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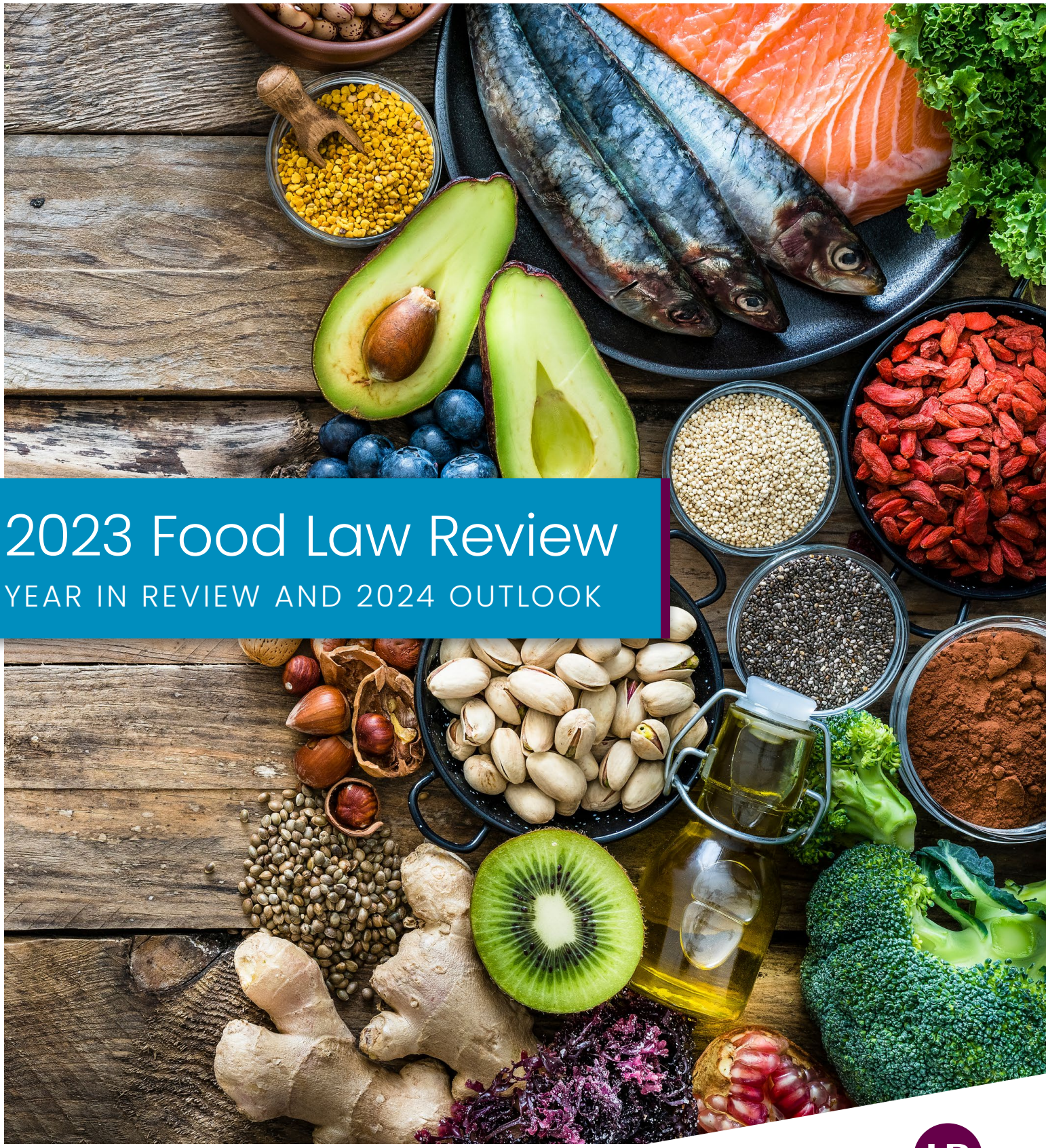

2023 Food Law Review

YEAR IN REVIEW AND 2024 OUTLOOK

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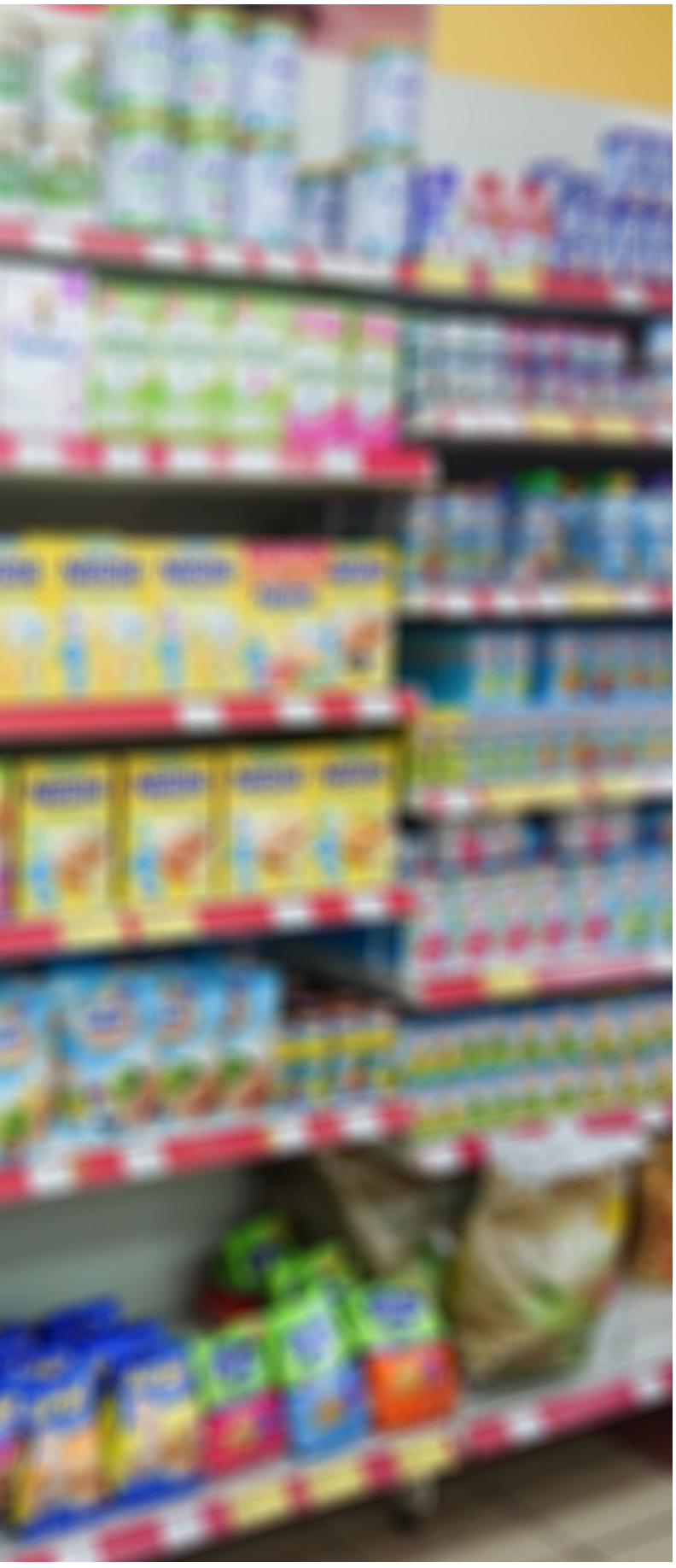


We began 2023 coming out of a food crisis, during which families sometimes drove hours, scoured store shelves, and asked their neighborhood Facebook groups for one simple, but critical staple: infant formula. This shook the nation's feeling of security in our food supply, strained families, and raised broader questions about how our food system is structured and who is responsible when it fails. As we enter 2024, essential staples for our youngest Americans have once again been cast in a harsh spotlight as FDA continues to investigate lead in cinnamon apple sauce pouches. Against this backdrop and new leadership of a restructured FDA Human Foods Program, food laws continued to develop and broaden in 2023, with some states passing laws that indicate waning patience for the perceived slow nature of federal developments.

