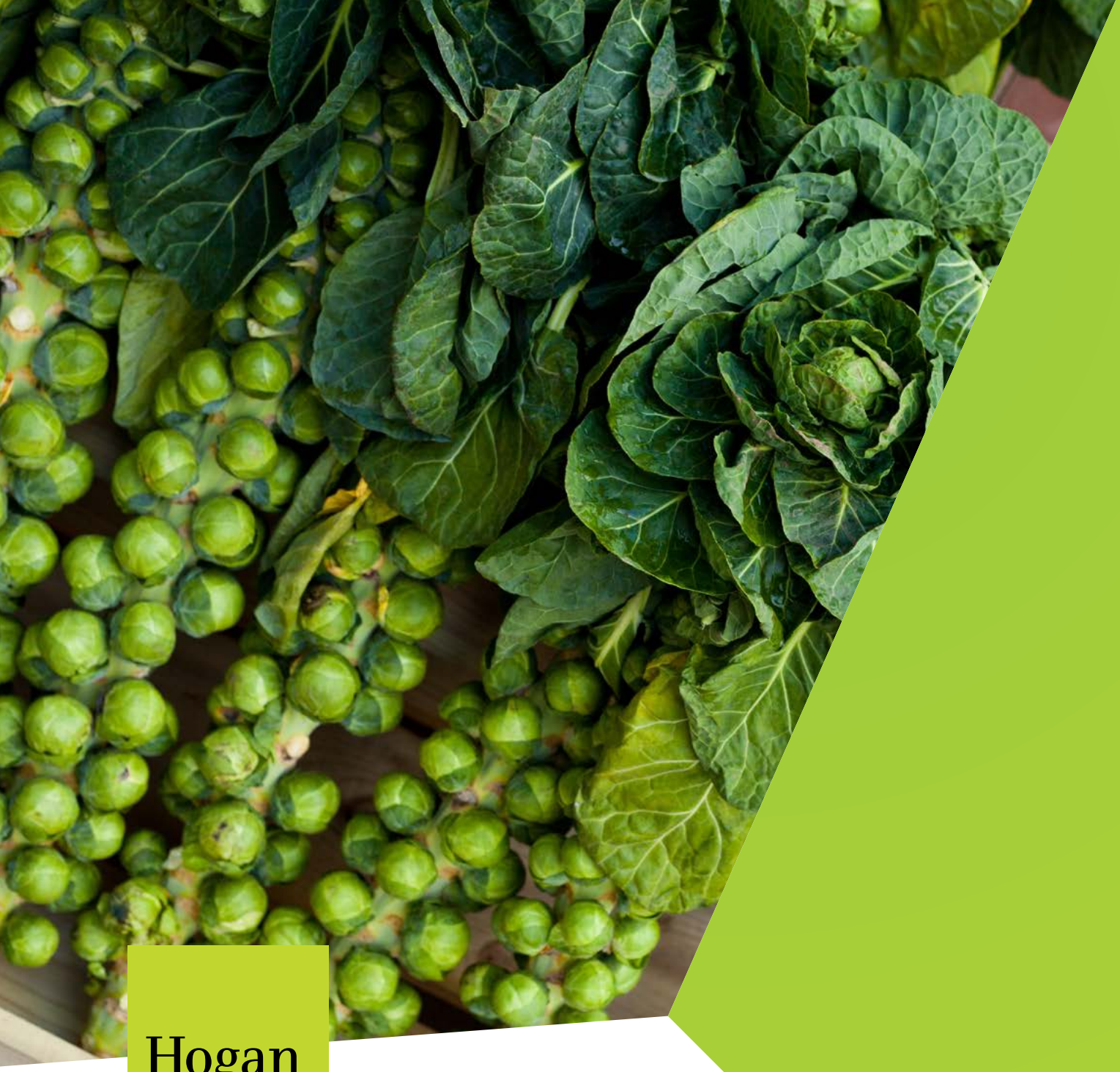


Hogan Lovells

Food Law Preview

Key issues affecting the food industry in 2023

We're a few weeks into 2023, and while some new year's resolutions may have already fallen to the wayside, there are plenty of food law issues that will take us through 2023 and beyond. Here are key issues the Hogan Lovells food and beverage team is keeping our eye on for the food industry this year.

