry, likely due to the difficulty that private equity firms continue to face in securing attractive financing given the high interest rates. Within the beauty industry, the clean beauty and celebrity-backed beauty trends from 2022 cooled, while haircare and medicated dermatological products continue to rise heading into the remainder of the year. The fragrance sector also remains trending, with Estee Lauder's notable acquisition of the Tom Ford Brand in late 2022 and Kering's acquisition of Creed in 2023. The wellness sector is expected to continue to grow throughout the second half of the 2023 as well, with focus on skin health, hair care and sexual wellness products.

On the financing side, despite inflation peaking in June 2022,[126] investors continue to express hesitation into the first half of 2023, as short-term interest rates remain high in the wake of economic uncertainty and the collapse of the Silicon Valley Bank. The numerous increases in interest rates that have continued into 2023 have made debt financing in the private equity sphere more expensive and on more unfavourable terms than the market has seen in prior years and is yet another factor in the lending slowdown. Private equity firms, while down 12 per cent from 2021, still hold record levels of capital at about US$1.1 trillion,[127] and face pressure to return capital to investors. Both investors and lenders alike remain cautious heading into the second half of 2023, in the wake of continued volatility in the financial markets. As economic uncertainty begins to fade and financing becomes available, however, many investors are hopeful for a wave of M&A in the coming months.

X SPECIAL ISSUES FOR CERTAIN PRODUCTS

i Alcohol

As previously discussed, alcohol is regulated by the TTB. In 2020, consumers were unable to sit inside their favourite establishments because of covid-19. In response, legislation moved quickly throughout the country to allow consumers to receive alcohol delivered to their doorstep. Approaches have differed by state. Alabama, for example, enacted a bill in 2021 that allows wineries to ship their goods directly but requires fulfilment houses to obtain licences from the state for each warehouse location that ships to Alabama residents.[128] Kentucky enacted similar legislation but also requires producers to collect three types of taxes from the consumer.[129] Other states, such as Florida, Oklahoma and Texas, opted to implement 'cocktail-to-go' laws, which allow not only for direct delivery but also for bars and restaurants to serve portable alcoholic beverages to patrons.[130] Although these laws are permanent in some states, other states' cocktail-to-go laws have sunset provisions; for example, Vermont currently permits curbside pickup or delivery of alcoholic beverages by licensed establishments only until 1 July 2023.[131] As the United States has emerged from the pandemic, fulfilment houses will want to continue to ship directly to consumers, whereas bars and other establishments will want consumers to come in person to be served. In addition, wholesalers and liquor

126 Food and beverage M&A update: H2 2022, BAKERTILLY, 27 March 2023.

127 Private equity embraces new investment strategies, PWC, 2023.

128 Ala. Code §28-3A-6.1.

129 Ky. Rev. Stat. §243.027 et seq.

130 Fla. SB 148; Okla. Cocktails To Go Act of 2021; Tex. HB 1024.

131 Vt. Act No. 70 (H.313).

stores have been pushing back against permanent cocktail-to-go legislation, citing concerns of losing business to restaurants. Consumers, however, will want as many options available to them as possible.

ii Drugs versus cosmetics debate

Drugs and cosmetics are both regulated by the FDA. The FDCA defines 'drugs' to include articles (other than food) intended to affect the structure or any function of the body of humans or other animals.[132] A 'cosmetic' is defined, in pertinent part, as 'articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance'.[133]

Under MoCRA, cosmetic manufacturers must report serious adverse events (SAERs), which are defined as:

a an adverse event that results in death;
b a life threatening experience;
c inpatient hospitalisation;
d a significant disability or incapacity;
e a congenital anomaly or birth defect;
f an infection; or
g significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual.[134]

In contrast the term 'serious adverse event' in the drug context is less expansive, and means:

a an adverse event that results in death;
b a life threatening experience;
c in patient hospitalisation;
d a persistent or significant disability or incapacity; or
e a congenital anomaly or birth defect.[135]

This definition is slightly different from that requiring SAER reporting for drugs, including OTC drugs. As of this year, both drug manufacturers and cosmetic manufacturers must comply with establishment listing and product listing requirements.[136]

New drugs require FDA approval before commercialising the products, whereas cosmetics do not. The FDA has stated that some products meet the definitions of both 'cosmetics' and 'drugs' and therefore must comply with the requirements for both.[137] A recent class action litigation trend is for plaintiffs to claim that they purchased a cosmetic

132 21 USC § 321(g)(1)(C).
133 id. § 321(i).
134 Pub. L. No. 117-328, § 3502 (Sec. 605(a) Serious Adverse Event Reporting Requirements.) (2022).
135 Pub. L. No. 109-462 § 760(a)(3)(2006).
136 See 21 CFR 207.17 (31 August 2016) (establishment listing); 21 CFR 207.49 (31 August 2016) (product listing); Pub. L. No. 117-328, § 3502 (Sec. 607 Registration and Product Listing).
137 FDA, Is it a Cosmetic, a Drug, or Both? (Or Is It Soap?), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap (last visited 20 July 2022).

but that they now believe that it is a drug that was sold without approval of a new drug application.[138] These plaintiffs sue under their state consumer fraud act, arguing that the product was misbranded.

XI OUTLOOK AND CONCLUSIONS

Regulatory or unofficial developments are expected in respect of new food trends and innovations, such as hemp, cannabidiol and tetrahydrocannabinol (THC), as well as the use of animal cell culture technology for meats and poultry. In addition, the FDA will continue to pursue its New Era of Smarter Food Safety initiative, first launched in April 2019. The blueprint that the FDA released in July 2020 for this initiative offers a vision for the next decade, with a focus on technology, modernisation and food safety culture. The FDA issued the Food Traceability Final Rule in November 2022, which established additional record-keeping requirements for certain foods, including leafy greens, fresh-cut fruits and vegetables, and some types of fish, shell eggs and nut butters, with the goal of standardising the data elements and information that companies establish and maintain, and the information needed to facilitate rapid and accurate traceability.[139]

The requirements of the Food Traceability Final Rule are focused on having persons who manufacture, process, pack or hold covered foods maintain and provide to their supply chain partners specific information for certain critical tracking events in the handling of the food, consistent with the approaches to food tracing. The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities that they perform with respect to a covered food, from harvesting or production of the food through processing, distribution and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording and sharing of traceability lot codes for covered foods, as well as linking these lot codes to other information identifying the foods as they move through the supply chain.[140]

138 See, e.g., *Complaint, Ribak v. Grande Cosmetics, LLC*, Case No. 2:21-cv-07973 (C.D. Cal.) (complaint filed 6 October 2021); *Somers v. Beiersdorf, Inc*, 847 F. App'x 456 (9th Cir. 2021); *Borchenko v. L'Oreal USA, Inc*, 389 F. Supp. 3d 769 (C.D. Cal. 2019).

139 87 Fed. Reg. 70910.

140 id. at 70910-11.

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