Industry has continued to assess how to best meet new and broadening requirements, such as traceability (with compliance required by 2026), strengthening National Organic Program regulations, and a continued focus on reducing contaminants in the food supply. With many smaller businesses still grappling with past FSMA rules and implementation (e.g., one third of FDA's inspection observations in FY 2023 pertained to Foreign Supplier Verification Programs, or FSVP), larger stakeholders must also ensure that their suppliers' lack of compliance does not create a ripple effect. As we progress further into 2024, let's review some key highlights from 2023 and some of what we may see in 2024.

TRACEABILITY UPDATES

Since FDA issued the final rule on food traceability (the "**Traceability Rule**") in late 2022, the 2026 compliance date established by the Traceability Rule has continued to creep closer. Though FDA has indicated that it will educate-while-it-regulates, and that it intends to delay routine inspections under the new regulations, industry continues to push forward with preparations as there is no time to spare. To assist industry with preparing for compliance, FDA published multiple resources in 2023 regarding the Traceability Rule and the obligations it creates.

In May 2023, FDA issued a Constituent Update announcing the release of an Institute of Food Technologists ("**IFT**") report commissioned by FDA that evaluates food traceability trends based on submissions provided during FDA's 2021 Low- or No-Cost Tech-Enabled Traceability Challenge.[1] The report reflects FDA's ongoing efforts to evaluate available hardware and software applications and determine how technology may play a role in streamlining industry traceability efforts. [2] Due to innovative improvements in interoperability, support, and infrastructure, IFT determined that end-to-end, tech-enabled traceability could be a reality and that user-friendly and cost-effective applications already exist to assist industry with complying with the requirements of the Traceability Rule. [3]

Also in May 2023, FDA published a Small Entity Compliance Guide summarizing the Traceability Rule's requirements and key compliance details.[4] This resource, which is targeted toward smaller businesses but nevertheless provides helpful overall insight into the Traceability Rule and its requirements, describes how smaller entities like farms and other small businesses can comply with the Traceability Rule, including by summarizing what should be in a firm's traceability plan, what records are required for certain critical tracking events and how to prepare and keep such records, and procedures for seeking waiver or modification of traceability requirements.[5]

In June 2023, FDA published a new set of frequently asked questions regarding the Traceability Rule[6] designed to provide industry with answers to commonly asked questions and links to additional tools that FDA has developed to further educate industry about the Traceability Rule. The list of FAQs answers questions FDA received through its Technical Assistance Network to help clarify for industry how the Traceability Rule will apply to specific real-world situations.[7] FDA also used the list of FAQs as an opportunity to highlight other helpful tools that are available to assist industry with learning about the Traceability Rule, including the following:

- The results for all foods and associated commodity-hazard pairs included in FDA's Risk-Ranking Model for Food Tracing;[8]
- Additional clarification regarding how "nut butters" is defined under the Traceability Rule;[9]
- Video supply chain examples showing how the Traceability Rule will apply in different situations for different types of commodities;[10]
- Fact sheets on recordkeeping information, coverage, and exemptions for produce farms;[11]
- A guide to Getting Started with the Traceability Rule; and
- Foreign language translations of the critical tracking event and key data elements interactive tool and supply chain examples.

In November 2023, FDA released another wave of tools and FAQs, including additional supply chain examples, an example traceability plan, and a webpage with details about traceability lot codes.[12]

In January 2024, the U.S. Government Accountability Office ("**GAO**") released a report encouraging FDA to finalize plans to implement the traceability rule. The report describes FDA's and stakeholders' views on the rule's recordkeeping requirements and examines FDA's implementation of the rule and the challenges that FDA and stakeholders may face in achieving compliance. GAO encouraged FDA to finalize and document an implementation plan that could elaborate on FDA's enforcement strategy, needed resources, and identify additional guidance, training, and tools for stakeholders. GAO noted that stakeholders' concerns include the number of foods covered by the traceability rule, FDA's potential underestimation of compliance costs, and complexity of available exemptions, among others.

FDA has indicated that it is considering issuing Guidance for industry on the Traceability Rule in 2024.

ALLERGEN UPDATES

The inadvertent inclusion or lack of declaration of food allergens remain a leading cause of food recalls. In addition, food allergies continue to threaten the lives of millions of Americans. Allergen-related topics held a significant place on FDA's list of priorities in 2023.

Sesame Became the Ninth Major Food Allergen

On January 1, 2023, Food Allergy Safety, Treatment, Education, and Research Act of 2021 (the "**FASTER Act**") took effect, adding sesame as the ninth major food allergen that manufacturers are required to declare on the labeling of packaged foods under the Food Allergen Labeling and Consumer Protection Act of 2004 ("**FALCPA**").[13] Now, the major food allergens for which label declarations are required include milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybeans, and sesame.[14] Industry adapted quickly, with most companies updating labels as required, but with one significant hurdle: in a production environment, sesame spreads like glitter in the hands of a kindergarten class. That means that if a facility uses sesame in one product, it can be difficult to prevent cross-contact with other food produced in the facility. Many companies that did not abandon sesame began including it as an ingredient in more food products, sparking pushback from consumer groups concerned about the increased use of sesame in packaged foods. This pushed FDA toward the issuance of two significant updates for industry on allergen controls, voluntary precautionary labeling, and cross contact.

Draft Compliance Policy Guide on Major Food Allergen Labeling and Cross-Contact

In May 2023, FDA also released a draft Compliance Policy Guide ("CPG") that will replace the agency's existing CPG on allergen labeling and cross-contact prevention once it is finalized.[15] FDA issued the CPG partly in response to complaints that food producers were adding sesame as an ingredient to products that did not previously contain sesame following the FASTER Act's addition of sesame to the list of major food allergens, instead of controlling for cross-contact. The draft CPG clarifies that this practice is not a favored approach to allergen control

and reiterates food manufacturers' responsibilities regarding allergen labeling and preventive controls for cross-contact.[16]

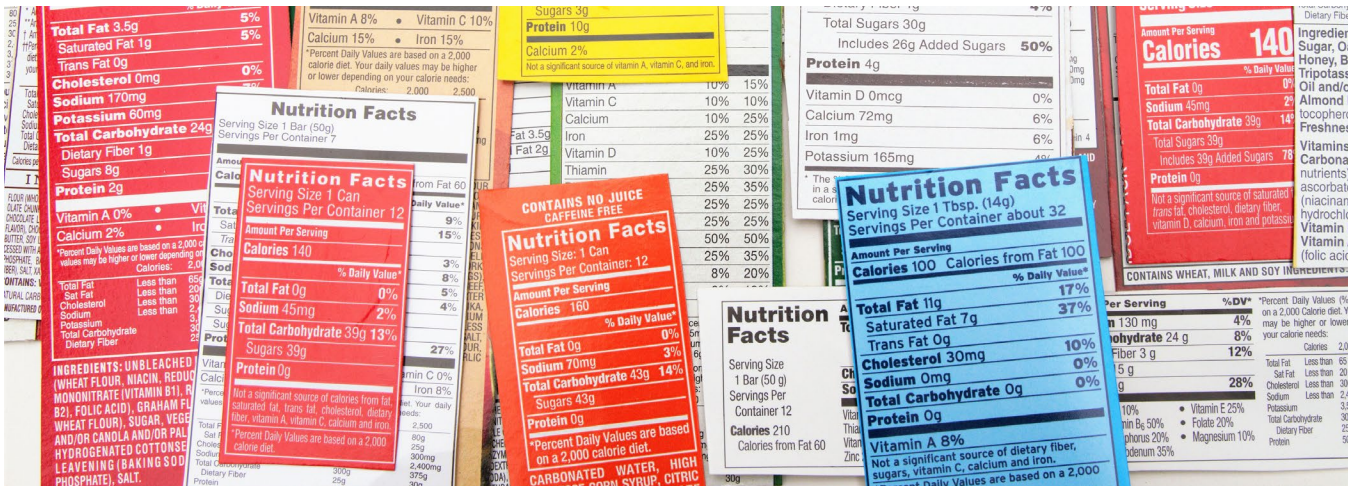
The draft CPG is structured as a guide for FDA staff on how the agency will handle enforcement related to major food allergen labeling and cross-contact. However, although it is structured with agency staff in mind, the CPG is also helpful for industry because it clarifies the agency's thinking on key topics like allergen control, cross-contact, labeling, and enforcement. The CPG also provides helpful information on FDA's existing enforcement priorities with respect to major food allergens and provides additional insight into how the agency views additional actions, like voluntary precautionary allergen labeling, within the context of an organization's allergen controls and procedures.