External FDA Scrutiny and Potential Restructuring

Last year's infant formula recall and subsequent shortage exposed FDA to considerable external scrutiny and criticism. News reports alleging infighting and resource shortfalls at the Center for Food Safety and Applied Nutrition (CFSAN), and a lack of action on issues like heavy metals, PFAS in food packaging, and sodium reduction, only increased the pressure. In December 2022, the Reagan-Udall Foundation (RUF) issued a report evaluating the FDA Human Foods Program, which was prepared at the request of FDA Commissioner Robert Califf. The RUF report focused its findings and recommendations on four key areas: (1) structure and leadership; (2) authorities; (3) resources; and (4) culture. Among other recommendations, the RUF report proposes structural changes, elevating the importance of nutrition issues, bolder use of existing authorities, and improved decision-making "with a preference towards action." It also describes the Human Foods Program as "significantly under-resourced."

Commissioner Califf has committed to carefully considering the report's observations to "help inform a new vision" for the Human Foods Program. The agency has pledged to provide a public update on the new vision at the end of January 2023 and additional public updates by the end of February 2023, including the planned leadership structure and any changes to key internal processes and procedures.

Why it matters: The RUF report reflects the seriousness of the criticism directed at the agency and the possibility for significant near-term changes in response. Changes to FDA's organizational structure and leadership could have significant impacts for industry and other stakeholders, as some policy initiatives are elevated and others receive less attention. Bolder use of existing authorities could impact inspection follow-up, nutrition policy, GRAS designations, and recalls, and result in the implementation of user fees, for example. Further, some of the changes recommended by the RUF report also would require legislative action, which could open the door to a broader package of FDA food regulatory reforms.

FDA Turns Up the Heat on Inspections and Enforcement

We expect FDA inspections to return to, if not exceed, their pre-COVID era frequency in 2023. The recent Omnibus funding bill included a comment from Congress expressing concern that human food facilities are not inspected frequently enough to adequately identify and respond to risks, and a direction to FDA to increase the frequency of domestic human food inspections. FDA enforcement (e.g., Warning Letters, regulatory meetings, injunctions) should ramp up correspondingly.

The agency also continues to apply a higher level of scrutiny during domestic inspections, having moved beyond the "educate while we regulate" approach that characterized the early years of FSMA regulation implementation. Particular areas of focus in 2023 will likely include allergen preventive controls (both generally and with an additional focus on sesame, now that it is the 9th major food allergen), sanitation preventive controls (including environmental monitoring), validation for process preventive controls, and foundational cGMP issues. For animal foods, 2022 was a breakout year for FDA enforcement under the preventive controls rule, which will likely escalate in 2023. In particular, formulation-related preventive controls have been a considerable focus of the agency's enforcement efforts for animal foods.

Why it matters: The agency is concerned that its reputation as an enforcer has been hurt by several high profile food safety issues in 2022, so look for FDA to use increased enforcement activity to convey the message that the cop is "on the beat" and FDA is hard at work keeping food safe. The agency also does not want to risk missing anything significant during its inspections, which will inevitably bring more detailed and numerous 483 observations. Given these considerations, it is more important than ever that companies receiving 483s retain counsel and commit to responding in a detailed, thorough, and timely manner. The downside risks to businesses that do not follow that path were on display all too plainly in 2022.

FDA Efforts to Implement FSMA and Advance Related Initiatives to Continue

In 2023 we expect FDA to take an active stance implementing FSMA and progressing efforts on its New Era of Smarter Food Safety initiative. Now that the agency has released its last major FSMA rule – traceability -- in final form, look for it to focus on finetuning FSMA through educational efforts and the release of additional guidance documents. Key forthcoming guidance documents include multiple chapters of the Preventive Controls for Human Foods (PCHF) Guidance, including an updated hazards table in Appendix 1 and chapters on allergen controls, acidified foods, and classification of ready-to-eat and not-ready-to-eat foods. FDA is also expected to publish a proposed rule to eliminate certain written assurance requirements from the PCHF and Foreign Supplier Verification rules.

Why it matters: With mandatory FSMA rulemaking now completed, FDA will be increasingly focused on providing information to industry about its expectations for full compliance. The agency also is working on related initiatives that take the FSMA principles to the next level, such as those under the New Era of Smarter Food Safety and Closer to Zero. And although they are non-binding, guidance documents do set forth the agency's expectations and are frequently used during inspections.

