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Food Law Preview

Key issues affecting the food industry in 2024

2024 is poised to be a big year for food regulation, particularly as federal agencies work to implement their regulatory agendas in preparation for a possible change in administration after the 2024 election. Here are the key issues the Hogan Lovells food and beverage team is keeping our eye on for the food industry this year.

1. FDA Setting Nutritional Guardrails for Foods on Multiple Fronts

In 2024, the Food and Drug Administration (FDA) plans to issue a proposed rule requiring – for the first time – front-of-package nutrition labeling to signal which foods are "high in" certain nutrients of concern. The agency is also expected to issue a final rule that will make substantial updates to the nutrition requirements for foods bearing a "healthy" nutrient content claim. These actions, particularly front-of-package nutrition labeling, raise significant legal questions as to FDA's authority under the Federal Food, Drug, and Cosmetic Act, as well as First Amendment issues. The agency also intends to advance voluntary initiatives to encourage industry to reduce sodium and added sugars content in foods. The Dietary Guidelines Advisory Committee, which is expected to issue its scientific report in 2024, may address "ultra-processed" foods and the role these foods play in the diet. All of these developments will impact food companies looking to make "better for you" products, and consumers looking to identify these foods, and we can expect plaintiff's attorneys looking to leverage them to their benefit.

2. State Laws Run Amok

In the past few years there has been a proliferation of activity at the state level affecting food companies, including restrictions on per- and poly- fluorinated substances (PFAS) in packaging, bans on particular ingredients in foods that are authorized at the federal level, heavy metal testing & disclosure requirements, and a spate of new environmental and animal welfare laws. These include laws on farm animal confinement, extended producer responsibility (EPR), minimum post-consumer recycled content requirements, restrictions on recyclable and compostable claims, climate reporting obligations, and more.

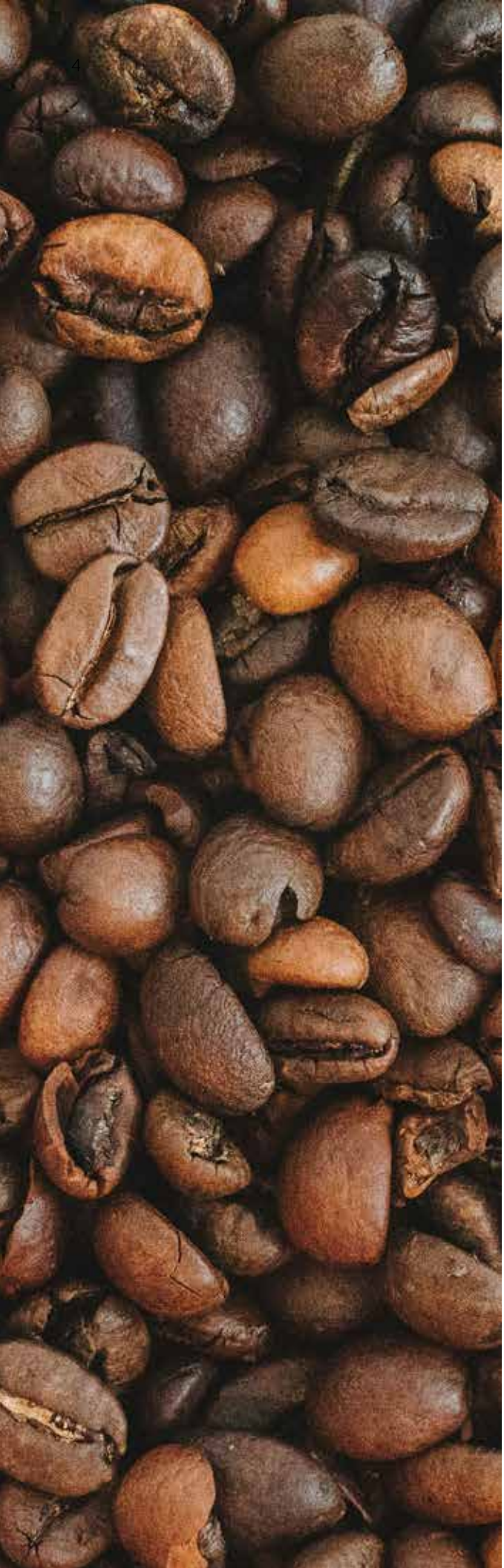
California's EPR law and new restrictions on "recyclable" claims, in particular, are poised to significantly disrupt food packaging. Starting in 2025, California's SB343 will impose a high bar for recyclable claims that differs from the federal standard under the Federal Trade Commission's Green Guides. The law also prohibits use of the three-chasing-arrows symbol on packaging that doesn't meet the new California recyclability criteria. In addition, California's SB54 establishes the nation's most substantive extended producer responsibility (EPR) regime, including targets for compostable and recyclable packing of consumer products. The state has taken initial steps to implement these laws, including issuing a preliminary report assessing the recyclability of various packaging materials, and selecting a producer responsibility organization, the Circular Action Alliance, which producers must join by 2027. Draft regulations were released in January 2024 and are expected to be formally proposed and finalized in 2024. As the California EPR law gets off the ground, producers will eventually need to take steps to use recyclable or compostable packaging, and to reduce the amount of packaging used.