Specifically, the draft CPG provides helpful takeaways on three major topics:

1. Allergen labeling (including voluntary precautionary labeling);
2. Allergen controls and cross-contact; and
3. FDA's allergen enforcement priorities.

With respect to labeling, the CPG provides examples of specific allergen labeling scenarios along with recommendations regarding FDA's preferences for the use of voluntary precautionary labeling, including a reminder that it cannot supplant the use of proper allergen controls. The CPG also reiterates the importance of facilities having adequate preventive controls in place to prevent adulteration caused by allergen cross-contact and suggests that FDA may take a more pragmatic approach going forward when it comes to responding to suspected allergen violations. The CPG even acknowledges that published data may become available to support the possibility that some low-level exposures to major food allergens may not pose a health hazard to most food allergic consumers, although industry should still be aware that FDA has not established permissible thresholds for any major allergen.[17]

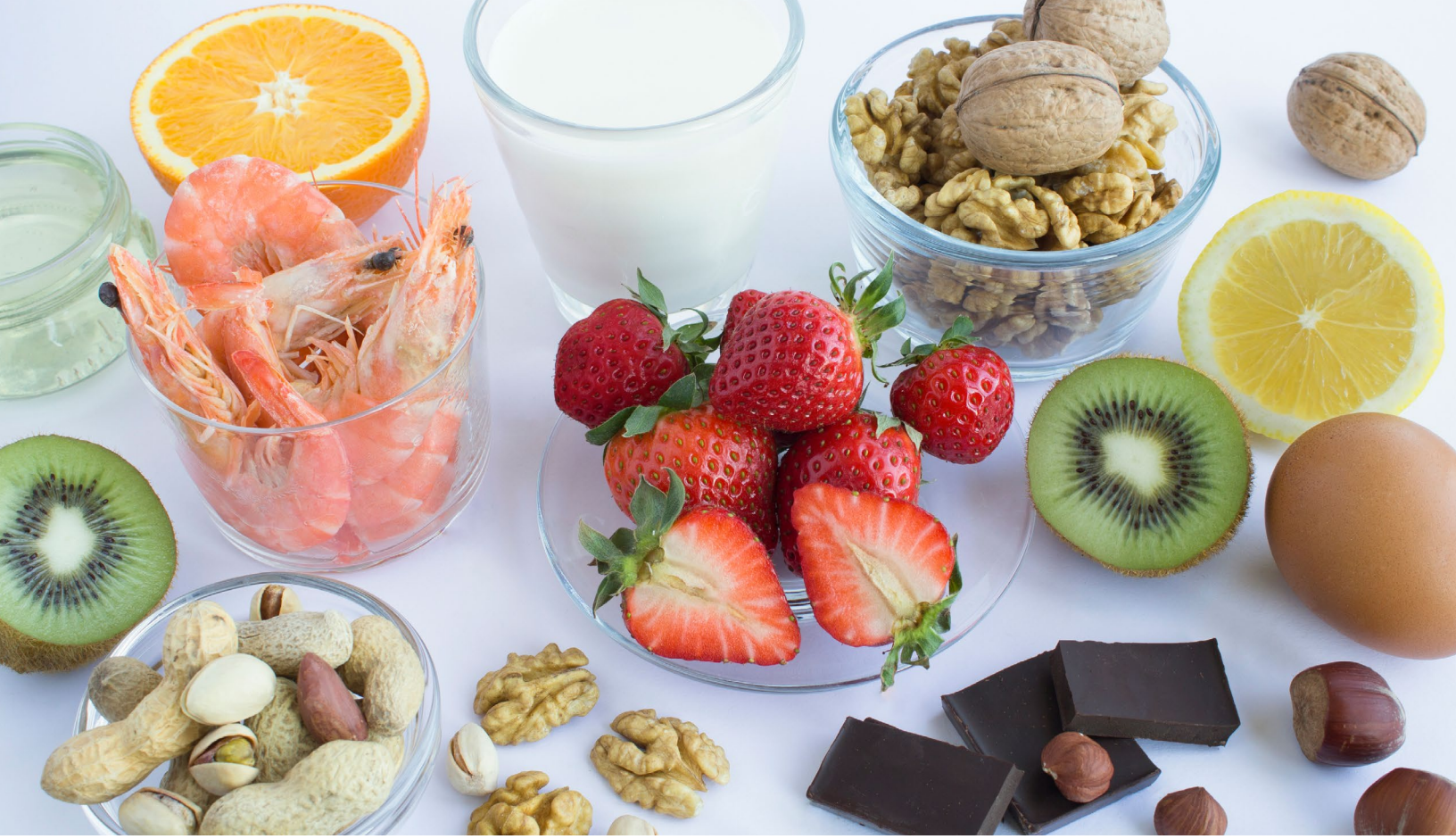
The draft CPG also provides some insight into how FDA instructs its field staff to address observed or suspected allergen violations. If FDA staff believe that an allergen violation presents a reasonable likelihood of serious adverse health consequences or death to humans or animals, and the applicable firm does not choose to initiate a voluntary recall, the FDA instructs its field staff to consider taking other actions to remove the product from commerce (e.g., mandatory recall, administrative detention, or suspending the applicable facility's FDA registration). FDA field staff are also instructed to gather a variety of detailed inspectional evidence when performing an inspection involving suspected allergen violations, including evidence to demonstrate whether a firm lacks appropriate Current Good Manufacturing Practices ("**CGMPs**"), preventive controls, or other controls to significantly minimize or prevent allergen cross-contact in its facility, along with photos of labels and testing to verify label accuracy. Industry can use the draft CPG as a resource to gain an understanding of FDA's expectations with respect to allergen compliance and the potential enforcement actions that FDA staff may be likely to take in the event of allergen-related issues.



New Hazard Analysis and Preventive Controls Guidance on Food Allergen Programs

Following the enactment of the Food Safety Modernization Act ("**FSMA**") and its implementing regulations, FDA has steadily worked to create a detailed Draft Guidance on Hazard Analysis and Risk-Based Preventive Controls for Human Food, one chapter at a time. In September 2023, FDA issued an update to this Draft Guidance containing two new chapters, including a new Chapter 11 addressing Food Allergen Programs ("**Chapter 11**").[18] The new Chapter 11 provides detailed practical recommendations for how food facilities can ensure that the foods they produce are properly labeled with respect to major food allergens and are protected from major food allergen cross-contact.[19] The topics that FDA addresses within the new Chapter 11 include:

- **Current Good Manufacturing Practices**
  Chapter 11 explains how food facilities can utilize their CGMPs as a component of an effective food allergen program by using CGMPs related to personnel, facility design and construction, sanitary operations, equipment and utensils, raw materials and other ingredients, manufacturing operations, and warehousing and distribution to prevent allergen cross-contact and thereby complement their preventive controls for allergen hazards. The new Chapter 11 also includes examples of CGMPs that could be implemented to minimize cross-contact potential.[20]
- **Allergen Cross-Contact Controls**
  Chapter 11 also clarifies how a facility's written allergen cross-contact controls can work in conjunction with its CGMPs to prevent allergen cross-contact. Specifically, FDA provides details on how allergen cleaning procedures and allergen ingredient procedures that are tailored to a facility and its operations can function as effective allergen cross-contact controls to complement the measures the facility takes to comply with the CGMP requirements in 21 C.F.R. part 117, subpart B.[21]
- **Label Controls**
  In addition to discussing controls to minimize or prevent allergen cross-contact, Chapter 11 also emphasizes the importance of implementing label controls to safeguard against misbranding by providing assurance that product labels will correctly name the food source of all ingredients containing major food allergens and that the correct label will be applied to the correct product. Within Chapter 11, FDA describes procedures that food facilities can implement to incorporate label controls into their system of allergen preventive controls, including close review and management of product labels during the different phases of label development, design, storage, and production.[22]
- **Supply-Chain Programs**
  Chapter 11 also emphasizes the importance of a firm's supply-chain program to controlling for allergen-related hazards and provides detailed recommendations explaining how firms should discuss the food allergen profiles of their suppliers' products up front to assess potential hazards that may arise from the supply chain, and establish and implement a supply-chain program to control for food allergen hazards if it is reasonably foreseeable that products provided by a supplier could lead to allergen cross-contact. Chapter 11 also contains a



breakdown of detailed hypothetical scenarios with examples of supplier approval and verification activities that would be appropriate to address a range of allergen risk profiles posed by different suppliers.[23]