Building Concern over Diet-Related Chronic Disease Drives Nutrition and Food Labeling Policy

FDA is pursuing a series of nutrition and food labeling policies that are intended to reduce risk of diet-related chronic disease. FDA's priorities for the coming year and beyond include:

- **Sodium**: Further work on the voluntary sodium reduction targets that FDA issued in October 2021, which ask the industry to reduce sodium in foods by about 12 percent over a 2.5 year period that ends April 2024. FDA was awarded $1 million in funding under the 2023 Omnibus spending bill to further these efforts, which would presumably be used to monitor and evaluate initial progress against the targets.

- **Added sugars**: Exploring approaches to "facilitate" reduction in added sugars consumption, which could in theory take a similar form to the sodium reduction guidance.
- **"Healthy"**: Redefining the term "healthy" for use in food labeling. FDA has issued a proposed rule to update the definition of healthy, which would include minimum food group contributions as well as new added sugars criteria. The proposed rule is quite restrictive, and is currently open for comment until February 16, 2023.
- **Front-of-pack Labeling**: Looking into developing a standardized front-of-pack nutrition labeling scheme (e.g., a star rating or traffic light symbol), as recommended in the National Strategy on Hunger, Nutrition & Health issued by the White House in follow up to the 2022 Conference on the same topic.

We expect FDA's work on "healthy" to take priority, whereas anything concrete on front-of-pack labeling will take longer. We suspect FDA's work to monitor and evaluate sodium reduction will start this year, but that added sugars will be deferred a bit.

Why it matters: If implemented, FDA's ambitious agenda, centered on using the food label as a tool to try to address diet-related disease, will have impacts on food labeling and nutrition policy for decades to come. Given what is at stake, all stakeholders should monitor the agency's activity closely, particularly given questions that surround the agency's legal authority to implement many of the items on the agenda.

The Future of QR Codes to Make Bioengineered Food Disclosures

In a September 2022 decision, a court held that use of a Quick Response (QR) code on packaging as a means to make the bioengineered food disclosure is invalid under the statute, unless it is accompanied by additional on-pack information, which the court suggests could include instructions to receive the disclosure via a text message. The U.S. Department of Agriculture (USDA) must now go back and revise its final rule to comply with the court decision, but in the meantime, QR codes may be used to comply with the law. Other elements of the bioengineered food disclosure rule (i.e., use of the term "bioengineered" rather than "GMO," exclusion of foods that were processed in such a way that they no longer contain detectable bioengineered material, and the federal preemption provision), were upheld by the court, though that decision is currently under appeal.

We also note that USDA's Agricultural Marketing Service (AMS) has started conducting recordkeeping audits to enforce the bioengineered food disclosure rule, in follow up to consumer complaints.

Why it matters: The USDA rulemaking, which we expect to begin this year with a proposed rule, will set the stage for the use of QR codes in the future, including what information food manufacturers may need to provide on food packages that rely on an electronic link for making disclosures. Upon completing an audit, AMS will share its final determination on the agency's website, which no doubt will draw interest from the class action bar.

Food Labeling Class Actions – Glimmers of Hope?