The emerging patchwork of state laws raises important questions about the scope and limits of federal preemption, the appropriate role of states in regulating food ingredients and packaging, and the continued viability of a single national marketplace for all nodes of the food supply chain.

3. Post-market Food Chemicals Surveillance: Can FDA Reassert Leadership and Stem the Rising Tide of State Action?

Debate about the adequacy of FDA's post-market oversight program for chemicals used in foods and food contact materials is not new. However, California's enactment of AB 418 (the Food Safety Act), the passage of numerous state prohibitions on the use of PFAS in food packaging, and differing conclusions from international food safety regulators about the safety of certain additives (e.g. titanium dioxide) have substantially increased stakeholders' focus on the issue. Sensitive to these concerns, FDA took steps over the past year to enhance communication about the breadth and depth of its ongoing food chemicals surveillance work, publishing an inventory of substances it does not consider to be generally recognized as safe for use in food as well as a list of chemicals in the food supply it is actively reviewing. The agency also announced plans to implement a new risk-based framework that prioritizes substances for in-depth review based on efficient mining of available data. In addition, Jim Jones, a former leader at the Environmental Protection Agency with a strong background in assessing chemical safety, joined FDA as its first Deputy Commissioner for Human Foods.

With Jones at the helm, we expect FDA to continue to raise the profile of its ongoing post-market food chemicals surveillance work. Early in the year, look for the agency to release a chemical safety work plan, which



Jones promised early in his tenure and should provide a more substantive look at just what the agency will focus its time and resources on in the near term. With NGOs looking beyond PFAS and the additives targeted by AB 418 to phthalates, phthalate substitutes, micro and nano-plastics, bisphenols, and various colors and preservatives, FDA will not only have to put forward a thoughtful, robust plan but deliver tangible results against it if it is to reassert its primacy on food chemical safety issues and dissuade state lawmakers from taking matters into their own hands with more hastily conceived state bans and restrictions.

4. Significant New Rulemakings Could Mean Operational Changes for Meat and Poultry Processors

2024 is shaping up to be a big year in the meat and poultry sector, with significant USDA rulemakings planned regarding *Salmonella*, product labeling, and livestock contracting. The implications for industry are substantial, costly, and disruptive.

USDA's Food Safety and Inspection Service plans to make *Salmonella* an adulterant in raw poultry products through two actions: (i) an interpretative policy change targeting *Salmonella* in raw breaded and stuffed chicken products that are not ready to eat but may appear ready to eat (such as frozen Chicken Corden Bleu), and (ii) a rulemaking declaring *Salmonella* an adulterant in all raw poultry. FSIS plans to release its interpretative policy change and its proposed rule on *Salmonella* this Spring. For *Salmonella* in raw poultry generally, FSIS appears interested in taking an approach that establishes a threshold level for certain *Salmonella* serotypes of public health concern, although details remain forthcoming. These changes would require substantial changes to how raw poultry is processed, lotted, and distributed, and it would have significant effects on companies producing raw poultry or sourcing raw poultry as ingredients.