- **Allergen Advisory Labeling**
  Chapter 11 also expands upon FDA's past commentary regarding including voluntary allergen disclosures—which FDA refers to as "allergen advisory statements"—on product labels. Importantly, although FDA still emphasizes that firms should not use allergen advisory statements as a replacement for adhering to CGMPs and allergen cross-contact controls, FDA also acknowledges in Chapter 11 that some circumstances exist where there may still be potential for allergen cross-contact even after a firm implements and follows appropriate CGMPs and controls. Chapter 11 clarifies that in such circumstances, a firm can include allergen advisory statements on a product's label to address such concerns as long as the firm's Preventive Controls Qualified Individual ("**PCQI**") provides a written justification in the firm's food safety plan explaining why allergen cross-contact controls cannot ensure total protection from cross-contact. Chapter 11 also provides helpful guidance on how food facilities should approach ingredient suppliers who use allergen advisory labeling to verify that such suppliers are not sidestepping adherence to CGMPs and appropriate allergen controls.[24]

EFFORTS TO REDUCE HEAVY METALS CONTINUE

FDA continues its toxicological research into, and its focus on initiatives to reduce, heavy metals in the food supply, especially in foods intended for babies and young children. 2023 also saw an increase in states taking similar action, whether via legislation or similar initiatives at the state level, to limit childhood exposure to heavy metals in foods. As we start 2024, industry is adapting to the first state baby food testing requirements as industry implements testing protocols to comply with California's A.B. 899. As 2024 continues, we are watching two federal bills – Baby Food Safety Act of 2023 (H.R. 6756) and the Infants Act (H.R. 6770). Notably, the Infants Act, introduced in December 2023, would, as proposed, establish a uniform federal standard for testing infant and toddler food for lead, cadmium, mercury, arsenic, and any other contaminant that may be specified by

regulation. Given that most marketers of such foods already test for toxic elements, and are also adapting to California's A.B. 899, a uniform federal standard may ultimately prove more feasible and to better level the playing field.

Closer to Zero

FDA recognizes that certain contaminants occur naturally in the environment and can be present in foods due to the soil, water, or air where foods are grown, raised, or processed.[25] However, heavy metals (e.g., arsenic, cadmium, lead, and mercury) have been of particular concern for FDA because of their potentially harmful effects on the brain development of children in the womb and throughout early childhood.[26]

This is why FDA created its Closer to Zero initiative, which aims to reduce dietary exposure to such contaminants while maintaining consumers' access to nutritious foods, with a particular focus on foods for babies and young children. In 2023, FDA continued working to advance the Closer to Zero initiative with the goal of reducing children's dietary exposure to heavy metals as much as possible.[27] In January 2023, FDA issued Draft Guidance identifying Action Levels for Lead in Processed Baby Foods.[28] Then, in June 2023, FDA issued Final Guidance on Action Levels for Inorganic Arsenic in Apple Juice.[29] Both Guidance documents reflect FDA's ongoing commitment to reducing childhood exposure to heavy metals, and FDA has indicated that it is aiming to complete its scientific evaluation of arsenic, cadmium, and mercury in foods intended for babies and young children by the end of 2023.[30] The data collected during such evaluation will further assist FDA in establishing other action levels for heavy metals to protect the safety of the food supply for young consumers.[31]

In August 2023, FDA also issued a new Chapter 4 of its Compliance Program Guidance Manual on Toxic Elements in Food and Foodware, which highlights procedures for monitoring foods and food contact materials that can be major dietary sources of toxic elements, like heavy metals, to help FDA collect valuable data and continue to work toward the completion of its Closer to Zero goals.[32] Since heavy metals can be introduced artificially or can potentially come from the environment, FDA plans to continue reviewing toxic element findings in foods and food contact materials on a case-by-case basis.[33]

Voluntary Recalls and Import Alerts

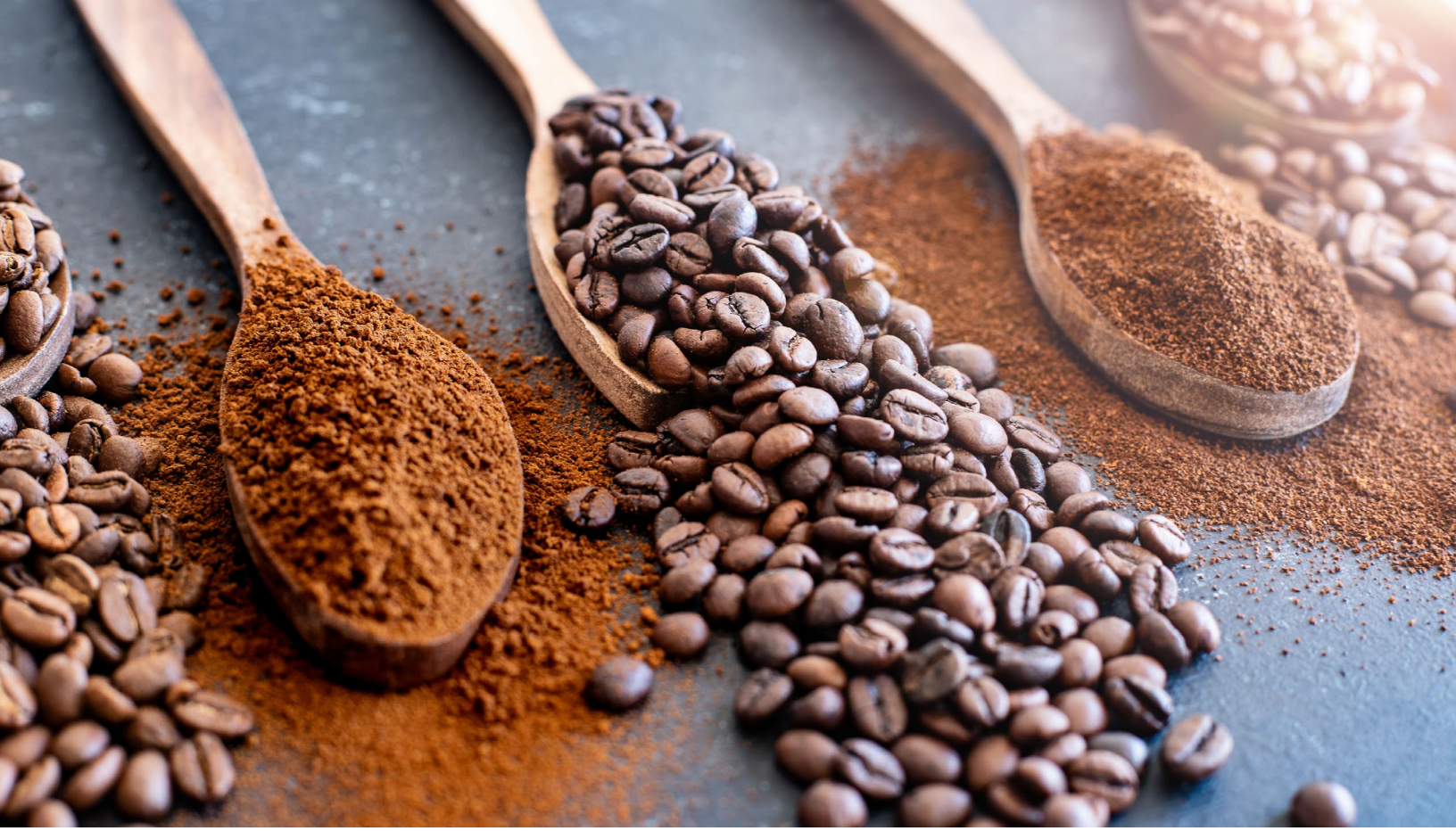
The increased regulatory focus on reducing exposure to heavy metals within the food supply led to several recalls and other enforcement actions in 2023, some of which involved products intended for infants or young children. For example, in October 2023, FDA, working in conjunction with the North Carolina Department of Health and Human Services, advised parents and caregivers against feeding certain Apple Cinnamon Fruit Puree Pouches to toddlers and young children due to elevated levels of lead in the product that were more than 200 times greater than the action level. The manufacturer announced a voluntary recall of the Fruit Puree Pouches on October 29, 2023, and later expanded the recall to include additional private label applesauce products.[34] FDA learned the cinnamon was contaminated with lead.[35] In 2023, FDA continued to add food products from different countries to Import Alert 99-42 for detention without physical examination due to the potential for heavy metal contamination.[36]