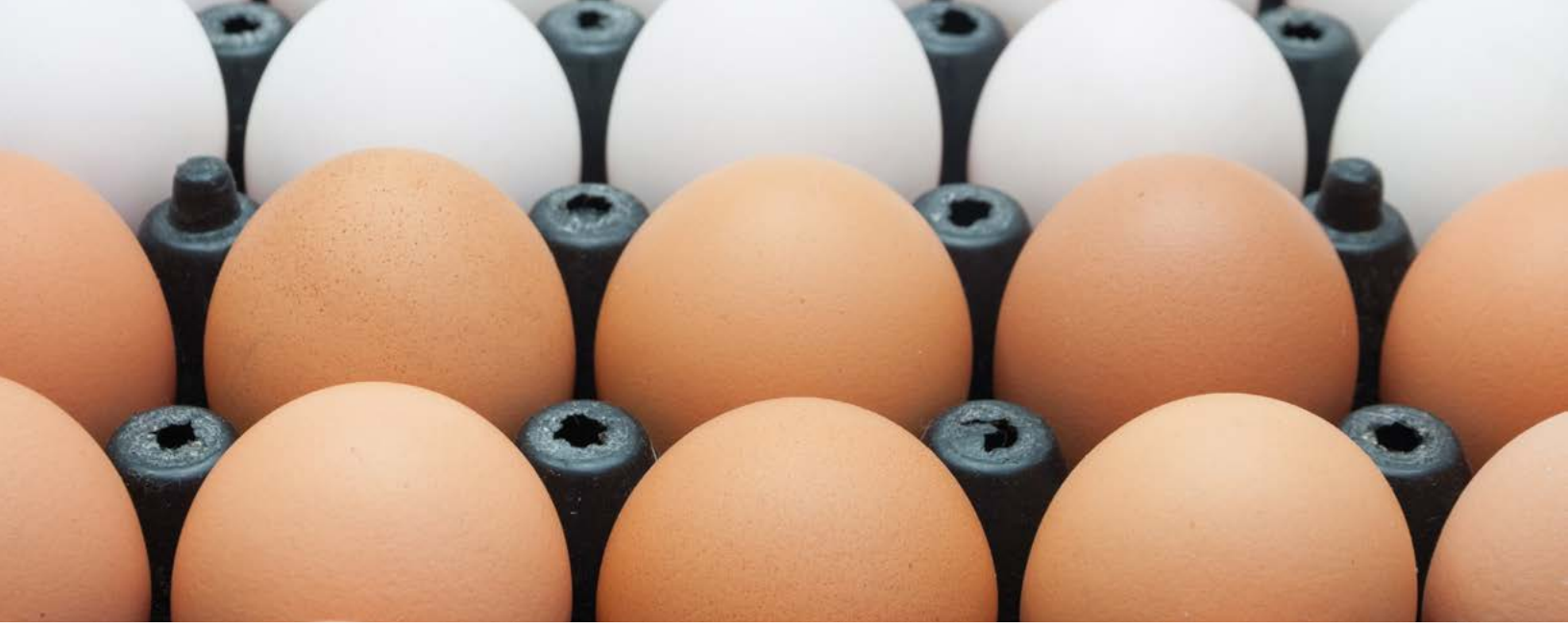
Class action plaintiffs will continue to target food labeling in 2023, but we are hopeful that the courts will continue issuing decisions that make clear the "reasonable consumer" standard indeed has teeth. We were encouraged, for example, by the many decisions in the last few years holding that when consumers see "vanilla" on the front of a food label, they understand it as a flavor cue and not as an ingredient representation, and that "made with" claims for ingredients don't necessarily signal that the food is made "exclusively" with that ingredient. That said, we expect to continue to see litigation over "high-value" ingredients and flavor representations, nutrient content claims, "no artificial…" claims, and others.

Why it matters: Class action labeling litigation continues to drain time and resources from food companies, but on the bright side, courts seem increasingly unwilling to conclude that the reasonable consumer would form a narrow, specific opinion from general representations in labeling and advertising, which may help tamp down new filings in 2023.

Sustainability – So Much to Do, So Little Time

Environmental topics will remain at the forefront in 2023, with the Federal Trade Commission (FTC) having initiated its process to update its Green Guides on environmental marketing claims (comments are due February 21). State laws in this area abound, including those on "recyclable" claims, minimum recycled content, and extended producer responsibility. Further, class action plaintiffs have set their sights on sustainability-related labeling claims, though with mixed success, as recently a court dismissed a case challenging sustainability statements in a company's corporate report, finding the statements to be aspirational and vague. Several cases challenging "recyclable" claims have also been dismissed.

Why it matters: Food companies will need to continue to navigate the many state laws related to sustainability, while trying to further their own environmental commitments related to their products and packaging. As previously-made corporate sustainability commitment become "due", companies will need to ensure these commitments are met and appropriately communicated.



PFAS in Food Packaging – A Growing Patchwork of State Laws

In response to growing health concerns about per- and polyfluoroalkyl substances, collectively known as PFAS and sometimes referred to as "forever chemicals," eleven states have now enacted some type of ban or restriction on their use in food packaging. Two of the bans (New York's and California's, applicable to paper-based packaging) have already taken effect, setting off an intense flurry of activity in late 2022 as companies up and down the food and beverage supply chain sought written assurances of compliance from their suppliers. Plaintiffs' lawyers also took up PFAS in 2022, filing several lawsuits against quick service restaurant chains (e.g., McDonald's) over PFAS they allege is found in wrappers and other packaging. The suits followed claims by *Consumer Reports* that it tested and found PFAS in a range of foodservice and retail packaging items.