FSIS is also planning to update its requirements for "Product of USA" claims for meat and poultry products. Last year, FSIS proposed to limit the use of this claim to products for which the meat, poultry, or egg components are derived from animals born, raised, slaughtered, and processed in the United States and made using other ingredients of "domestic origin," except for spices and flavors. This change would move FSIS's position closer to FTC's policy for "Made in USA" that is applied to FDA-regulated foods. Companies making this claim for meat and poultry products would need to review their labels and potentially update their marketing strategies.

USDA also plans to move forward with a suite of up to four rulemakings under the Packers and Stockyards Act that promise to substantially upend livestock and poultry

contracting. In particular, USDA plans to (i) implement a recently finalized rule requiring disclosures in broiler chicken grow-out contracting, (ii) finalize a proposed rule intended to promote "inclusive competition" within livestock and poultry contracting, (iii) begin a rulemaking attempting to counteract judicial interpretations requiring a showing of injury to competition when pursuing violations of Section 202 of the Packers and Stockyards Act, and (iv) begin another rulemaking imposing restrictions on the use of performance-based compensation systems in broiler chicken production contracts. USDA has attempted to pursue similar rules under Democratic administrations for the past 15 years, to staunch industry opposition and Congressional pushback out of concerns about cost, disruption, and litigation. USDA has pursued a short and inflexible implementation period for the one rule that has been finalized, suggesting USDA intends to pursue these rulemakings aggressively and quickly. If finalized, the rules could require substantial changes to how livestock and poultry production contracts are structured, administered, monitored, and enforced. Companies engaged in livestock and poultry production contracting should follow these developments closely and evaluate contingency strategies should the rulemakings be completed.

5. Heavy Focus on Heavy Metals to Continue Unabated

Another critical area for 2024 is heavy metals. Since a Congressional oversight committee first reported finding lead, arsenic, cadmium, and mercury in leading brands of baby food in 2021, this area has gotten significant attention from legislators, the press, plaintiff's lawyers, and FDA. Expect much more of the same in 2024 but potentially at a faster pace. Look for legislators at both the state and federal levels to introduce more bills requiring testing and disclosure; states and FDA to increase sampling activity; and FDA to publish draft action levels for cadmium, and perhaps arsenic, in infant and toddler foods. FDA may even finalize previously proposed action levels for lead in those same foods. Indeed FDA has already issued a conservative health-based toxicological reference value for cadmium and, if the draft actions levels for lead are any indication, expect the proposed levels for cadmium to be low and rest on rather small data sets (particularly for some covered commodities). Unfortunately, despite all this FDA activity, we expect judges to continue to cite uncertainty over the pace and timing of FDA's actions as a basis for rejecting calls to stay or dismiss class action challenges over the presence of heavy metals in chocolate, baby food, and other products.

The potential data gaps in FDA's data notwithstanding, when they come the FDA action levels and draft action levels will be an all-important yardstick, inevitably setting expectations about just what is reasonable and achievable when it comes to limiting heavy metal contaminants up and down the food supply chain. Knowing that, what activities should industry stakeholders prioritize for 2024? First, stay current and engaged. How FDA approaches infant and toddler foods matters for all foods, as FDA's Closer to Zero initiative for infant and toddler foods is just step one in a longer term effort to drive down overall dietary exposure to heavy metals. So read FDA's draft documents, support the submission of thoughtful comments to the docket, and consider submitting occurrence data if available. Second, review facility food safety plans as they relate to the risk of contamination with heavy metals. Do the plans fully account for that risk? In particular, do supplier audit and raw material specifications and testing requirements remain adequate in light of the guidance and expectations FDA is laying down (e.g., Do raw material specification and testing requirements take into account the draft action levels? If not, why not?). Finally, check commercial agreements. How do they allocate responsibility for controlling heavy metal contamination and does that allocation track with the specifics of your updated supply chain programs? For optimal protection, these documents should all work together.