Warning Letters

FDA is also concerned when companies' preventive controls do not account for heavy metals and this deficiency may result in an observation following FDA's review and may escalate to a warning letter under some circumstances. For example, on March 16, 2023, FDA issued a warning letter to Sol-ti Inc. in which the agency asserted that the company's ready-to-drink juice products and juice ingredients were adulterated, in part, because the company's hazard analysis and critical control point plan allegedly did not identify food hazards, including heavy metals, that FDA determined were reasonably likely to occur.[37]

State Laws

In addition to FDA's efforts to curb risks of consumer exposure to heavy metals in the food supply, several states also took legislative action in 2023 to address heavy metal concerns, the most notable of those being California. Our analysis of California's A.B. 899 is available here.



CLASS ACTION TRENDS

Class action litigation remains a concern for the food industry. In 2023, many courts seemed "over it" and granted defendants' motions to dismiss. Still, given the investment needed to win a motion to dismiss, for many marketers, preventing the demand letter, and if not the demand letter, the filing, is the best solution.

In November 2023, the Northern District of New York hopefully caught the attention of plaintiff's attorneys when it targeted one of Spencer Sheehan's class actions.[38] Spencer Sheehan had assisted his client in filing a putative class action against a coffee company alleging that the company's ground coffee product was not actually 100% ground coffee as advertised.[39] In the class action complaint, the consumer argued that the coffee company charged a premium price for its French Roast Ground 100% Arabica Coffee, but that the coffee contained additives and added potassium, meaning coffee could not possibly comprise 100% of its ingredients.[40]

The court found that the plaintiff's references to evidence in the form of "recent reports of laboratory analysis" were too vague.[41] The court also noted that Sheehan had previously filed no fewer than 18 class action lawsuits in the Northern District of New York since 2021, all of which were dismissed, often before the defendant could even file an answer.[42] As many reading this summary will readily recognize, the class actions noted by the court are a small fraction of Sheehan's filings over the past several years. In this district, Sheehan had filed class action lawsuits against many other food manufacturers, including the makers of Pop-Tarts, Hint of Lime Tostitos, Snapple "all natural" fruit drinks, Keebler's fudge-mint cookies, Cheesecake Factory brown bread, and Trident original-flavor gum. The court opined that Sheehan's filing was devoid of plausible pleadings and was not backed up by sufficient evidence in the form of studies, relevant caselaw, or any reasonable interpretations of the wording on a food product label.[43]

While it does seem that the tide is finally turning a bit on the lawyers who endlessly sue food companies, there are still some helpful takeaways to reduce the chance of a demand letter or class action filing:

- **Limit, or better, avoid, health halos.** With a continued focus on nutrition initiatives including reducing sodium and added sugars consumption, as well as finalizing updated standards for "healthy" nutrient content claims,

it is likely we will see more developments on the FDA's nutrition initiatives in 2024. In the meantime, class action lawsuits continue to target labeling and advertising that is perceived as adding a "health halo" to a product that may have one or more less-healthy features. Marketers should be mindful of the overall net impression of labels and advertising and should keep a watchful eye on claims made about products that have significant added sugar, saturated fat, or sodium, all of which are a concern for FDA.

- **Consider "dual function" ingredients carefully.** Often, food marketers label their products with claims such as "no preservatives," or "no artificial flavors," and do so with pure intent. However, some ingredients, like citric acid, can have more than one function, which can lead to an allegation that a label claim is untrue. For example, in April 2023, parties agreed to settle a class action lawsuit in which plaintiffs alleged that a marketer falsely advertised its drinks as containing "No Preservatives," when the products allegedly contained citric acid.[44] Under the settlement agreement, the marketer agreed to a payout of $7.9 million.[45]
- **Consider origin claims carefully.** In October 2023, the Central District Court of California dismissed a class action against a marketer allegedly misrepresenting its Texas Pete® brand of hot sauce products as "Texas" products.[46] The plaintiff alleged that the company's representations constituted fraud because, although the labeling and advertising for Texas Pete® products contained references to Texas, the products were allegedly made in North Carolina and were not made with "Texas" ingredients.[47] The parties may have settled because the plaintiff later requested voluntary dismissal of the case without a decision from the court on the merits.[48]
- **Verify preparation instructions carefully.** We continue to see creative attempts to attack the preparation instructions on packaged foods, such as the number of servings that ground coffee will yield. Therefore, it is helpful to verify all preparation instructions and keep substantiation. In July 2023, the Southern District of Florida dismissed a class action against a food company[49] in which the plaintiff alleged that microwaveable, single-serving macaroni and cheese products took longer to prepare than what was represented on the product packaging.[50] Specifically, the plaintiff argued that a "READY IN 3½ MINUTES" claim on the package was false and misleading because the three and one-half minutes of cooking time made up only one of several steps needed to prepare the product for consumption.[51] Although the plaintiff claimed that the false and misleading marketing allowed the marketer to sell the product at a premium price that was higher than other comparable products that were not so advertised, the court did not agree and concluded that the plaintiff failed to demonstrate that she was injured by the marketing.[52]
- **Carefully vet and substantiate "green claims" during labeling and advertising reviews.** More on this below.

TOUT "GREEN" BENEFITS CAREFULLY

In line with plaintiffs' general willingness to challenge claims made in food advertising and labeling, allegations of "greenwashing" products' labeling and advertising continue. At the same time, industry is still awaiting planned updates to the Federal Trade Commission's ("FTC's") Green Guides. In early 2023, the FTC requested public comments for consideration in its ongoing efforts to update the Green Guides. FTC's solicitation ranged from seeking general suggestions and feedback on the Green Guides to requesting feedback on specific claims such as "carbon neutral," "compostable," "degradable," "ozone-safe," "recyclable," "recycled content," "energy efficient," "organic," "sustainable," and similar variations. The comment period ended on April 24, 2023, and the FTC has not yet issued any subsequent updates to the Green Guides.[53] In the meantime, plaintiffs have continued to target "green" claims in litigation, including so-called allegations of "greenwashing" by food companies that target claims made about food packaging materials or manufacturing practices.