Why it matters: Additional state bans will take effect in 2023, beginning with Vermont's on July 1, and passage of bans in more states seems likely. Confronted with this rapidly evolving landscape, companies will have to track developments at the state level, recognize and account for differences among the various state prohibitions, update sourcing protocols as needed to comply, and satisfy their customers' demands for assurances of compliance, particularly those of retailers that are beginning to develop their own policies around PFAS. All these challenges, plus the ongoing risk of litigation and the inability of current analytical methods to detect most types of PFAS, will doubtless leave many looking for a federal solution, which may be a tall order in today's grid-locked Washington.

A Heavy Focus on Heavy Metals

Heavy metals was at the top of the list for the food industry in 2022. For its part, FDA advanced work on its Closer to Zero initiative to reduce babies' and toddlers' exposure to heavy metals from foods to the lowest levels possible. To that end, FDA published a draft action level for lead in juices and purees (20 ppb for all juices and purees other than apple, which is 10 ppb) but many criticized the agency's overall progress on the heavy metals challenge as too slow. See, e.g., Politico (April 2022) and Bloomberg (January 2023). Meanwhile, armed with test results from Congressional committees, Consumer Reports and other NGOs, plaintiffs' lawyers continued to press dozens of cases against food manufacturers for allegedly exposing consumers to "unsafe" levels of heavy metals, particularly in baby foods. Although many of the cases remain in their early stages, judges have begun to weigh in with substantive rulings, with a few defendants scoring early victories on standing arguments (e.g., failure to allege actual or imminent harm) raised in motions to dismiss. See, e.g., here (Plum Organics) and here (Gerber).

Why it matters: We expect the heavy focus on heavy metals to continue in 2023. Companies will have to monitor Closer to Zero developments and evaluate their impact on material sourcing protocols and specifications. In particular, we expect FDA to publish a draft action level for lead in foods consumed by babies and young children. Although the precise scope and application of what FDA plans to propose remains unclear (will the agency establish quantitative levels for lead on a product-by-product basis or instead address the issue for baby and toddler foods as a class?), look for whatever FDA says to

have a ripple effect on expectations surrounding lead content across the food supply given the wide variety of foods and food ingredients used in products consumed by young children. At the same time, food manufacturers will have to manage the ongoing potential for litigation. Expect plaintiffs' lawyers to continue to leverage test results from NGOs, the press, and other sources to bring cases claiming companies failed to warn or otherwise disclose to consumers that their products contain "unsafe" levels of heavy metals. Time will tell whether the types of arguments put forward by defendants in some of the early-filed motions to dismiss in the baby food cases will continue to have traction with judges.

Is the Future Finally Now for Cell-Cultured Proteins?

Last year saw the first cell-cultured protein product complete FDA's premarket consultation process, but 2023 could be even more significant for this developing product class. Now that FDA has demonstrated that completing its premarket review is possible and has provided an indication of what documentation the agency finds acceptable, more completed consultations are likely to follow. And if FDA's biotechnology review process is any indication, FDA is likely to issue its planned draft guidance outlining the premarket consultation process once it has substantially completed several consultations.

Labeling and claims also remain outstanding issues, and due to its label review process, FSIS is likely to drive that process. FSIS has indicated that FSIS-regulated cell-cultured protein labels initially will require sketch approval, which means FSIS will have to review any labels for the UPSIDE product cleared by FDA, in the process providing insight into what product nomenclature and claims FSIS finds acceptable. FSIS is also looking at product naming more broadly. After previously soliciting stakeholder input through an Advanced Notice of Proposed Rulemaking, FSIS announced in the Unified Regulatory Agenda that it is developing a proposed rule governing the labeling of cell-cultured proteins under its jurisdiction, targeted for release this summer or fall. FDA also earlier solicited stakeholder input on product naming but has not taken further steps publicly, leaving it unclear whether or how the agencies will coordinate product naming policies.

Finally, as products move toward commercialization, FDA and FSIS will have to resolve lingering questions around how preventive controls and HACCP will apply to the production process and how the agencies will handle the jurisdictional hand-off for products under FSIS jurisdiction.

Why it matters: Clearing the FDA consultation process is one thing, commercializing a product is another. Important unresolved issues around product names, food standards, marketing claims, and manufacturing oversight have to be addressed, but doing so will ease the path to market and provide much more clarity around how this product category will be positioned.