6. FSMA Implementation Will Continue, But at a Slower Pace

Thirteen years after the FDA Food Safety Modernization Act (FSMA) was signed into law, it may appear that FSMA implementation is complete. However, FDA continues to issue guidance documents to assist with implementation of the law, and the compliance date for the Final Rule Requirements for Additional Traceability Records for Certain Foods looms on the horizon (January 2026). In 2024, we will be watching for the release of a revised version Appendix 1: Potential Hazards for Foods and Processes, which is commonly used by industry and investigators when reviewing the hazard analysis in a facility's food safety plan. FDA also intends to release draft guidance on validation for process preventive controls. If you haven't read FDA's Draft Guidance on Food Allergen Controls, released in the fall of 2023, we encourage you to do so and then to evaluate your own allergen control programs and to support the submission of thoughtful comments to the docket on this topic (due March 25, 2024). For example, the draft guidance outlines recommendations for detailed supplier verification programs, including testing, when suppliers handle more than one food allergen. And if you haven't yet conducted a traceability gap assessment and developed your implementation plan for compliance with the traceability rule, we recommend you do so now. 2026 will be here before you know it, and your own compliance is critical for your supply chain partners' compliance (and theirs for yours).

7. Some Inspections, With a Dash of Enforcement

After steeply declining in 2020, facility inspections have continued to climb back toward pre-pandemic numbers. For example, in 2023, FDA conducted 4,415 domestic GMP inspections, and 409 domestic Preventive Controls for Human Food inspections. The states conducted even more (5,060 and 591, respectively). We expect those numbers to remain steady or increase. The observations in 483s continue to largely be focused on GMPs, which we have heard FDA credit to the visual nature of these observations and the corresponding ease of identification by the relatively new inspectorate. FDA also continues to conduct for-cause inspections following filing of significant Reportable Food Registry submissions for Class I recall issues, reflecting a risk prioritization approach to inspections. As we move into 2024, we predict FDA's focus with respect to inspections and enforcement will remain on the infant formula industry, as well as with reorganizing the Office of Regulatory Affairs (ORA) into the Office of Inspections and Investigations (OII). We will be looking for the results of FDA's pilot of its Observations and Corrective Action Report (OCAR) Industry Portal to which participants will upload corrective action descriptions and supporting documentation. As you prepare for 2024, we recommend a focus on GMPs and robust environmental monitoring programs, coupled with root cause investigations and corrective actions. It's also a good time to review your food defense plans, as FDA will move beyond quick checks and start assessing adequacy in late 2024.

8. Guidance and Enforcement by the Federal Trade Commission (FTC)

The FTC is in process of updating the Green Guides, which provide guidance on environmental marketing claims, and which have been incorporated as mandatory requirements in some states. The FTC is expected to address issues such as whether recyclable claims must be based on *actual* recycling rates, as well as claims more commonly used today such as "carbon neutral."

We also anticipate an uptick in FTC enforcement in 2024. After issuing notices to more than 700 companies in April 2023 to put them on notice of their obligations to substantiate claims and comply with the FTC's Endorsement Guides, and issuing some high profile warning letters over endorsements by influencers without a disclosure of the paid connection, we expect that the FTC will be pursuing enforcement actions in these areas in 2024.

Antitrust enforcement will also continue to be robust, as regulators pursue the Administration's competition policy. DOJ is actively pursuing competition cases in the food sector, including in the animal agriculture industries, and DOJ and FTC continue to scrutinize food industry mergers.