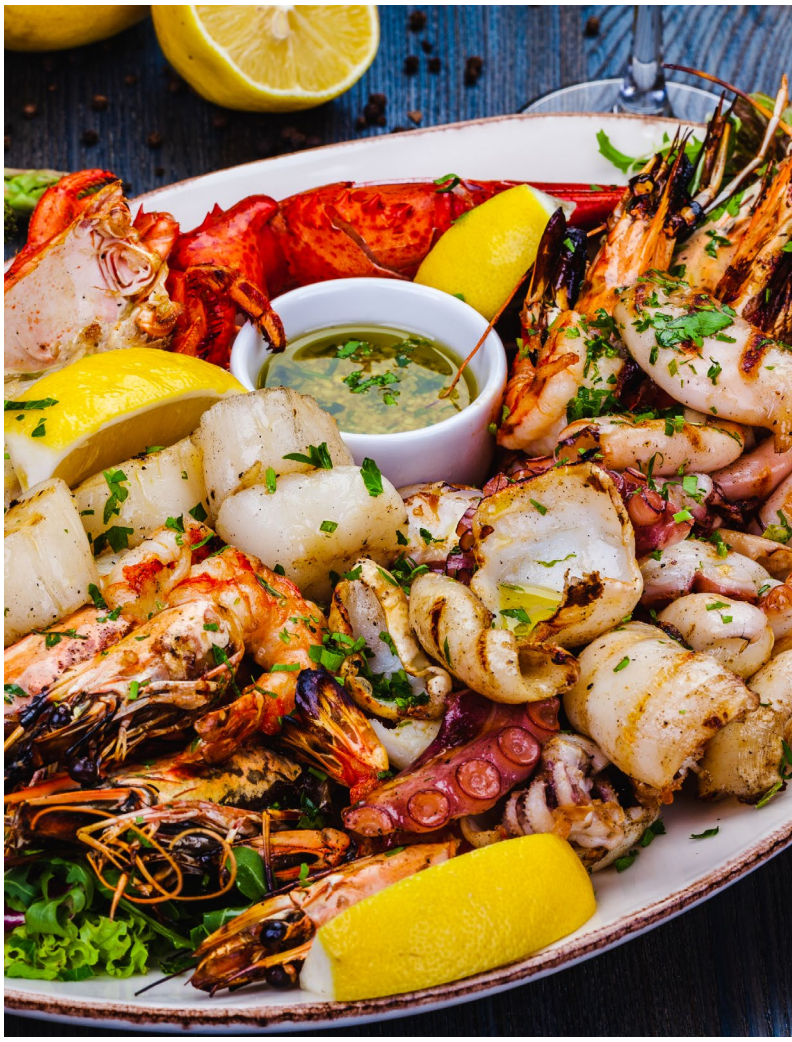
Challenges Targeting Alleged Unsustainable Fishing Practices

Food marketers faced litigation in 2023 for marketing seafood products as sustainable while using allegedly unsustainable fishing practices. For example, plaintiffs alleged in a class action lawsuit that products labeled as "certified sustainable seafood" with a certification mark from the Marine Stewardship Council ("**MSC**") misled reasonable consumers because the marketer "sources its products using fishing practices that indiscriminately harm ocean ecosystems." Additionally, plaintiffs attacked the MSC certification by alleging that many MSC certified fisheries engage in numerous practices that harm ocean ecosystems, and that MSC "also allows its members to obtain their certification with a paid membership, creating a potential conflict of interest." Plaintiffs demanded nearly $10 million in the suit, which is still ongoing.[54] Plaintiffs also filed nearly identical class action suits against another seafood company and a major retailer within the same month.[55] The seafood company settled its lawsuit just two weeks after the complaint was filed, and as of the date of this writing, the other actions remain pending.

Challenges Targeting PFAS and Sustainability Claims

Plaintiffs are more frequently alleging that "sustainability" claims are misleading if used on products allegedly containing per- and polyfluoroalkyl substances ("**PFAS**"). For example, plaintiffs sued a sports nutrition company in January 2023 for making claims such as "eco-friendly" and "good for you and the environment" on its sports drink packaging when third-party testing allegedly revealed the presence of PFAS in the products.[56]

General sustainability claims have also been a popular target in 2023. One beverage company has been involved in litigation over claims that the company supports "Earth-friendly growing practices and social responsibility standards" and that "each of [its] coffee suppliers is a 'family-owned farm'."[57] The plaintiffs have alleged that such claims are inaccurate because not all of the company's suppliers are family-owned farms and the company's "products, growers, and goods are causing severe harm to the planet, the environment and ecosystems.[58]



Track and Benchmark Aspirational Claims

Food marketers and others have, over the past several years, turned to aspirational claims to talk about efforts to reduce environmental impacts and pursue longer-term goals. Industry is likely to see additional standards for aspirational claims, and in the meantime, should be mindful that such claims cannot be merely illusory and that the marketer must be taking steps toward (and recording progress toward) their goals. In 2023, the National Advertising Division ("**NAD**") reviewed sustainability claims made by "the second-largest food company and the largest animal protein producer in the world," and ultimately recommended that the company discontinue its "'Net Zero' Emissions by 2040 Claims" because it lacked adequate evidence of steps taken to achieve such goal.[59] NAD clarified that when aspirational sustainability claims are tied to empirical metrics, companies must be able to substantiate those

claims, and it found that the advertiser had failed to adequately substantiate its aspirational claims, which included the general net-zero emissions claims as well as sustainability claims tied explicitly to the company's bacon, chicken wing, and steak production.

RETAIL AND RESTAURANT UPDATES

Updated Food Code

On January 18, 2023, FDA issued the most recent version of the Food Code, which provides a model for state, local, tribal, and territorial government agencies for regulating retail food establishments ("**RFEs**") and restaurants. On February 14, 2023, FDA also published a Constituent Update describing how the recently released 2022 Food Code helps to reduce barriers to food donation by allowing, for the first time, food donations from RFEs if proper food safety practices are followed.[60] This addition to the Food Code is part of the Biden-Harris Administration's National Strategy on Hunger, Nutrition, and Health, which provides a roadmap of actions the federal government will take to help reduce hunger, diet-related diseases, and disparities that affect our nation's food supply.

The Traceability Rule's Impact on Restaurants and Retailers

Restaurants and retailers are less accustomed to answering to FDA's expansive FSMA regulations and their business models and volume make some facets of FDA's traceability rule untenable. As the debate continues, restaurants and retailers must continue to take steps toward meeting the 2026 compliance date.

In January 2023, FDA released a fact sheet summarizing information that RFEs and restaurants need to know about the Traceability Rule, to assist these types of entities with understanding their potential traceability obligations. Under the Traceability Rule, an RFE is defined as an establishment that sells food products directly to consumers as its primary function, and a restaurant is a facility that prepares and sells food directly to consumers for immediate consumption.[61] The fact sheet provided by FDA clarifies a number of key points regarding how the Traceability Rule applies—or does not apply—to restaurants and RFEs by explaining the various exemptions that may affect these types of businesses.[62] However, the exemptions do little, if anything, to mitigate the traceability rule's impact on large restaurant chains and retailers.

Reduction of the Risk of Foodborne Illness in Restaurants

According to the Centers for Disease Control and Prevention ("CDC"), more than half of all foodborne illness outbreaks that occur each year are associated with food from restaurants.[63] To address such risks, FDA released a Technical Report on June 20, 2023 containing compiled surveillance data collected by the CDC from 2017 to 2018 on the major risk factors that contribute to foodborne illness in fast-food and full-service restaurants.[64] The Technical Report identifies issues like poor personal hygiene; improper food holding, including with respect to time and temperature; use of contaminated equipment and a lack of protection from contamination; inadequate cooking; and unsafe food sourcing as key contributors to potential foodborne illness outbreaks.[65] The Technical Report provides a helpful tool that industry can use to develop retail food safety initiatives, policies, and strategies to address the risk factors that are responsible for a large portion of the foodborne illness outbreaks that occur in the U.S. each year.

Class Actions Targeting Major Food Chains

Restaurant chains and retailers do not have to fear being left out of the class action frenzy. Class action targeting major restaurant chains continued to make news in 2023. Notably, plaintiffs focused on the perceived differences between the restaurant chains' advertised products and the products received.

In August 2023, the Southern District of Florida issued an order granting in part and denying in part a motion to dismiss a class action against a burger chain in which plaintiffs alleged that the advertiser "materially overstate[d]" the size and amount of beef in its burgers and sandwiches.[66] The plaintiffs testified that they bought the products based on representations made in advertisements and ordering boards, but were disappointed to find that the burgers and sandwiches had much less meat than advertised.[67] In response, the advertiser argued that it was industry practice for food to be styled in advertisements to look as appetizing as

possible and that reasonable consumers viewing the advertisements knew about such practices.[68] In addition, the amount of beef in each burger was clearly stated in pounds in the advertisements, along with an asterisked disclaimer explaining that the "[w]eight [was] based on a pre-cooked patty."[69]

The court granted in part and denied in part the defendant's motion to dismiss.[70]

In September 2023, the Eastern District of New York dismissed a similar class action against two other restaurant chains, in which the plaintiff alleged that the restaurant chains' products looked more appealing on menus and in television commercials than they did when they were actually served to customers.[71] As evidence of the alleged deception, the plaintiff presented complaints from several social media influencers and "food reviewers."[72] The court determined that the plaintiff could not prove that he was injured or that a reasonable consumer would have been misled by the advertisements.[73] Though the court conceded that the size of the burgers was an objective fact, and not puffery, the court held that the plaintiff's failure to allege that the companies used more meat in the advertisements than what was served was fatal to the claims.[74] Therefore, the court dismissed the class action and denied the plaintiff an opportunity to amend the complaint.[75]