The Long Arm of California's Proposition 12 and Animal Raising Standards

This year will see important questions answered about the scope and implementation of state laws establishing animal raising standards, including California's Proposition 12. Prop 12 is the leading example of a spate of similar state ballot initiatives passed over the last several years. Like its brethren, Prop 12 requires that certain egg, veal, and pork products sold within the state come from animals raised under minimal animal care standards, regardless of where the animal was raised or the food produced. Two important lawsuits about Prop 12's extraterritorial reach and implementation likely will be resolved this year: (1) In *National Pork Producers' Council v. Harris*, the U.S. Supreme Court granted cert and heard arguments in 2022 about the constitutionality of Prop 12's extraterritorial reach, and a decision is expected in the Spring or early Summer of 2023; and (2) In *California Hispanic Chambers of Commerce v. Ross*, a state trial court stayed enforcement of Prop 12 with respect to pork meat until after the California Department of Food and Agriculture (CDFA) issued implementing regulations, and the stay was later extended to July 1, 2023, in anticipation of the Supreme Court's decision in the *NPPC* case.

While the courts resolve questions about the scope of Prop 12, CDFA has moved forward with regulations implementing the law, including requiring distributors to register and self-certify compliance, with further requirements coming online in 2024. Other states have passed and are implementing similar requirements.

Why it matters: With the size of the California market and the law's broad extraterritorial reach, Prop 12 affects supply chains even for products that never enter the state. Prop 12's certification system will be complex and costly, and its pig confinement requirements are proving especially difficult to meet, threatening supply chain disruptions. This year will reveal how CDFA intends to enforce its new regulations and require the creation in 2023 of an entire third-party certification system to certify distributors and producers by 2024, and could answer important questions about the ability of California and other states to impose animal raising requirements beyond their borders.

FSIS to Advance Actions to Control Salmonella in Raw Poultry

Two important potential changes to FSIS's Salmonella policy for raw poultry will play out over 2023. First, FSIS announced over the summer its intent to declare Salmonella as an adulterant when present above specific levels in certain frozen not ready to eat (NRTE) breaded and stuffed products, such as chicken cordon bleu. FSIS in December sent a notice regarding this planned policy to the White House Office of Management and Budget and Budget for regulatory review, indicating that FSIS is likely to formally address this policy in the near future. Second, through its *Proposed Regulatory Framework to Reduce Salmonella Illnesses Attributable to Poultry* released in the fall of 2022, FSIS has telegraphed plans to impose a threshold level for Salmonella in all raw poultry. FSIS is expected to take steps this year to further develop this policy.

Why it matters: Historically, Salmonella has not been considered an adulterant in raw poultry, and these changes would have significant consequences for companies producing and selling raw poultry, could affect cost and availability of raw poultry throughout the supply chain, and could portend future policy changes toward pathogens in other raw products.

FDA Developing CBD Guidance

FDA has suggested that it is getting closer to providing guidance on the use of hemp-derived cannabidiol (CBD) in foods and dietary supplements. Confronted with a growing patchwork of differing state laws surrounding cannabis and Congress's legalization of certain hemp products in the 2018 Farm Bill, FDA has consistently taken the position that CBD cannot be lawfully added to foods or dietary supplements. FDA has issued a number of Warning Letters to companies marketing CBD-containing human and animal foods and supplements, including a set of five letters issued in November 2022. The November round of Warning Letters and accompanying Constituent Update highlight that the agency is especially concerned with "products that people may confuse for traditional foods or beverages which may result in unintentional consumption or overconsumption of CBD" and "CBD-containing products in forms that are appealing to children, such as gummies, hard candies and cookies."

With calls growing for a more fulsome regulatory approach than the sporadic issuance of Warning Letters, FDA has indicated it is developing guidance to specifically address the use of CBD in food and dietary supplements, and last year FDA added to its staff a former state cannabis regulation official, presumably to lead that effort. In a separate but related development, the Office of Management and Budget recently completed its review of final FDA guidance regarding clinical research undertaken to support the development of drugs that contain cannabis and cannabis-derived compounds. The guidance, which should publish soon, will address sourcing and quality control considerations, among other topics.

Why it matters: Companies considering the market for CBD-enhanced foods and supplements face a confusing array of state and federal laws, regulations, and policies. FDA guidance could help clarify FDA's position, and companies already in or considering entering the market would need to take FDA's updated position into consideration.

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