9. The Supreme Court Could Rewrite Administrative Law

The Supreme Court's term will feature yet another case that could substantially redefine administrative law. After embracing the major question doctrine in *West Virginia v. EPA* and several cases related to the COVID-19 emergency response, the Court in a highly fractured decision in *National Pork Producers Council v. Ross* declined to revive the Dormant Commerce Clause to restrict California's ability to enforce regulations on pork production of that reach nationwide. This term, the Court will rule on *Loper Bright Enterprises v. Raimondo*, a case challenging *Chevron* deference, as well as a companion case, *Relentless Inc. v. Department of Commerce*. *Chevron* deference essentially says that courts should defer to an agency's reasonable interpretation of its statutory authority when there is ambiguity in the statute. Through *Chevron*, agencies have significant flexibility to expand (or contract) their regulatory authority when it's unclear what the statute calls for. This lets agencies "fill in the details" for complex regulatory schemes but also makes it more difficult to challenge an agency's interpretation of its own authority. During oral argument on January 17, the Court's conservative Justices voiced skepticism toward various aspects of the doctrine, suggesting it could be limited or even potentially struck down. If *Chevron* is substantially curtailed, it could limit FDA's and USDA's (as well as other agencies') freedom to expand their regulatory authorities into new areas, open new pathways for challenging agency rulemakings, and potentially even call into question existing regulations. The Justices could also decide the case in ways that leave *Chevron* partly or wholly intact. It will therefore be important to watch how the Court rules and to understand whether *Loper* extends the recent conservative trend of limiting agency discretion. The Court is expected to announce its decision later this Spring.

10. Class Action Litigation and Proposition 65

Food products continue to be routine targets of plaintiff's lawyers, including both filed and threatened litigation. There has been a significant increase in the number of demands as well as in the "going rate" for resolving marginal claims. While we have seen a handful of helpful decisions from the 9th Circuit in labeling cases, they have yet to dampen the growth in this area. Based on the nature of the food labeling class action complaints we saw and reported on weekly in 2023, we recommend food and supplement manufacturers keep several "hot spots" in mind as they survey their portfolios and look to mitigate risk and control litigation costs moving into 2024, specifically: "no (artificial) preservatives" claims; "no artificial flavors" claims; quantitative protein claims; representations about "high value" ingredients (e.g., "made with real butter"); health-related messaging for "high sugar" products; affirmative safety/purity-related messaging for products that may contain measurable levels of unavoidable contaminants (e.g., heavy metals; PFAS); ESG-related messaging (e.g., sustainable, traceable, carbon neutral), and claims that any product is 100% anything.

The threat of Proposition 65 bounty hunter litigation will continue to pose a challenge for industry in 2024. Bounty hunters filed hundreds of lawsuits for failure to warn in 2023, particularly over lead and cadmium in specialty foods, spices, and supplements, netting more settlement dollars than ever. Although those dollars are likely to keep the notices of violation flowing in 2024, longer-term defense initiatives to mitigate the impact of Proposition 65 are beginning to bear fruit. In 2023, the Ninth Circuit affirmed a district court decision barring enforcement of Proposition 65 warning requirements for glyphosate on First Amendment grounds given scientific controversy over whether glyphosate actually causes cancer. In 2024 we expect to see substantive rulings in other very similar First Amendment-based challenges, including a pending challenge over warnings for acrylamide. As a result of that challenge, a preliminary injunction bars the filing of new Proposition 65 complaints for failure to warn about acrylamide in food. Certainly the 9th Circuit's glyphosate decision bodes well for entry of a permanent injunction in that case. Likewise look for industry defendants to continue to leverage the landmark ruling in *Environmental Law Foundation v. Beech-Nut Nutrition Corp*. to confirm the appropriate measure for evaluating exposure to a listed chemical is average consumption rates, not a single serving. Finally, expect OEHHA to continue to progress its agenda, adding new chemicals to the ever-expanding Proposition 65 list and likely finalizing a rulemaking that would modify the content requirements of so-called short-form warnings for a variety of products, including foods.

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