LOOKING AHEAD IN 2024

2023 welcomed several new developments within the food industry and also reinforced some of the existing risk areas, such as class action litigation and allergen cross-contamination. FDA also issued Guidance documents on several food-focused topics that it planned to prioritize in 2023, including a draft CPG on Major Food Allergen Labeling and Cross Contact;[76] a new Chapter 11 on Food Allergen Programs and Chapter 16 on Acidified Foods within its Draft Guidance on Hazard Analysis and Risk-Based Preventive Controls for Human Food (the "**PC Guidance**");[77] Final Guidance on Standards for Growing, Harvesting, Packing, and Holding Sprouts for Human Consumption;[78] Draft Guidance on Protein Efficiency Ratio (PER) Rat Bioassay Studies to Demonstrate that a New Infant Formula Supports the Quality Factor of Sufficient Biological Quality of Protein;[79] and Final Guidance on the Action Level for Inorganic Arsenic in Apple Juice.[80]

However, the Guidance documents described above represent only a portion of the Guidance documents that FDA planned to prioritize and share in 2023. Other Guidance documents that the agency hoped to issue, but ultimately did not publish, in 2023 included updates to Guidance regarding allergen labeling and evaluating allergens other than major food allergens, an updated Compliance Policy Guide on *Listeria monocytogenes*, and other updates to the PC Guidance.

As we proceed into 2024, FDA has indicated its intent to consider 23 Guidance documents. We are watching, among other topics, whether FDA issues an up-to-date Compliance Policy Guide regarding *Listeria monocytogenes*, additional action levels for heavy metals in foods intended for babies and young children, and an additional chapter to the PC Guidance regarding Preventive Controls for Chemical Hazards.

[1] *See* U.S. Food and Drug Admin., Constituent Update: IFT Recommends Collaboration and Innovation to Advance Food Traceability (May 17, 2023).
[2] *Id.*
[3] *See* U.S. Food and Drug Admin., Constituent Update: IFT Recommends Collaboration and Innovation to Advance Food Traceability (May 17, 2023).
[4] *See* U.S. Food and Drug Admin., Constituent Update: Small Entity Compliance Guide for the Food Safety Modernization Act (FSMA) Food Traceability Rule (May 18, 2023).
[5] *Id.*; *see also* U.S. Food and Drug Admin., Guidance for Industry: Small Entity Compliance Guide: Requirements for Additional Traceability Records for Certain Foods: What You Need to Know About the FDA Regulation, 88 Fed. Reg. 32104 (May 2023).
[6] *See* U.S. Food and Drug Admin., Constituent Update: FDA Publishes New FAQs and Additional Tools for the Food Traceability Rule, (June 26, 2023); U.S. Food and Drug Admin., Frequently Asked Questions: FSMA Food Traceability Rule (Nov. 20, 2023).
[7] U.S. Food and Drug Admin., Frequently Asked Questions: FSMA Food Traceability Rule (Nov. 20, 2023).
[8] *Id.* at TFTL.1, TRRM.1–2.
[9] *Id.* at TFTL.14–19.
[10] *Id.*; *see e.g.,* U.S. Food and Drug Admin., How the Food Traceability Rule Works: Cheese Supply Chain Example, YOUTUBE (Nov. 15, 2022); U.S. Food and Drug Admin., How the Food Traceability Rule Works: Produce Supply Chain Example, YOUTUBE (Nov. 15, 2022); U.S. Food and Drug Admin., How the Food Traceability Rule Works: Seafood Supply Chain Example, YOUTUBE (Nov. 15, 2022).
[11] *See* U.S. Food and Drug Admin., What You Need to Know About the Food Traceability Rule: Recordkeeping Information for Produce Farms (June 2023)*; see also* U.S. Food and Drug Admin., What You Need to Know About the Food Traceability Rule: Coverage and Exemptions for Produce Farms (June 2023).
[12] *See* U.S. Food and Drug Admin., Frequently Asked Questions: FSMA Food Traceability Rule (Nov. 20, 2023).
[13] Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act of 2021), Pub. L. No. 117-11, § 2, 135 Stat. 262 (2021).
[14] *See id*.; *see also* 21 U.S.C. § 321(qq)(1).
[15] *See* U.S. Food and Drug Admin., Constituent Update: FDA Releases Draft Compliance Policy Guide on Major Food Allergen Labeling and Cross-Contact (May 16, 2023).
[16] *See* U.S. Food and Drug Admin.*,* Sec. 555.250 Major Food Allergen Labeling and Cross-contact Draft Compliance Policy Guide Guidance for FDA Staff (May 2023) (downloaded Dec. 6, 2023).
[17] *Id*. at 6–9.
[18] *See* U.S. Food and Drug Admin., Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (Sept. 2023), at chapter 11 (hereinafter, "*Draft Chapter 11 Guidance*").
[19] *See* U.S. Food and Drug Admin., FDA News Release: FDA Draft Guidance Could Result in Safer Food Options for People with Allergies to Sesame, Other Food Allergens (Sept. 26, 2023).
[20] *See Draft Chapter 11 Guidance*, at 14–15, 54.
[21] *See Draft Chapter 11 Guidance*, at 20–26.
[22] *See Draft Chapter 11 Guidance*, at 26–35.
[23] *See Draft Chapter 11 Guidance*, at 36–50.
[24] *See Draft Chapter 11 Guidance*, at 50–53.
[25] *See* 21 C.F.R. Part 109*;* U.S. Food and Drug Admin., Environmental Contaminants in Food (Jan. 24, 2023).
[26] *See* U.S. Food and Drug Admin., Environmental Contaminants in Food (Jan. 24, 2023).
[27] *See* U.S. Food and Drug Admin., Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods (Aug. 10, 2023).
[28] *Id*. at "Planned Action Items" (Aug. 10, 2023); *see also* U.S. Food and Drug Admin., Draft Guidance for Industry: Action Levels for Lead in Foods Intended for Babies and Young Children (Jan. 2023).
[29] *See* U.S. Food and Drug Admin., Guidance for Industry: Action Level for Inorganic Arsenic in Apple Juice (June 2023).
[30] *See* U.S. Food and Drug Admin., Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods, at "Planned Action Items" (Aug. 10, 2023).
[31] *Id.*
[32] *See* U.S. Food and Drug Admin., Compliance Program Guidance Manual 7304.019: Toxic Elements in Food and Foodware, and Radionuclides in Food – Import and Domestic, at 5 (Aug. 8, 2023).
[33] *Id.*
[34] *See* U.S. Food and Drug Admin., Company Announcement: WanaBana Issues Voluntary Recall of WanaBana Apple Cinnamon Fruit Purée Pouches Due to Elevated Lead Levels (Oct. 29, 2023); *see also* U.S. Food and Drug Admin., WanaBana Recalls WanaBana, Weis, and Schnucks Apple Cinnamon Fruit Purée Pouches & Cinnamon Apple Sauce Due to Elevated Lead Levels (Nov. 9, 2023).
[35] *See* U.S. Food and Drug Admin., Investigation of Elevated Lead Levels: Cinnamon Applesauce Pouches (Nov. 2023).
[36] *See* U.S. Food and Drug Admin., Import Alert 99-42, at Ecuador ustrofood Cia LDA (Nov. 11, 2023).

[37] *See* U.S. Food and Drug Admin., Warning Letter to Sol-ti Inc. (Mar. 16, 2023).
[38] *Brownell v. Starbucks Coffee Co*., No. 5:22-CV-1199 (FJS/ATB) (N.D.N.Y. Nov. 30, 2023) (mem. op.).
[39] *Id*. at 2023 WL 4489494, at 1 (N.D.N.Y. July 12, 2023).
[40] *Id*. at No. 5:22-CV-1199 (FJS/ATB) (N.D.N.Y. Nov. 30, 2023) (mem. op.).
[41] *Id*.
[42] *Id*.
[43] *Id*.
[44] *See* Settlement Agreement, *Hezi v. Celsius Holdings, Inc.*, No. 1:21-CV-09892-JHR, 2023 WL 2786820 (S.D.N.Y. April 5, 2023); Class Action Complaint, *Hezi v. Celsius Holdings, Inc*, No. 1:21-CV-09892 (S.D.N.Y filed Nov. 23, 2021).
[45] *See* Martina Barash, *Drink Maker Celsius Agrees to $7.9 Million Deal with Investors*, BLOOMBERG (Aug. 4, 2023).
[46] *See* Class Action Complaint, *White v. T.W. Garner Food Co*., No. 2:22-CV-06503 (C.D. Cal. Sept. 12, 2022).
[47] *Id.*
[48] *White v. T.W. Garner Food Co*., No. 2:22-CV-06503 (C.D. Cal. Sept. 12, 2022).
[49] *Ramirez v. Kraft Heinz Foods Co.*, No. 22-CV-23782-BLOOM/Otazo-Reyes, 2023 WL 4788012, at 6 (S.D. Fla. July 27, 2023).
[50] *Id*. at 1.
[51] *Id*. at 1.
[52] *Id*. at 4.
[53] U.S. Fed. Trade Comm'n, Guides for the Use of Environmental Marketing Claims, A Proposed Rule, 87 FR 77766 (Dec. 20, 2022).
[54] *Bohen et al. v. ConAgra Brands Inc*., 23-cv-1298 (N.D. Ill. March 2023).
[55] *Nasser et al. v. Bumble Bee Foods, LLC*., 23-cv-1558 (C.D. Cal. March 2023); *Sanchez et al. v. Walmart Inc*., 23-cv-1297 (N.D. Ill. March 2023).
[56] *Bedson et al. v. BioSteel Sports Nutrition Inc*., 23-cv-620 (E.D.N.Y. Jan. 2023).
[57] *Fisher et al. v. International Coffee & Tea, LLC*., 23-cv-1816/3:23-cv-1816-L-DDL. (S.D. Cal. Aug. 2023).
[58] *Id*. at p.2 of Complaint.
[59] *See JBS Appeals National Advertising Division Recommendation to Discontinue 'Net Zero' Emissions by 2040 Claims*, BBB NATIONAL PROGRAMS NEWSROOM (Feb. 15, 2023).
[60] *See* U.S. Food and Drug Admin., New FDA Food Code Reduces Barriers to Food Donations (Feb. 14, 2023).
[61] 21 C.F.R. § 1.227.
[62] *See* U.S. Food and Drug Admin., Retail Food Establishments (RFEs) and Restaurants: What You Need to Know About the Food Traceability Rule (Jan. 2023).
[63] *See* U.S. Food and Drug Admin., FDA Releases 2017–2018 Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-Service Restaurants (June 20, 2023).
[64] *See* U.S. Food and Drug Admin., Technical Report: FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast-Food and Full-Service Restaurants (2017–2018) (June 2023).
[65] *Id*.
[66] *Coleman, et al. v. Burger King Corp.*, No. 22-CV-20925-ALTMAN/Reid, 2023 WL 5507730, at 1 (S.D. Fla. Aug. 25, 2023).
[67] *Id*.
[68] *Id*.
[69] *Id*.
[70] *Id*. at 8–11.
[71] *Chimienti v. Wendy's International, LLC and McDonald's Corp.*, No. 22-CV-02880 (HG), 2023 WL 6385346, at 1 (E.D.N.Y. Sept. 30, 2023).
[72] *Id*.
[73] *Id*. at 3.
[74] *Id*. at 4.
[75] *Id*. at 9.
[76] *See* U.S. Food and Drug Admin., Sec. 555.250 Major Food Allergen Labeling and Cross-contact Draft Compliance Policy Guide (May 16, 2023).
[77] *See* U.S. Food and Drug Admin., Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (Sept. 2023).
[78] *See* U.S. Food and Drug Admin., Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Sprouts for Human Consumption (Sept. 28, 2023).
[79] *See* U.S. Food and Drug Admin., Draft Guidance for Industry: Protein Efficiency Ratio Rat Bioassay Studies To Demonstrate That a New Infant Formula Supports the Quality Factor of Sufficient Biological Quality of Protein (Feb. 9, 2023).
[80] *See* U.S. Food and Drug Admin., Action Level for Inorganic Arse in Apple Juice: Guidance for Industry (June 1, 2023).

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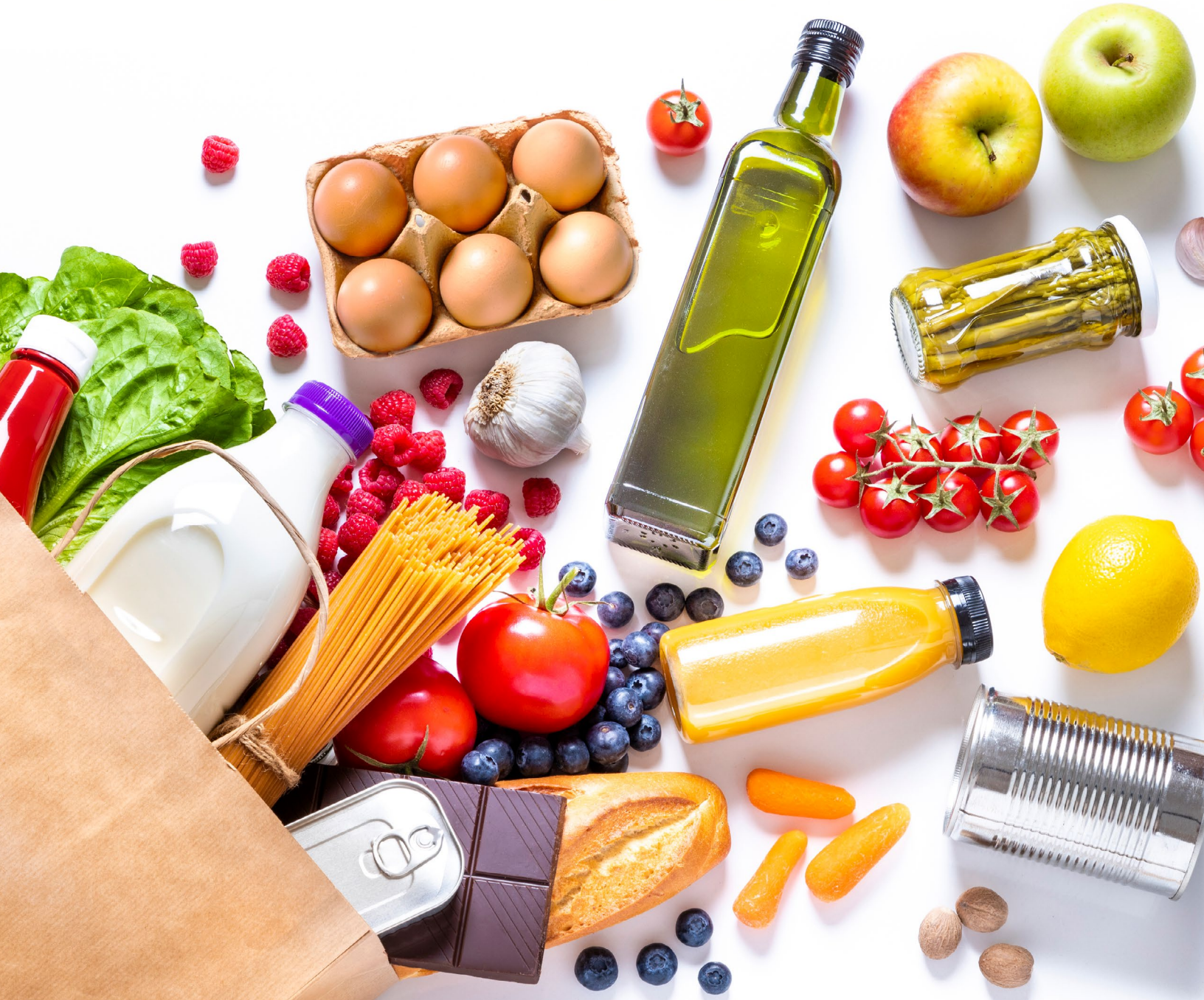

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